Medicare Program Integrity Manual

Chapter 10 – Medicare Enrollment

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10.1 – Introduction to Medicare Provider Enrollment
(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

This chapter specifies the resources and procedures Medicare Administrative Contractors (MACs) must use to establish and maintain provider and supplier enrollment in the Medicare program. These procedures apply to the MACs (hereafter occasionally referred to collectively as simply "the contractor"), unless contract specifications state otherwise.

10.1.1 – Definitions
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Below is a list of terms commonly used in the Medicare enrollment process:

Accredited provider/supplier means a supplier that has been accredited by a CMS-designated accreditation organization.

Add – For purposes of completing the Form CMS-855 or Form CMS-20134 enrollment applications, you are adding enrollment information to your existing enrollment record (e.g., practice locations). When adding a practice location, an application fee may be required for applicable institutions. (For further information, see the term "institutional provider" as defined in 42 CFR § 424.502, the application fee requirements in 42 CFR § 424.514, and the application fee guidance in section 10.6.14 of this chapter.)

Administrative location means a physical location associated with a Medicare Diabetes Prevention Program (MDPP) supplier's operations from where: (1) coaches are dispatched or based; and (2) MDPP services may or may not be furnished.

Advanced diagnostic imaging service means any of the following diagnostic services:

(i) Magnetic Resonance Imaging (MRI)
(ii) Computed Tomography (CT)
(iii) Nuclear Medicine
(iv) Positron Emission Tomography (PET)

Applicant means the individual (practitioner/supplier) or organization who is seeking enrollment into the Medicare program.

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to: (1) receive a Medicare billing number and be granted Medicare billing privileges; or (2) enroll to solely order, certify, or refer the items or services described in 42 CFR § 424.507.

Authorized official (as defined by 42 CFR § 424.502) means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of

the Medicare program. For purposes of this definition only, the term "organization" means the enrolling entity as identified by its legal business name and tax identification number.

Billing agency means an entity that furnishes billing and collection services on behalf of a provider or supplier. A billing agency is not enrolled in the Medicare program. A billing agency submits claims to Medicare in the name and billing number of the provider or supplier that furnished the service or services. In order to receive payment directly from Medicare on behalf of a provider or supplier, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act. (For further information, see CMS Publication (Pub.) 100-04, Claims Processing Manual, chapter 1, section 30.2.4.)

Change - For purposes of completing the Form CMS-855 or CMS-20134 enrollment applications, you are replacing existing information with new information (e.g. practice location, ownership) or updating existing information (e.g. change in suite #, telephone #). If you are changing a practice location an application fee is not required.

Change in majority ownership occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a home health agency (HHA) or hospice during the 36 months following the HHA's or hospice's initial enrollment into the Medicare program or the 36 months following the HHA's or hospice's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA or hospice through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's or hospice's most recent change in majority ownership. (See 42 CFR § 424.550(b) for more information on HHA and hospice changes of ownership.)

Change of ownership (CHOW) is defined in 42 CFR § 489.18(a) and generally means, in the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law. In the case of a corporation, the term generally means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions/deeming activities specified. (See 42 CFR §§ 488.1 and 488.5 for more information on accrediting organizations.)

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Community setting means a location where the MDPP supplier furnishes MDPP services outside of its administrative locations in meeting locations open to the public. A community setting is a location not primarily associated with the supplier where many activities occur, including, but not limited to, MDPP services. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

Deactivate means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

Delegated official (as defined by 42 CFR § 424.502) means an individual who is delegated by the "Authorized Official" the authority to report changes and updates to the provider/supplier's enrollment record. The delegated official must be an individual with an ownership or control interest in (as that term is defined in section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the provider or supplier.

Delete/Remove – For purposes of completing the Form CMS-855 enrollment and Form CMS-20134 applications, you are removing existing enrollment information. If you are deleting or removing a practice location, an application fee is not required.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to: (1) receive Medicare billing privileges; or (2) enroll to solely order, certify, or refer the items or services described in 42 CFR § 424.507.

Director means a director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member; said body could be a board of directors, board of trustees, or similar body.

Effective Date means the date on which a provider's or supplier's eligibility was initially established for the purposes of submitting claims for Medicare-covered items and services and/or ordering or certifying Medicare-covered items and services. (This is not the same as a reactivation effective date.)

Eligible coach means an individual who CMS has screened and determined can provide MDPP services on behalf of an MDPP supplier.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.

Enrollment application means a paper Form CMS-855 or Form CMS-20134 enrollment application or the equivalent electronic enrollment process approved by the Office of Management and Budget (OMB).

Final adverse legal action means the following:

For purposes of the definition of this term in § 424.502, final adverse action means one or more of the following:

(1) A Medicare-imposed revocation of any Medicare billing privileges;

(2) Suspension or revocation of a license to provide health care by any state licensing authority;

(3) Revocation or suspension by an accreditation organization;

(4) A conviction of a federal or state felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a federal or state health care program.

For purposes of the reporting requirements on the Form CMS-855 or Form CMS-20134, final adverse action means one or more of the following:

Convictions (as defined in 42 CFR 1001.2) within the preceding 10 years

1. Any federal or state felony conviction(s).
2. Any misdemeanor conviction, under federal or state law, related to: (a) the delivery of an item or service under Medicare or a state health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
3. Any misdemeanor conviction, under federal or state law, related to the theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any misdemeanor conviction, under federal or state law, related to the interference with or obstruction of any investigation into any criminal offence described in 42 C.F.R. section 1001.101 or 1001.201.
5. Any misdemeanor conviction, under federal or state law, related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations, or Suspensions

1. Any current or past revocation, suspension, or voluntary surrender of a medical license in lieu of further disciplinary action.
2. Any current or past revocation or suspension of accreditation.
3. Any current or past suspension or exclusion imposed by the U.S. Department of Health and Human Service's Office of Inspector General (OIG).
4. Any current or past debarment from participation in any Federal Executive Branch procurement or non- procurement program.
5. Any other current or past federal sanctions.
6. Any Medicaid exclusion, revocation, or termination of any billing number.

Immediate family member or member of a physician's immediate family means – under 42 CFR § 411.351 - a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier; or

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

Ineligible coach means an individual whom CMS has screened and determined cannot provide MDPP services on behalf of an MDPP supplier.

Institutional provider means – for purposes of the Medicare application fee only - any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations), Form CMS–855S, or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application.
Legal business name is the name that is reported to the Internal Revenue Service (IRS).

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier. For purposes of this definition of managing employee, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

Managing organization means an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

Medicare identification number - For Part A providers, the Medicare identification number is the CMS Certification Number (CCN). For Part B suppliers the Medicare identification number is the Provider Transaction Access Number (PTAN).

National Provider Identifier is the standard unique health identifier for health care providers (including Medicare suppliers) and is assigned by the National Plan and Provider Enumeration System (NPPES).

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

Operational – under 42 CFR § 424.502 – means that the provider or supplier has a qualified physical practice location; is open to the public for the purpose of providing health care related services; is prepared to submit valid Medicare claims; and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) to furnish these items or services.

Other eligible professional – as defined in 1848(k)(3)(B) of the Social Security Act – means: (i) a physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) a qualified audiologist (as defined in section 1861(ll)(3)(B)). (For (ii), "practitioner" is defined in section 1842(b)(18)(C) as a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional.)

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier as defined in sections 1124 and 1124(A) of the Social Security Act.

Ownership or investment interest – under 42 CFR § 411.354(b) – means an ownership or investment interest in the entity that may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes designated health services.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Social Security Act.

Physician-owned hospital – under 42 CFR § 489.3 – means any participating hospital in which a physician, or an immediate family member of a physician, has a direct or indirect ownership or investment interest, regardless of the percentage of that interest.

Physician owner or investor – under 42 CFR § 411.362(a) – means a physician (or an immediate family member) with a direct or an indirect ownership or investment interest in the hospital.

Prospective provider means any entity specified in the definition of "provider" in 42 CFR § 498.2 that seeks to be approved for coverage of its services by Medicare.

Prospective supplier means any entity specified in the definition of "supplier" in 42 CFR § 405.802 that seeks to be approved for coverage of its services under Medicare.

Provider is defined at 42 CFR § 400.202 and generally means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice, that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Reassignment means that an individual physician, non-physician practitioner, or other supplier has granted a Medicare-enrolled provider or supplier the right to receive payment for the physician's, non-physician practitioner's or other supplier's services. (For further information, see § 1842(b)(6) of the Social Security Act, the Medicare regulations at 42 CFR §§424.70 - 424.90, and CMS Pub. 100-04, chapter 1, sections 30.2 – 30.2.16.)

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information or that additional information or corrected information was not received from the provider or supplier in a timely manner. (See 42 CFR § 424.525 for more information.)

Retrospective Billing Privileges means that certain Part B suppliers can bill retrospectively for up to 30 or 90 days prior to their enrollment effective date as described in 42 CFR §§ 424.520(d) and 424.521(a).

Revoke/Revocation means that the provider's or supplier's billing privileges are terminated.

Supplier means (for purposes of 42 CFR Part 424, subpart P) all the following:

(1) The individuals and entities that qualify as suppliers under § 400.202
(2) Physical therapists in private practice
(3) Occupational therapists in private practice
(4) Speech-language pathologists

Tax identification number means the number (either the Social Security Number (SSN) or Employer Identification Number (EIN) that the individual or organization uses to report tax information to the IRS.

10.1.2 – Enrolling to Receive Medicare Payment

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

No provider or supplier shall receive payment for services furnished to a Medicare beneficiary unless the provider or supplier is enrolled in the Medicare program. Further, it is essential that each provider and supplier enroll with the appropriate Medicare Administrative Contractor. We use the term "enrollment" generally to include activities a provider or supplier undertakes to enroll in the Medicare program and maintain enrollment in good standing, which includes, but is not limited to, initially enrolling, revalidating enrollment, and reporting changes of information as described within this chapter.

A. Initial Enrollment

In general, a provider or supplier shall enroll as an initial applicant if it is:

- Initially enrolling in the Medicare program or enrolling as a provider or supplier in a new geographic jurisdiction.

- Seeking to reestablish itself in the Medicare program after a voluntary withdrawal from the Medicare program, or subsequent to a termination or revocation of enrollment based upon any CMS authority under Title 42 of the CFR.

For additional information, refer to sections of this chapter concerning unique provider and supplier types, the applications that correspond to Medicare enrollment by provider/supplier type and purpose, and a general discussion of enrollment topics.

B. Revalidation

Pursuant to 42 CFR §§ 424.515, 410.41(c), and 424.57(g), providers and suppliers use the CMS enrollment application process to periodically revalidate their Medicare enrollment record. Suppliers of durable medical equipment, prosthetics, orthotics, and supplies are required to revalidate every 3 years and all other providers and suppliers every 5 years.

C. Changes of Information

Consistent with 42 CFR § 424.516, providers and suppliers use the CMS enrollment application process to report changes of information as required to remain in compliance with the requirements to participate in Medicare.

10.1.3 - General Summary of Process to Enroll in Medicare

(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

Providers and suppliers, including physicians, may enroll or update their Medicare enrollment record using the:

- Internet-based Provider Enrollment, Chain and Ownership System (PECOS), or
- Paper enrollment application process (e.g., Form CMS-855).

The Medicare enrollment applications are issued by CMS and approved by the Office of Management and Budget.

Paper applications can be accessed at the Web site https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

PECOS can be accessed at https://pecos.cms.hhs.gov/pecos/login.do.

Web Sites

The contractor must link to CMS' provider/supplier enrollment Web site located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html?redirect=/MedicareProviderSupEnroll/. The link shall: (1) be available on the contractor's existing provider outreach Web site (which should be an established sub-domain of the contractor's current commercial Web site); and (2) comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications Budget and Performance Requirements. Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index?redirect=/MedicareProviderSupEnroll/, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis (specifically, no later than the 15th day of January, April, July, and October), each contractor shall review and provide updates regarding its contact information shown at URL: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/contact_list.pdf

If the contractor services several states with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only such information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the contractor's CMS Provider Enrollment & Oversight Group Business Function Lead.

10.1.4 - General Overview of Medicare Enrollment Application Forms

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

The enrollment applications are available online as well as in paper form:

A. General Overview of Form CMS-855 and CMS-20134

Each Form CMS-855 application is used to enroll a specific provider or supplier type for a specific purpose.

1. CMS-855A – Medicare Enrollment Application for Institutional Providers

This application should be completed by institutional providers (e.g., hospitals) that will furnish Medicare Part A services to beneficiaries.

2. CMS-855B –Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers

This application should be completed by supplier organizations (e.g., ambulance companies) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.

3. CMS-855I - Medicare Enrollment Application for Physicians and Non-Physician Practitioners

This application should be completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries. (This includes a physician or practitioner who is: (1) the sole owner of a professional corporation, professional association, or limited liability company and will bill Medicare through this business entity; or (2) a sole proprietor.) (See section 10.6.4 of this chapter for more information on the business types discussed in this paragraph.) The CMS-855I captures reassignment information that was previously collected via the CMS-855R, which has been discontinued.

4. CMS-855S – Medicare Enrollment Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers

This application should be completed by DMEPOS suppliers.

5. CMS-855O – Medicare Enrollment Application for Eligible Ordering, Certifying Physicians, and other Eligible Professionals

This form is used for physicians and other eligible professionals who wish to register in Medicare solely for the purpose of ordering and certifying the items and services described in 42 CFR § 424.507. These physicians and other eligible professionals do not and will not send claims to a MAC for any services they furnish.

6. CMS-20134 – Medicare Enrollment Application for Medicare Diabetes Prevention Program (MDPP) Suppliers

This application should be completed by any supplier organizations that will furnish and bill Medicare Part B for the MDPP services furnished to Medicare beneficiaries.

B. General Overview of Additional Enrollment Forms

The following forms or form types are routinely submitted with an enrollment application:

1. CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement

The EFT Agreement authorizes CMS to deposit Medicare payments directly into a provider/supplier's bank account.

For Form CMS-855S enrollments, CMS only requires collection of the Form CMS-588 with initial enrollment applications.

2. CMS-460 – Medicare Participating Physician or Supplier Agreement

This agreement establishes that the Medicare provider/supplier accepts assignment of the Medicare Part B payment for all services for which the participant is eligible to accept assignment under the Medicare law and regulations and which are furnished while the agreement is in effect. The contractor shall explain to the provider or supplier the purpose of the agreement

and how it differs from the actual enrollment process. (This only applies to suppliers that complete the Forms CMS-855B, CMS-855I and CMS-855S.)

3. CMS Standard Electronic Data Interchange (EDI) Enrollment Form

See CMS Publication 100-04, Medicare Claims Processing Manual, chapter 24, sections 30 - 30.5 for further information.

4. State-Specific Forms for Certified Providers/Certified Suppliers

If the applicant is a certified supplier or certified provider, it will need to contact the state agency for any state-specific forms and to begin preparations for a state survey. (This does not apply to those certified entities, such as federally qualified health centers, that do not receive a state survey.)

10.2 – Provider and Supplier Types/Services
(Rev. 10672; Issued: 03-18-21; Effective: 03-12-21; Implementation: 03-22-21)

The contractor shall consult other Medicare manuals for more information on how these providers and suppliers bill Medicare, their conditions of coverage, their conditions of participation, etc.

Provider and supplier specialty codes can be found at CMS Publication 100-04, chapter 26, sections 10.8 through 10.8.3.

10.2.1 – Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A
(Rev. 11139; Issued: 11-23-21; Effective: 10-15-21; Implementation: 01-03-22)

(For purposes of sections 10.2.1.1 through 10.2.1.14, the term "SOG Locations" refers to CMS Survey & Operations Group (SOG) Locations (formerly CMS Regional Offices)).

Sections 10.2.1.1 through 10.2.1.14 address the specific types of providers and suppliers that complete the Form CMS-855A. While these sections mostly address the unique statutory and regulatory requirements for these types, some of them also contain detailed application processing instructions, which the contractor shall follow.

10.2.1.1 - Community Mental Health Centers (CMHCs)
(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

A CMHC is a facility that provides mental health services. A CMHC must perform certain "core services." These are:

1. Outpatient services (This includes services for (a) children, (b) the elderly, (c) persons who are chronically mentally ill, and (d) certain persons who have been discharged from a mental health facility for inpatient treatment.)

2. 24-hour-a-day emergency psychiatric services;

3. Day treatment or other partial hospitalization (PH) services, or psychosocial rehabilitation services; and

4. Screening for patients being considered for admission to state mental health facilities.

NOTE: Partial hospitalization is the only core service for which a CMHC can bill Medicare as a CMHC. Thus, while a facility must furnish certain "core" services in order to qualify as a CMHC, it can only get reimbursed for one of them – partial hospitalization. However, the facility may still be able to enroll in Medicare as a Part B clinic if it does not perform partial hospitalization services.

In some instances, these core services can be furnished under arrangement. This generally means that the facility can arrange for another facility to perform the service if, among other things, CMS determines that the following conditions are met:

- The CMHC arranging for the particular service is authorized by State law to perform the service itself;

- The arranging CMHC accepts full legal responsibility for the service; and

- There is a written agreement between the two entities

While the CMHC generally has the option to furnish services under arrangement, there is actually an instance where the facility must do so. If the CMHC is located in a state that prohibits CMHCs from furnishing screening services (service (4) above), it must contract with another entity to have the latter perform the services. Any such arrangement must be approved by the SOG Location. (See CMS Pub. 100-07, State Operations Manual, chapter 2, section 2250 for additional information on core services and arrangements.)

A CMHC must provide mental health services principally to individuals who reside in a defined geographic area (service area); that is, it must service a distinct and definable community.

B. Initial Enrollment and Certification

1. Introduction

As of October 29, 2014, CMHCs are required to meet the conditions of participation outlined in 42 CFR Part 485, subpart J. CMHCs, like many other types of certified providers and certified suppliers, are therefore required to undergo a state survey as part of the certification and enrollment process. The SOG Location no longer performs the site visit nor does the CMHC need to submit the previously-required attestation statement. Except as otherwise noted in this

chapter 10 or in another CMS directive, CMHC initial applications shall – on and after October 29, 2014 - be processed in the same manner as those for all other certified providers.

2. Processing Instructions for CMHC Initial Form CMS-855A Applications

In the past, the SOG Location had vital functions in reviewing CMHC requests for Medicare participation and finalizing CMS' decision. With the transition of certain SOG activities to the state agencies, the contractors, and CMS PEOG, however, the operational process of reviewing CMHC requests for participation and enrollment now generally involves (and with exceptions) the following:

- The contractor sends the enrollment application (and all supporting documentation) and its recommendation for approval to the state for review
- The state notifies the contractor of its recommendation
- A site visit is performed
- The contractor notifies PEOG of the recommendation. PEOG signs the provider agreement and performs other administrative functions pertaining to the enrollment
- Once PEOG completes the required administrative actions, PEOG will notify the contractor thereof
- The contractor completes processing and notifies the provider of the approval of the transaction using the appropriate model letter (sending a copy thereof to the state).

(Thus, and except as otherwise stated, SOG Locations are no longer involved in the CMHC initial application process for Form CMS-855As.)

Specific details on these steps are outlined in this section 10.2.1.1(B)(2). Said instructions take precedence over any conflicting processing directives in this chapter.

i. Receipt of Application

Upon receipt of a CMHC initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the CMHC has submitted all documentation otherwise required per this chapter. For CMHC initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The CMHC must complete, sign, date, and include the Form CMS-1561, though the CMHC need not complete those sections of the form reserved for CMS. For organizational CMHCs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

ii. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.1(B)(2) prohibits the contractor from returning or rejecting the CMHC application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.1(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the CMHC, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

iii. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (B)(3)(a) below need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.1(B)(2)(ii)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (B)(3)(a) below.

If the CMHC fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(ii)(B) above. If the CMHC passes the site visit, the contractor shall (within 3 business days of completing its review of the results) send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application or PECOS Application Data Report and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the CMHC; (2) send a copy of both the approval letter and the provider agreement to the state and/or AO (as applicable)); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

3. Site Visits

a. Initial Enrollment

The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter; the National Site Visit Contractor (NSVC) will perform the site visit. The contractor

shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

b. Practice Locations

Each CMHC location must separately and independently meet the CMHC conditions of participation in 42 CFR Part 485, subpart J. Accordingly, a CMHC must separately enroll each of its practice locations. It cannot have multiple locations on a single application.

If a CMHC is changing its physical location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. Revalidation Site Visits

If the CMHC submits a Form CMS-855A revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 10.6.20 of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

C. CMHC 40 Percent Rule

Effective October 29, 2014, under § 485.918(b)(1) a CMHC must provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Social Security Act; this is measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC in the applicable timeframe.

Pursuant to this requirement, a CMHC is required to submit to CMS a certification statement provided by an independent entity (such as an accounting technician). The document must certify that the entity has reviewed the CMHC's client care data for:

- Initial enrollments: The CMHC meets the 40 percent requirement for the prior 3 months.

- Revalidations: The CMHC meets the 40 percent requirement for each of the intervening 12-month periods between initial enrollment and revalidation.

The statement must be submitted as part of any initial enrollment or revalidation (including off-cycle revalidations).

When processing the application, the contractor shall abide by the following:

1. Contractor Does Not Receive the Certification

If the contractor does not receive the certification with the Form CMS-855, the contractor shall develop for the certification as it would with any other form of required supporting documentation. If the CMHC fails to submit the certification within the applicable time period, the contractor shall follow the instructions in section 10.4.1.4.3 of this chapter.

2. Contractor Receives the Certification

If the contractor receives the certification with the Form CMS-855 or timely receives the certification as part of a development request, the contractor shall review the certification to ensure that it complies with § 485.918(b)(1) and the provisions of this section 10.2.1.1(C). If the certification is compliant, the contractor shall continue processing the application; if the certification is not compliant, the contractor shall deny the application or, if it chooses, develop for a revised certification.

Section 10.2.1.1(C) does not apply if the contractor determines that the Form CMS-855 can be returned under section 10.4.1.4.2 of this chapter.

If the contractor exceeds applicable timeliness standards due to the instructions in this section 10.2.1.1(C), the contractor shall accordingly document the provider file consistent with section 10.6.19(H) of this chapter.

3. Special Guidelines

The following additional guidelines concerning certification apply:

(i) As previously indicated, an appropriate official of the certifying entity must sign the document. (Notarization is not required unless CMS requests it.) Such persons may include accounting technicians, CEOs, officers, directors, etc.

(ii) The certification should be on the certifying entity's letterhead or should otherwise indicate that the document is clearly from the entity.

(iii) The contractor shall include the certification in the recommendation package it sends to the state agency.

Unless CMS instructs the contractor otherwise, the appropriate denial bases for failing to comply with § 485.918(b)(1) are §§ 424.530(a)(1) and 485.918(b)(1). The appropriate revocation bases are §§ 424.535(a)(1) and 485.918(b)(1). In cases involving the latter, CMS will determine the appropriate re-enrollment bar length under § 424.535(c) and will notify the contractor thereof.

D. CHOWs and Changes of Information

For CMHC CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter. For CMHC changes of information, the contractor shall follow the instructions in section 10.6.1.2 of this chapter.

E. Additional Information

For more information on CMHCs, refer to:

- Section 1861(ff) of the Social Security Act
- 42 CFR §§ 410.2, 410.43, and 410.110
- Pub. 100-07, chapter 2, sections 2250 - 2251F
- 42 CFR § 489.18(b)(1)

10.2.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. Specific examples of such services include:

- Physician services (*)
- Physical therapy (*)
- Occupational therapy
- Respiratory therapy
- Speech pathology
- Social work or psychological services (*)
- Prosthetic/orthotic devices
- Lab services (must meet 42 CFR Part 493 requirements)

(* Services that the CORF must provide)

In addition:

- If the state determines that sufficient functional and operational independence exists, a CORF may be able to share space with another Medicare provider. However, the CORF may not operate in the same space at the same time with another Medicare provider. (See Pub. 100-07, chapter 2, sections 2364 - 2364C for more information.)

- Like most certified providers, CORFs must be surveyed by the state agency and must sign a provider agreement.

- On occasion, an outpatient physical therapy/speech language pathology location might convert to a CORF; prior to enrolling in Medicare, however, it must be surveyed to ensure that the CORF conditions of participation are met.

B. Processing Instructions for CORF Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of a CORF initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the CORF has submitted all documentation otherwise required per this chapter. For CORF initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The CORF must complete, sign, date, and include the Form CMS-1561, though the CORF need not complete those sections of the form reserved for CMS. For organizational CORFs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.2(B) prohibits the contractor from returning or rejecting the CORF application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.2(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the CORF, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (D)(1) below need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.2(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (D)(1) below.

If the CORF fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(B) above. If the CORF passes the site visit, the contractor (within 3 business

days of completing its review of the results) shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the CORF; (2) send a copy of both the approval letter and the provider agreement to the state and/or AO (as applicable)); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Offsite Locations – Initial Enrollment Applications

Notwithstanding the "single fixed location" language cited in section 10.2.1.2(A) above, there may be isolated cases where CMS or the state permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy, occupational therapy, or speech language pathology services away from the primary location. (This is permitted under 42 CFR § 485.58(e)(2)). The offsite location would not necessarily be separately surveyed but would be listed as a practice location on the CORF's initial Form CMS-855A application.

D. Site Visits

1. Initial application - The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. Revalidation – If a CORF submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. New/changed location - If a CORF is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends

to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

E. CHOWs and Changes of Information

For CORF CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter. For CORF changes of information, the contractor shall follow the instructions in section 10.6.1.2 of this chapter.

F. Additional Information

For more information on CORFs, refer to:

- Section 1861(cc) of the Social Security Act
- 42 CFR Part 485, Subpart B
- Pub. 100-07, chapter 2
- Pub. 100-07, Appendix K
- Pub. 100-02, Benefit Policy Manual, chapter 12

10.2.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

(In this section 10.2.1.3, the terms "ESRD" and "ESRD facility" have the same meaning and will be used interchangeably).

A. General Background Information

ESRD facilities are entities that provide renal services and related care for patients with irreversible and permanent kidney failure.

The provider-based rules for ESRD facilities are outlined in 42 CFR § 413.174 and are slightly different than those in the main provider-based regulation (42 CFR § 413.65). (For instance, § 413.174 uses the term "hospital-based" as opposed to "provider-based.")

The ESRD Network is a group of organizations under contract with CMS that serve as liaisons between the agency and ESRD providers. The organizations oversee the care that ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

B. Types of ESRD Facilities

Pub. 100-07, State Operations Manual, lists several classifications of ESRD facilities. They are summarized as follows:

1. Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that (1) is an outpatient department of a hospital and (2) meets the ESRD conditions of coverage at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CCN and be separately enrolled.

A hospital-based ESRD facility is discussed at 42 CFR § 413.174(c) and must meet the criteria listed therein (e.g., ESRD facility and hospital have a common governing body and are financially integrated). Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

2. Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility: (1) is separately certified and surveyed; (2) must independently meet the ESRD conditions of coverage; (3) is assigned its own CCN; and (4) be separately enrolled. Satellite renal dialysis facilities (hospital-based) are assigned CCNs in the 3500-3699 series.

3. Independent Renal Dialysis Facility

An independent renal dialysis facility is any outpatient ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but it is not owned and/or administered by the hospital. Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series and are individually enrolled.

4. Special Purpose Renal Dialysis Facility (SPRDF) (§ 494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e., up to 8 months in any 12-month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area. The SOG Location must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications. The special locations for SPRDF fall into two categories:

(A) Vacation Camps - Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding interruption of the camping experience. Vacation camps may be approved for the duration of the camp but up to a maximum of 8 months in any 12-month period.

(B) Emergency Circumstance SPRDFs - These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their

geographical area resulting from a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location. The CMS SOG Location may extend the time-period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

SPRDFs are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities. Although they are individually enrolled, they cannot convert to a permanent ESRD facility (i.e., to a non-SPRDF). They must instead reapply as a brand new ESRD facility and receive an initial certification survey.

C. Processing Instructions for ESRD Initial Form CMS-855A Applications

An ESRD facility is separately and individually certified and does not have any branch, multiple, or parent locations. As such, each type of ESRD facility/location must independently and separately enroll as such via the Form CMS-855A; multiple sites cannot be listed on a single application.

Note that the instructions in this section 10.2.1.3(C) apply to all ESRD facility types except for SPRDFs. This ESRD type is not "transitioning" as that term is described in this chapter. Accordingly, the contractor shall continue to process initial applications from SPRDFs consistent with longstanding instructions rather than those described in this section 10.2.1.3(C) (e.g., receiving the final approval from the SOG location rather than the state; no need to send the application to PEOG after final SOG location approval).

1. Receipt of Application

Upon receipt of an initial ESRD Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this section 10.2.1.3 and this chapter.

(C) Ensure that the ESRD facility has submitted all documentation otherwise required per this chapter. For ESRD initial enrollment, this also includes the following:

- Part I of the Form CMS-3427A (End Stage Renal Disease Application and Survey and Certification Report) (See Pub. 100-07, chapter 2, section 2274B for more information on this form.)

- A certificate of need (CON) if required by state law (though SPRDFs need not submit a CON)

(The ESRD must complete and submit Part I of the Form CMS-3427A, though the ESRD need not complete those sections of the form reserved for CMS. For organizational ESRDs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole

proprietor must sign. Note that there is no provider agreement for ESRD facilities; the Form CMS-3427A is a survey and certification document, not a provider/supplier agreement.)

Notwithstanding the foregoing, if Part I of the Form-CMS-3427A and/or CON evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon. (Nor need the contractor: (1) research individual state laws to ascertain whether the state requires a CON; or (2) review the data on the CON.) The contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.3(C) prohibits the contractor from returning or rejecting the ESRD application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.3(C) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the ESRD, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof----typically via the Form CMS-1539, although the contractor may accept any notification that is in writing (e-mail is fine). No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.1.3(C)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically do so via a Form CMS-1539; however, the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 from the state or similar documentation received from the AO
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

(As required per section 10.6.21 of this chapter, the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.))

PEOG will review the documentation. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the relevant data into the applicable national database, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the effective date, and CCN the contractor shall: (1) send the approval letter to the ESRD provider, with a copy to the state and/or AO (as applicable); and (2) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

D. Additional/Changed Stations

If an enrolled ESRD seeks to add/change services or stations (e.g., add ESRD services in SNFs, additional modalities), the ESRD need not submit a Form CMS-855A application to do so, for these services and stations do not constitute practice locations and cannot otherwise be reported on the application. Instead, the ESRD contacts the state or accreditation organization (AO) to request these changes. The ESRD must complete a Form CMS-3427 and submit it to the state or AO (as applicable). A survey may be performed, and the state will update the applicable national database with any administrative changes.

The state will also send a CMS-1539 or approval letter to the contractor as notification of the additional/change service(s) or station(s). When the contractor receives such a notice, it shall abide by the following:

- As applicable, and consistent with longstanding practice, the contractor shall enter all relevant data into PECOS. No referral to or prior approval from PEOG is necessary. However, the contractor may contact its PEOG BFL if it has questions regarding the Form CMS-1539 or the supplier's PECOS record.
- For situations involving new/expanded/changed ESRD stations, the contractor shall send to the supplier the "ESRD Service Station/Modality Changes" letter identified in section 10.7.19 of this chapter. (The state and, as applicable, the AO shall be copied on said letter.)

E. ESRD Location Changes

An ESRD facility that is changing its location must submit either a Form CMS-855A change of information application or an initial enrollment application. The specific transaction type involved (change request or initial) will depend on the particular situation. These situations include the following, and they will generally trigger the termination of the ESRD's existing CCN and the issuance of a new one.

(i) A hospital-based ESRD facility is relocating to an off-campus location in the same state.

In this situation, the ESRD's current CCN will be retired.

If the off-campus location will still function under a common governing body, operate under the hospital's policies and practices, continue to serve the same community, and utilize the same staff at this new location, the new CCN will be that of a renal satellite facility. The application can be processed as a change of information pursuant to the instructions in section 10.6.1.2(A).

If the off-campus location will no longer be operationally, administratively, or financially integrated with the hospital, the new CCN will be that of an independent dialysis facility. The hospital must voluntarily terminate this location from its enrollment, and the site must enroll as a new ESRD facility.

If the contractor has any questions as to whether the relocated location will still be sufficiently integrated with the hospital to permit a change of information application rather than an initial enrollment, the contractor may contact the state for guidance. The processing time clock stops while the contractor awaits the state's guidance.

(ii) An independent ESRD facility is relocating to become a hospital-based facility or a renal satellite facility of a hospital

Since the ESRD facility will be serving a different community under different policies, etc., the facility must terminate its existing enrollment and enroll as a new ESRD facility.

(iii) An independent ESRD facility is relocating to another location and will remain independent

If the ESRD facility will be serving a different community, the facility must terminate its existing enrollment and enroll as a new/initial ESRD facility. If it will serve the same community, the relocation can be processed as a change of information.

(iv) ESRD facility relocating out-of-state

If an ESRD facility of any type (e.g., independent, satellite) is relocating out-of-state --- and notwithstanding any other instruction to the contrary in this chapter ---- it must terminate its existing enrollment and enroll as an initial/new applicant.

F. CHOWs and Changes of Information

For ESRD CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter. For ESRD changes of information, the contractor shall follow the instructions in section 10.6.1.2 of this chapter.

G. New ESRD Model Letters

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use the applicable ESRD letters in section 10.7.19 of this chapter for initial enrollments and state-approved changes of ownership.

H. Beds and Services

A Form CMS-3427 from the state must be included with an initial or CHOW Form CMS-1539 that identifies, as applicable, the services or number of beds at issue. If, nonetheless, this data is not furnished by the state to the contractor for an initial or CHOW application, the contractor may secure it from the state (or, for CHOWs, and as applicable, the AO).

I. ESRD Survey, Certification, and Modalities

As previously indicated, the standard CMS survey and certification form used for ESRDs is the Form CMS-3427. The modalities listed on the Form CMS-3427 are:

- In-center Hemodialysis (HD)
- In-center Peritoneal Dialysis (PD)
- In-center Nocturnal HD
- Home HD Training & Support
- HD in LTC
- Home PD Training & Support
- PD in LTC
- Dialyzer Reuse

For further information on ESRD facilities, refer to:

- Section § 1881 of the Social Security Act
- 42 CFR Part 405, Subpart U
- Pub. 100-07, chapter 2, section 2270 – 2287B
- Pub. 100-02, chapter 11
- Pub. 100-04, Claims Processing Manual, chapter 8

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Statutory Background

Section 4161(a)(2) of OBRA '90 (P.L. 101-508) amended §1861(aa) of the Act and established FQHC services as a benefit under the Medicare program effective October 1, 1991. The statutory requirements that entities must meet to be considered an FQHC for Medicare purposes are at §1861(aa)(4) of the Act. Regulations establishing the FQHC benefit and outlining the Conditions for Coverage for FQHCs were published on June 12, 1992, in the Federal Register (57 FR 24961) and became effective on the date of publication. These regulations were amended on April 3, 1996 (61 FR 14640). Section 13556 of OBRA 1993 (P.L. 103-66) amended §1861(aa) of the Act by adding outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, as entities eligible to participate in Medicare as FQHCs.

B. Requirements

FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, certified nurse-midwives, and clinical social workers. This also includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See Pub. 100-02, chapter 13 for more information). To participate in the Medicare program, applicants seeking initial enrollment as an FQHC must submit a Form CMS-855A application to the appropriate Medicare Administrative Contractor (MAC). Even though they complete the Form CMS-855A application, FQHCs are considered Part B certified suppliers and are paid Part B benefits for FQHC services.

FQHCs are not required to obtain a state survey. However, FQHCs still must meet all applicable state and local requirements and submit all applicable licenses. Typically, the Health Resources and Services Administration (HRSA) will verify such state/local compliance by asking the FQHC to attest that it meets all state/local laws.

FQHCs can be located in a rural or urban area that is designated as either a health professional shortage area or an area that has a medically underserved population.

For purposes of Medicare enrollment, an FQHC is defined as an entity that has entered into an agreement with CMS to meet Medicare program requirements under 42 CFR § 405.2434(a), and (as outlined in Pub. 100-07, chapter 9, exhibit 179):

- Is receiving a grant under § 330 of the Public Health Service (PHS) Act;
- Is receiving funding under a contract with the recipient of a § 330 grant, and meets the requirements to receive a grant under § 330 of the PHS Act;
- Is an FQHC "Look-Alike" (i.e., HRSA), has notified it that it meets the requirements for receiving a § 330 grant, even though it is not actually receiving such a grant);
- Was treated by CMS as a comprehensive federally funded health center as of January 1, 1990; or
- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

C. Initial FQHC Applications

1. Contractor Review and Required Documents

In contrast to both past practice and the process that is normally followed with other certified provider/certified supplier types, the contractor does not make a recommendation for approval to the state/SOG Location for FQHC applications. Instead, the contractor will either approve or deny the application at the contractor level pursuant to the instructions in this section.

The following documents must be included with the FQHC's completed Form CMS-855A application:

- Exhibit 177 (Attestation Statement) signed and dated by an authorized official (as defined in 424.502). To attest to being in compliance, the facility must be open and operating when the attestation is signed. Since FQHCs must sign an agreement stipulating that they will comply with § 1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC benefit (or provider/supplier) agreement when it is also signed and dated by PEOG. (See Pub. 100-07, chapter 2, section 2826B.)
- HRSA Notice of Grant Award (NOA) or FQHC Look-Alike Designation that: (1) includes an address for the site of the applicant which matches the practice location reported on the Form CMS-855A; and (2) has valid project period and budget period dates (designation period and annual certification period dates for the FQHC Look-Alike document). A Notice of Grant Award by HRSA verifies that the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies look-alike status.
- Form CMS-588; Electronic Funds Transfer (EFT) Authorization Agreement.
- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station

receives specimens to be forwarded to a laboratory performing diagnostics test. Pub. 100-07, chapter 6, section 6002 provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the FQHC's responsibility to review the CLIA requirements and obtain a CLIA certificate if needed. Neither the contractor nor CMS determines whether the FQHC needs to obtain and submit a CLIA certificate.

- Copy of state license (if applicable). The state license must be effective and cannot have expired. The facility name and address must be listed on the license.

2. General Processing Concepts

(A) Practice Locations - An FQHC cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own CCN. Moreover, an FQHC cannot share a practice location. There must be a suite number, floor, etc. to distinguish it from another facility that shares the same building address.

(B) Date on the NOA - The project period (Line 26 of the NOA) and budget period (Line 19 of the NOA) must be valid through the date on which the FQHC's application was complete (as determined by the contractor). For the HRSA Look-Alike document, the designation period (Line 6) and Annual Certification Period (Line 7) must be valid through the date on which the FQHC's application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if either the project period or budget period (or designation period and annual certification period) do not meet the above-mentioned requirement. (In developing for this data, the contractor may (but is not required to) send the "Reminder and Assistance for Health Centers for CMS FQHC Site Enrollment" guidance to the FQHC.)

(C) Practice Location Address on NOA - The practice location must be on the HRSA NOA or HRSA Look-Alike document and match the address on the Form CMS-855A. If the location information is not on the current NOA, an expired NOA that has the address in the terms and conditions (or the Self Update print-out) can be referenced alongside the official NOA as supporting documentation. The award number, project period, and budget period on the Self-Update must match the current official NOA and must say ACTIVE. The Self Update print-out by itself is not acceptable in lieu of the official HRSA Notice of Award.

(D) Name on Exhibit 177 - The contractor shall ensure that Exhibit 177 contains the same legal business name, DBA or practice location name, and address as that which the FQHC provided in Section 2 and Section 4, respectively, of the Form CMS-855A. If the attestation contains a different name, the contractor shall develop for the correct name.

(E) Date on Exhibit 177 - The contractor shall ensure that the date on which the Exhibit 177 was signed is on or after the date the FQHC listed as its effective date in Section 4 on the Form CMS-855A application. If the Exhibit 177 was signed prior to the listed effective date, the contractor shall (using the development procedures outlined in this chapter) develop for an Exhibit 177 signed on or after the FQHC's listed effective date; the FQHC should be providing services in order to meet the regulations noted in Exhibit 177.

(F) Date Application Complete - When reviewing an initial FQHC application, the contractor shall determine the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing,

so the contractor requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its approval letter as the CCN/PTAN effective date of the FQHC. The CCN/PTAN effective date cannot be made retroactive (see section 10.6.2).

(G) Contractor Jurisdiction - Except for tribal and Urban Indian FQHCs, a freestanding FQHC that is initially enrolling is assigned to the Medicare Administrative Contractor (MAC) that covers the state in which the FQHC is located. An initially enrolling tribal or Urban Indian FQHC is assigned to the Jurisdiction H MAC.

(H) Tribal/Urban Indian Organizations – Certain outpatient health programs or facilities may be operated by a tribe or tribal organization or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act. The contractor shall confirm the applicant's attestation and tribal/urban Indian status if the FQHC indicates on the application that it has such status; several means are available:

- The applicable Indian Health Service (IHS) web link at https://www.ihs.gov/locations/. The contractor can search for the facility by clicking on the "Find Health Care" sub-link https://www.ihs.gov/findhealthcare/?CFID=15011511&CFTOKEN=36378825 or downloading the Excel complete listing of HIS facilities. (These are the highly recommended means of verification.)

- Contacting (1) the IHS directly, (2) contacting the applicable SOG Location, or (3) the contractor's PEOG BFL.

(I) Potential RHC Relationship – On occasion, a rural health clinic (RHC) may seek to convert to an FQHC. (A supplier cannot be both an RHC and an FQHC and occupy the same practice location.) Accordingly, in its review of an initial FQHC application, the contractor shall check PECOS to determine whether an RHC is enrolled at the same location. If one is, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov. In doing so, the contractor shall furnish to PEOG (1) the names, NPIs, and shared address of the RHC and FQHC, and (2) a copy of all information submitted with the FQHC application; the e-mail's subject line shall state: "RHC & FQHC shared address".

3. Determination

a. Approval

The contractor shall contact PEOG via email at MedicareProviderEnrollment@cms.hhs.gov if it believes that the FQHC's initial application should be approved. The contractor shall provide to PEOG: (1) a copy of the draft approval letter (see section 10.7.5.1(N) of this chapter for a model FQHC approval letter); (2) the Form CMS-855A application or PECOS Application Data Report (ADR) and all supporting documentation; (3) a copy of the FQHC's HRSA documentation; (4) Exhibit 177; and (5) the valid state license IF the facility is located in California..

While awaiting PEOG's final determination---and beginning on the date following the sending of the above-mentioned e-mail---the application processing time clock is stopped. It resumes on the

date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.
(As required per section 10.6.21 of this chapter, the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.))

b. Denial

If the contractor believes that the FQHC's application should be denied, the contractor shall notify the applicant of the denial using the appropriate model letter guidance in section 10.7.8 of this chapter. If the contractor is uncertain as to whether a denial is warranted or what the appropriate denial ground under 42 CFR 424.530(a) should be, it may contact its PEOG BFL for guidance.

4. Post-PEOG Review and Response to Contractor

If PEOG determines (based on the information the contractor furnished) that the FQHC's application should be approved, PEOG will:

- Assign the CCN, which will be part of the 1000-1199 or 1800-1989 series
- Assign the effective date, which will be the date the FQHC application was considered complete by the contractor
- Make any necessary revisions to the draft approval letter
- Sign and date the attestation using the completion date, which is also the effective date (Exhibit 177)
- E-mail all of the foregoing documents and data to the contractor, at which point the aforementioned processing time clock resumes.

5. Post-Approval Contractor Action

If PEOG notifies the contractor that the FQHC's application should be approved, the contractor shall send the approval letter to the FQHC with a copy of the signed Exhibit 177.

D. Changes of Information

1. Location Changes

a. Verification

If an FQHC is changing the physical location of an existing site, the FQHC must submit the following documentation (as applicable to that FQHC) to the contractor:

- For §330 grantees, a HRSA Notice of Grant Award approving the physical location change and the new address; or
- For look-alikes, an updated Notice of Look-Alike Designation from HRSA approving the physical location change and listing the new address.

(Consistent with the instructions in this chapter, the contractor shall develop for this documentation with the FQHC if the latter fails to submit it.)

For tribal/Urban Indian organizations, the contractor may confirm the new location via the IHS website or by contacting IHS. (See section 10.2.1.4(C)(2)(G) above for the web link.)

In all cases, the new address listed on the notice of grant award (NOA), IHS website, etc., must match that listed on the Form CMS-855A change request. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter.
In addition, both the budget date and the project date on the NOA (or designation period and annual certification period on the Look-Alike document) must be valid through the date on which the FQHC's change request application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if either the project period and/or budget period or the designation period and/or annual certification period do not meet the above-mentioned requirement.

b. Approval

If approving the location change or updating the contact information (as described in section 10.6.1.2 of this chapter), the contractor does not issue a recommendation of approval to the SOG Location, notwithstanding any instruction to the contrary in this chapter; rather, the contractor shall approve the location change in PECOS and issue an approval letter to the FQHC (with an e-mailed copy to PEOG at MedicareProviderEnrollment@cms.hhs.gov (Subject line: FQHC COI—Facility Name, Address Change/Contact Change/Other, NPI, PTAN). PEOG will update ASPEN accordingly.). Beginning on March 15, 2021, tie-in notices will not be issued for address changes.

c. Denial

If the contractor does not approve the location change (i.e., the FQHC is no longer located in a shortage area, the FQHC fails to submit the applicable HRSA supporting documentation after contractor development (discussed above), or another reason is implicated), the contractor shall refer the matter to PEOG at ProviderEnrollmentRevocations@cms.hhs.gov consistent with all applicable instructions in this chapter and other CMS directives. (The referral shall include, at a minimum, the FQHC's LBN and NPI as well as a brief explanation of the situation and the reason for referral.) PEOG will review the matter and instruct the contractor on how to proceed.

2. LBN, TIN, or DBA Name Changes Not Involving a CHOW

The contractor shall process LBN, TIN, or DBA name changes not involving a CHOW consistent with the instructions in sections 10.6.1.2(B)(1) and (3) of this chapter. No notification to the state or SOG Location regarding the change is needed.

3. All Other Change Requests

For all change requests not described in subsections (D)(1) and (2) above, the contractor shall follow the instructions in sections 10.6.1.2(C)(1) and (2) of this chapter.

E. Changes of Ownership (CHOWs)

This section 10.2.1.4(E) addresses procedures for processing FQHC CHOWs. Except as noted otherwise, these instructions take precedence over those in section 10.6.1.1.3 et seq. of this chapter.

For background information on CHOWs (which, for purposes of section 10.2.1.4(E), includes acquisitions/mergers and consolidations) and potential CHOW situations, see sections 10.6.1.1.1 and 10.6.1.1.2 of this chapter. The contractor shall, as needed, refer to these instructions in examining whether a CHOW has occurred. In reviewing said sections, the contractor shall note the following:

- The "provider agreement" for FQHCs is the Exhibit 177.
- No recommendations to the state or SOG Location are involved. The contractor and PEOG alone will handle the transaction. In particular, the contractor---in lieu of making a recommendation to the state/SOG Location---will send its "final analysis" to PEOG. PEOG will then: (i) review the transaction; (ii) determine whether the CHOW should be approved; (iii) as needed, update ASPEN and perform any other related tasks; and (iv) notify the contractor of the results of its review and provide any required direction. The above-described process, in effect, combines a recommendation to the state/SOG Location and the contractor's post-recommendation e-mail to PEOG (described in section 10.6.1.1.3.3(B)) into a single step. For purposes of this section 10.2.1.4(E), the term "final analysis" (in the context of FQHC CHOWs) is roughly the equivalent of a recommendation to the state. Accordingly, when sending its "final analysis" to PEOG as described above, the contractor may—but is not required to—change the application's status in PECOS to "approval recommended."

In addition---and except as otherwise stated---the contractor shall adhere to the following subsections and instructions in sections 10.6.1.1.3 et seq. and 10.6.1.1.4:

(i) Section 10.6.1.1.3.1(A) (This does not include the list of documents in section 10.6.1.1.3.1(A)(iii), although all other instructions in section 10.6.1.1.3.1(A)(iii) shall be followed (e.g., development for missing/deficient documents). The required FQHC CHOW documents are identified in this section 10.2.1.4(E).)

(ii) Section 10.6.1.1.3.1(B) (Regarding section 10.6.1.1.3.1(B)(4), the contractor shall make this referral to PEOG before (and separate from) sending its final analysis to PEOG.)

(iii) Sections 10.6.1.1.3.1.1(A)(1), (A)(2), (A)(3), (B)(1), (B)(2), (B)(3)(a) and (c), (F), and (G). (The contractor can disregard references to state recommendations in these sections.) The remaining topics/instructions in section 10.6.1.1.3.1.1 are either inapplicable to FQHC CHOWs or addressed in this section 10.2.1.4(E).

(iv) Sections 10.6.1.1.4(A), (B), (C), (D), (E), (F), (G), and (H) (With respect to the application of 10.6.1.1.4(C) to FQHC CHOWs, receipt of an approval recommendation from the state (as described in 10.6.1.1.4(C)) is the equivalent of the contractor sending its final analysis to PEOG.)

The following instructions address FQHC-specific CHOW processing activities that the contractor shall follow in addition to the procedures contained in the section 10.6.1.1 et seq. subsections outlined in (i) through (iv) above. If any inconsistency exists between these two sets of instructions (i.e., recommending approval to the state as described in 10.6.1.1 et seq. versus making a final analysis to PEOG as described below), the latter takes precedence.

1. Special Processing Steps

a. Required Documents – The contractor shall ensure that the FQHC submits all documentation otherwise required per this chapter. For FQHC CHOW purposes, this also includes:

- Legal Documentation of CHOW - The legal documents that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1(B) for more information on such documents.)

- Evidence of state licensure of the new entity, if applicable. (This can be furnished consistent with existing instructions in this chapter concerning submission of evidence of state licensure.)

- Exhibit 177 containing the new owner's information.

- HRSA NOA or FQHC Look-Alike Designation containing the new owner's information. (NOTE: Both the budget date and the project date on the NOA (or designation period and annual certification period on the HRSA Look-Alike document) must be valid through the date on which the FQHC's CHOW application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if either the project period and/or budget period or the designation period and/or annual certification period dates do not meet the above-mentioned requirement.)

b. Old and New Owner Applications

i. Order of Receipt - To the maximum extent practicable, FQHC CHOW applications from the previous and new owners should be processed as they arrive.

ii. Non-Receipt of Previous Owner's Application – Although the contractor shall attempt to collect the old owner's application, it may make its final analysis without it.

c. Relocation of Entity - A new owner may seek to relocate the FQHC concurrent with a CHOW. In such cases, the contractor shall ensure that the FQHC submits (along with the documents in (E)(1)(a) above):

- For § 330 grantees, a Notice of Grant Award approving the physical location change and the new address; or
- For look-alikes, an updated Notice of Look-Alike Designation from HRSA approving the physical location change and listing the new address.

For tribal/Urban Indian organizations, the contractor may confirm the new location via the IHS website or by contacting IHS. (See section 10.2.1.4(C)(2)(H) above for the web link.)

The new address listed on the notice of grant award, IHS website, etc., must match that on the Form CMS-855A CHOW application. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter.

Notwithstanding the foregoing, the entire transaction shall be processed as a CHOW rather than a COI.

d. Intervening Change of Ownership

In situations where the FQHC (1) submits a Form CMS-855 initial application or CHOW application and (2) subsequently submits a Form CMS-855 CHOW application, the contractor shall adhere to the following:

Situation 1 – The FQHC submitted an initial application followed by a CHOW application, and the contractor has not yet sent its final analysis to PEOG: The contractor shall return both applications and require the FQHC to re-submit an initial application with the new owner's information.

Situation 2 - The FQHC submitted a CHOW application followed by another CHOW application, and the contractor has not yet sent its final analysis to PEOG regarding the first application: The contractor shall process both applications, preferably in the order they were received. When sending its final analysis to PEOG, the contractor shall explain the dual CHOW application submission.

Situation 3 - The FQHC submitted an initial application followed by a CHOW application, and the contactor has sent its final analysis of the initial application to PEOG but before it has notified the FQHC of the approval of the initial application: The contractor shall:

- Return the CHOW application.

- Notify PEOG via e-mail that a change of ownership has occurred (the new owner should be identified) and that the contractor will require the FQHC to resubmit a new initial application containing the new owner's information.

- Request via letter that the FQHC submit a new initial Form CMS-855 application containing

the new owner's information within 30 days of the date of the letter. If the FQHC fails to do so, the contractor shall return the originally submitted initial application and notify the FQHC accordingly. If the FQHC submits the requested application, the contractor shall process it consistent with the instructions in this chapter; the originally submitted initial application becomes moot. If the newly submitted/second initial application is denied, however, the first submitted application is denied as well; the contractor shall notify the FQHC accordingly.

Situation 4 - The FQHC submitted a CHOW application followed by another CHOW application, and the contactor has sent its final analysis of the first CHOW application to PEOG but before it has notified the FQHC of the approval thereof - The contractor shall:

- Notify PEOG via e-mail that (1) a subsequent change of ownership has occurred (the new owner should be identified) and (2) the contractor will require the FQHC to resubmit a new CHOW application containing the subsequent/second new owner's information.

- Process the new/second CHOW application as normal. If a final analysis to PEOG is made for this application, the contractor shall explain this situation in its e-mail; the first CHOW application becomes moot. If the newly submitted/second CHOW application is returned or rejected per the instructions in this chapter, the first application should, too, be returned or rejected (as applicable). The contractor shall notify the provider and PEOG accordingly.

2. Post-Initial Review Actions and Scenarios

After the contractor completes the tasks described in the above-referenced sections, several results are possible. These are discussed below. Should the contractor encounter a scenario not addressed herein, it may contact its PEOG BFL for guidance prior to its final analysis. As a reminder, nothing in this section 10.2.1.4(E)(2) prohibits the contractor from returning or rejecting the application if otherwise permitted to do so per this chapter.

a. The contractor ascertains that the transaction falls within the scope of § 489.18 and that the new owner has accepted assignment – If there are no apparent grounds for denying the CHOW application, the contractor shall send its final analysis to PEOG via e-mail at MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application or PECOS Application Data Report; (2) a copy of the final sales/transfer agreement; (3) a copy of the provider-signed Exhibit 177; and (4) NOA. PEOG will countersign the Exhibit 177 and assign an effective date of the CHOW based on the date the application was complete (as determined by the contractor). Within 5 business days of receiving from PEOG the signed Exhibit 177 and effective date, the contractor shall: (1) send the CHOW approval letter and a copy of the CMS-countersigned Exhibit 177 to the FQHC; and (2) switch the PECOS record to "approved" consistent with existing instructions.

If a denial ground exists, however, the contractor shall refer the matter to its PEOG BFL for guidance notwithstanding any other instruction in this chapter to the contrary. The contractor should include an explanation of the ground(s) it believes exists for the denial (including the regulatory citation); the e-mail referral shall state in the subject line "FQHC Guidance Required."

b. The contractor ascertains that the transaction falls within the scope of § 489.18 but the new owner has not accepted assignment – The contractor shall: (a) return the application; and (b) notify the new owner in the return letter that it must submit the following within 30 days from the date of the return letter: (1) an initial Form CMS-855 application to enroll as a new FQHC; and (2) a voluntary termination application for the existing FQHC. If the new owner fails to do so within 30 days of the request, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter. PEOG will review the matter and respond to the contractor.

c. The contractor ascertains that the transaction does not fall within the scope of § 489.18 (e.g., stock transfer), regardless of whether the new owner accepted assignment - This qualifies as an ownership change under 42 CFR § 424.516 rather than a CHOW under § 489.18. The contractor shall: (A) return the application; and (B) notify the FQHC in the return letter that it must submit a Form CMS-855 application to report the ownership change within 30 days of the return letter and provide all supporting documentation (including a revised NOA and agreement). If the provider fails to do so, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

F. Timeframes and Alternatives

While awaiting PEOG's final determination (and beginning on the date following the sending of the aforementioned e-mail) for the applications described in subsections (C), (D), and (E), the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock. In addition, nothing in this section 10.2.1.4 negates other processing alternatives outlined in this chapter that can apply to the processing of FQHC applications.

G. Supporting Documentation

1. Revalidations

Upon revalidation of an FQHC site, the FQHC must submit --- along with any other supporting documentation required per this chapter --- either an NOA (for awardees) or notice of look-alike designation (NLD, for look-alikes) approving the site. If an NOA or NLD is unavailable for the site, a copy of the FQHC's "Form 5B: Service Sites" list downloaded from HRSA's Electronic Handbooks documenting all of the provider's approved FQHC program sites is acceptable. However, any NOA, NLD, or Form 5B must include the physical address of the site in question that matches the physical address on file with CMS and the address submitted on the Form CMS-855A application. If the addresses do not match, the contractor shall develop for additional information.

2. Initial Applications, CHOWs, and Location Changes

The contractor cannot accept a copy of the Form 5B as documentation for initial applications, CHOWs, and new/changed FQHC locations. As explained previously, only a valid, "in effect" NOA or NLD is acceptable.

H. Revocations and Other Transactions

Except as otherwise stated or required by CMS, the contractor shall continue to adhere to the applicable instructions in this chapter and all other CMS directives regarding:

- Potential FQHC revocations and referrals (including sending the referral/information to the appropriate PEOG mailbox)
- Changes of ownership
- Changes of information
- Revalidations
- Reactivations

I. Complaint Investigations

The CMS SOG Locations investigate complaints that raise credible allegations of an FQHC's noncompliance with health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR 491 Subpart A (except for 42 CFR § 491.3). The contractor shall refer such complaints to the SOG Location that has jurisdiction over the FQHC.

J. FQHC DPV Errors

(This only applies to initial applications (subsection (C)(1) above) and location changes (subsection (D)(1).)

A site visit for FQHCs is generally not required. However, the contractor shall order a site visit if there is a DPV error. The site visit shall be ordered before the contractor sends the applicable e-mail described in subsections (C)(3)(a) and (D)(1)(b) above. If the site visit finds that the facility is not open and operational, the contractor shall deny the application. If the facility is open and operational, the contractor can proceed as normal.

K. Additional Data

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Act
- 42 CFR Part 491 and 42 CFR Part 405, subpart X
- Pub. 100-07, chapter 2, sections 2825 – 2826H
- Pub. 100-07, chapter 9, exhibits 177 and 179
- Admin Info 21 06-ALL – Transitioning FQHC Certification Enrollment Performed by the CMS SOG (Standard Operating Procedures attached)
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

For additional information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see Pub. 100-04, chapter 1, section 20 as well as Pub. 100-07, chapter 9, exhibit 179.

10.2.1.5 - Histocompatibility Laboratories
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A histocompatibility laboratory does "matching" tests in preparation for procedures such as kidney transplants, bone marrow transplants, and blood platelet transfusions. It is the only type of laboratory that must submit a Form CMS-855A application. Each histocompatibility lab must meet all applicable requirements in 42 CFR Part 493 (see 42 CFR § 493.1 in particular) and undergo a state survey.
For information on the appropriate contractor jurisdiction for incoming histocompatibility lab applications, see Pub. 100-04, chapter 1, section 20.

10.2.1.6 - Home Health Agencies (HHAs)
(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Background

1. General Information

An HHA is an entity that provides skilled nursing services and at least one of the following therapeutic services: speech therapy, physical therapy, occupational therapy, home health aide services, and medical social services. The services must be furnished in a place of residence used as the patient's home.

Like most certified providers, HHAs receive a state survey (or a survey from an approved accrediting organization) to determine compliance with federal, state, and local laws) and must sign a provider agreement.

There are two potential "components" of an HHA organization:

Parent – The parent HHA is the entity that maintains overall administrative control of its location(s).

Branch – A branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the conditions of participation as an HHA; the branch can thus be listed as practice locations on the main provider's Form CMS-855A. Though the branch receives a 10-digit CCN identifier, it bills under the parent HHA's CCN.

See Pub. 100-07, chapter 2 for more information on branches.

2. Out-of-State HHA Operations

Pub. 100-07, chapter 2, section 2184 states that when an HHA provides services across state lines:

- It must be certified by the state in which its CCN is based.

- The involved states must have a written reciprocal agreement permitting the HHA to provide services in this manner. In those states that have a reciprocal agreement, HHAs are not required to be separately approved in each state; consequently, they would not have to obtain a separate Medicare provider agreement/number in each state. HHAs residing in a state that does not have a written reciprocal survey agreement with a contiguous state are precluded from providing services across state lines; the HHA must establish a separate parent agency in the state in which it wishes to provide services.

- A CMS approved branch office may be physically located in a neighboring state if the state agencies responsible for certification in each state approve the operation.

See section 10.3.1(A)(1)(d)(iii) of this chapter for additional information regarding the enrollment of out-of-state HHA locations.

B. Processing Instructions for HHA Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of an HHA initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter

(C) Ensure that the HHA has submitted all documentation otherwise required per this chapter. For HHA initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The HHA must complete, sign, date, and include the Form CMS-1561, though the HHA need not complete those sections of the form reserved for CMS. For organizational HHAs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all

other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.6(B) prohibits the contractor from returning or rejecting the HHA application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.6(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the HHA, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) A site visit need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.6(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)
No later than 5 business days after receiving the state's recommendation, the contractor shall commence the following activities:

(i) Order a site visit
(ii) Undertake the 3rd capitalization review discussed in section 10.6.1.2.2 of this chapter.

(iii) Ensure that each entity and individual listed in Sections 2, 5 and 6 of the HHA's Form CMS-855A application is again reviewed against the Medicare Exclusion Database (MED) and the System for Award Management (SAM). (This activity applies: (1) regardless of whether the HHA is provider-based or freestanding; and (2) only to initial enrollments).)

If:

a. The HHA is still in compliance (e.g., no owners or managing employees are excluded/debarred; capitalization is met; site visit is passed): No later than 3 business days after all of these activities are complete (i.e., the 3-day period begins when the last of the three activities has been completed), the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all applicable documents
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the HHA; (2) send a copy of both the approval letter and the provider agreement to the state and/or AO (as applicable)); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

b. The HHA is not in compliance (e.g., the HHA does not meet one of the requirements): The contractor shall deny the application in accordance with the instructions in this chapter.

C. Site Visits

1. Initial application –The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not

convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. Revalidation – If an HHA submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. New/changed location - If an HHA is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Nursing Registries

If the HHA checks "Yes" in Section 12B of the Form CMS-855A, the contractor shall ensure that the information furnished about the HHA nursing registry is accurate. (A nursing registry is akin to a staffing agency, whereby a private company furnishes nursing personnel to hospitals, clinics, and other medical providers.)

E. Recommendation before New HHA Location Established

If an HHA is adding a branch or changing the location of its main location or an existing branch, the contractor may make a recommendation for approval to the state prior to the establishment of the new/changed location (notwithstanding any other instruction in this chapter to the contrary). If the contractor opts to make such a recommendation prior to the establishment of the new/changed location, it shall note in its recommendation letter that the HHA location has not yet moved or been established.

F. CHOWs and Changes of Information

HHA changes of ownership shall be processed in accordance with, as applicable, section 10.6.1.1.5 or section 10.6.1.1. HHA changes of information shall be processed in accordance with section 10.6.1.2.

G. Additional Information

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act

- 42 CFR Part 484
- 42 CFR § 489.28 (capitalization)
- Pub. 100-07, chapter 2
- Pub. 100-04, chapter 10
- Pub. 100-02, chapter 7

10.2.1.6.1 – Reserved for Future Use
(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

10.2.1.6.2 – HHA Capitalization
(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

A. Background

Effective January 1, 2011, and pursuant to 42 CFR §§ 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program - including a new HHA resulting from a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds (known as initial reserve operating funds) at (1) the time of application submission and (2) all times during the enrollment process, to operate the HHA for the three-month period after the Medicare contractor conveys billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

B. Points of Review

At a minimum, the contractor shall verify that the HHA meets the required amount of capitalization at the following times:

- 1st Review - Prior to making its recommendation for approval to the state

- 2nd Review – Between 30 and 35 calendar days after making its recommendation to the state. (Only the request for proof of capitalization need be initiated between 30 and 35 calendar days. The verification need not be completed within or by this timeframe.)

- 3rd Review - After the contractor receives the state recommendation but before it sends to PEOG the e-mail described in section 10.2.1.6(B)(3)(B)

- 4th Review - During the 3-month period after the contractor conveys Medicare billing privileges to the HHA

For initial applications, the contractor shall verify that the HHA meets all of the capitalization requirements addressed in 42 CFR §489.28. (Note that capitalization need not be reviewed for revalidation, reactivation applications, and changes of ownership that do not require a new/initial enrollment under §424.550(b).) The contractor may request from the HHA any and all documentation deemed necessary to perform this task.

The HHA must submit proof of capitalization within 30 calendar days of the contractor's request to do so. Should the HHA fail to furnish said proof and billing privileges have not yet been conveyed, the contractor shall deny the HHA's application pursuant to §424.530(a)(8)(i) or (ii), as applicable. If billing privileges have been conveyed, the contractor shall revoke the HHA's billing privileges per §424.535(a)(11).

Should the contractor deem it necessary to verify the HHA's level of capitalization more than once within a given period (e.g., more than once between the time a recommendation is made and the completion of the state review process), the contractor shall seek approval from its PEOG BFL.

C. Determining Initial Reserve Operating Funds

Initial reserve operating funds are sufficient to meet the requirement of 42 CFR §489.28(a) if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of three or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first 3 months of operation--or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs--whichever is greater.

The contractor shall determine the amount of the initial reserve operating funds by using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the contractor serves that are comparable to the HHA seeking to enter the Medicare program. Factors to be used in making this determination shall include:

- Geographic location and urban/rural status;
- Number of visits;
- Provider-based versus free-standing status; and
- Proprietary versus non-proprietary status.

The adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first 3 months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a 3-month period for the HHAs used in determining the average cost per visit.

D. Proof of Operating Funds

As described further in section 10.2.1.6.2(E) and (G) below, the HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For purposes of the capitalization requirement, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify as meeting the initial reserve operating funds requirement. Examples of cash

equivalents for purposes of the capitalization requirement are Treasury bills, commercial paper, and money market funds.

As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS may later require the HHA to furnish: (1) another attestation from the financial institution that the funds remain available; and/or (2) documentation from the HHA that any cash equivalents remain available until a date when the HHA will have been surveyed by the state agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds constitutes non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

E. Borrowed Funds

1. General Information

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA. As part of this, and except as stated in section 10.2.1.6.2(E)(2) and (H) below, the HHA must (at a minimum) furnish: (1) a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds; and (2) an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds; this could include furnishing an attestation from a financial institution or other source (as may be appropriate) to establish that such funds will remain available until a date when the HHA will have been surveyed by the state agency or by an approved accrediting organization.

2. Inability to Obtain Attestation Statements

Several national bank chains are no longer providing the attestation statements referenced in 42 CFR § 489.28(d) and § 489.28(e) (e.g., to verify the existence of capitalization funds for HHAs). Accordingly, the contractor may accept a current bank statement unaccompanied by an attestation from an officer of the bank or other financial institution if the HHA cannot secure the attestation. (See the phrase "(if the financial institution offers such attestations)" in revised § 489.28(d) and (e).) All efforts must be exhausted, however, to obtain the attestation of funds statement before the contractor can forgo this requirement. In no circumstances shall the contractor instruct the HHA to obtain a different bank that will provide an attestation statement. All other documents listed in section 10.2.1.6(G) must be obtained if required.

F. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification

into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

G. Documents

As part of ensuring the prospective HHA's compliance with the capitalization requirements, the contractor shall obtain the following from the HHA:

- A document outlining the HHA's projected budget – preferably, a full year's budget broken out by month
- A document outlining the number of anticipated visits - preferably a full year broken out by month
- An attestation statement from an officer of the HHA defining the source of funds
- Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)
- Except as stated in section 10.2.1.6.2(E)(2) above, a letter from an officer of the bank attesting that funds are available
- If available, audited financial statements

The contractor shall also ensure that the capitalization information in Section 12 of the Form CMS-855A is provided.

10.2.1.7 - Hospices

(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

A. General Background Information

A hospice is a public agency or private organization or subdivision of either of these that is primarily engaged in providing a comprehensive set of services such as the assessment and management of pain. Typically, the need for services is identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

B. Processing Instructions for Hospice Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of a hospice initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the hospice has submitted all documentation otherwise required per this chapter. For hospice initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The hospice must complete, sign, date, and include the Form CMS-1561, though the hospice need not complete those sections of the form reserved for CMS. For organizational hospices, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.7(B) prohibits the contractor from returning or rejecting the hospice application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.7(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the hospice, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall

notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (D)(1) below need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.1.7(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically do so via a Form CMS-1539; however, the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (D)(1) below.

If the hospice fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(B) above. If the hospice passes the site visit, the contractor (within 3 business days of completing its review of the results) shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments.
- A copy of the Form CMS-1539 from the state or similar documentation received from the accrediting organization.
- A copy of the provider-signed Form CMS-1561.
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, (3) enter the relevant data into the applicable national database, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the hospice; (2) send a copy of both the approval letter and the provider agreement to the state and/or accrediting organization (as applicable)); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Multiple Practice Locations

Hospices are not precluded from having multiple practice locations if permitted by the state. If the state disapproves an additional practice location, the location must seek Medicare approval as a separate hospice with its own enrollment and provider agreement. (See Pub. 100-07, chapter 2, section 2088 for the policies regarding multiple hospice locations.)

If the hospice submits a change of information application to add or relocate a practice location, the contractor shall process the application consistent with section 10.6.1.2 of this chapter. The contractor should be aware, however, that the state may not approve the location addition/change.

D. Site Visits

1. Initial application - The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. Revalidation – If a hospice submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. New/changed location - If a hospice is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

E. Out-of-State Hospice Operations

Pub. 100-07, chapter 2, section 2085 states that when a hospice furnishes services across state lines:

- It must be certified by the state in which its CCN is based.

- The involved states must have a written reciprocal agreement permitting the hospice to provide services in this manner. In those states that have a reciprocal agreement, hospices need not be separately enrolled in each state; consequently, they would not have to obtain a separate Medicare provider agreement/number in each state. Hospices residing in a state that does not have a written reciprocal survey agreement with a contiguous state are precluded from providing services across state lines; the hospice must establish a separate location in the state in which it wishes to provide services.

See section 10.3.1.1.4(D) of this chapter for additional information regarding the enrollment of out-of-state hospice locations. In the event of any inconsistency between the instructions in sections 10.3.1.1.4(D) and 10.2.1.7(E), the latter takes precedence.

F. Recommendation Before New Hospice Location Established

If a hospice is adding a new location or changing the site of an existing one, the contractor can make a recommendation for approval to the state prior to the establishment of the new/changed location (notwithstanding any other instruction in this chapter to the contrary) in accordance with Pub. 100-07, chapter 2, section 2088. If the contractor opts to make such a recommendation prior to the location's establishment or movement, it shall note in its recommendation letter that the location is not yet established or has not yet moved.

G. Practice Locations and Mergers/Acquisitions

Notwithstanding section 10.2.1.7(C) above, hospices cannot merge and allow the other locations to become multiple locations of the hospice because this hinders CMS and/or the state in evaluating compliance with 42 CFR § 418.100(f). The hospice will need to file a CHOW or a voluntary termination of the non-surviving site; the surviving hospice can then submit a Form CMS-855A to add a new multiple location in accordance with Pub. 100-07, chapter 2, section 2088.

H. Additional Information:

For more information on hospices, refer to:

- Sections 1861(u) and 1861(dd) of the Social Security Act
- 42 CFR Part 418
- Pub. 100-07, chapter 2, sections 2080 – 2089
- Pub. 100-04, chapter 11
- Pub. 100-02, chapter 9

10.2.1.8 - Hospitals and Hospital Units

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(This section 10.2.1.8 applies to "standard" hospitals (as the term "hospital" is defined in § 1861(e)(1)), psychiatric hospitals, hospital units, and transplant programs. It does not apply to critical access hospitals, which are a separate provider type and are not "transitioning.")

A. General Background Information

Hospitals and hospital units are a provider type that enrolls via the Form CMS-855A. An exception to this is when the hospital is requesting enrollment to bill for practitioner services for hospital departments, outpatient departments, outpatient locations, and/or hospital clinics; in this circumstance, a new Form CMS-855B enrollment application is required.

B. Processing Instructions for Hospital Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of a hospital initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the hospital has submitted all documentation otherwise required per this chapter. For hospital initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(An authorized official (as defined in § 424.502) must complete, sign, date, and include the Form CMS-1561, though the hospital need not complete those sections of the form reserved for CMS.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.8(B) prohibits the contractor from returning or rejecting the hospital application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.8(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the hospital, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (D)(1) below need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.1.8(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 from the state or similar documentation received from the accrediting organization
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into the applicable national database, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the hospital; (2) send a copy of both the approval letter and the provider agreement to the state and/or accrediting organization (as applicable); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Additional Enrollment Information

1. Swing-Bed Designation

A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital skilled nursing facility (SNF) services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital. Thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional CCN to bill for swing-bed services. (The third digit of the CCN will be the letter U, W, Y or Z.)

In general, and as stated in 42 CFR § 482.58, in order to obtain swing-bed status the hospital must, among other things: (1) have a Medicare provider agreement; (2) be located in a rural area; and (3) have fewer than 100 non-newborn or intensive care beds. Swing-bed hospitals, therefore, are generally small hospitals in rural areas where there may not be enough SNFs, and the hospital is thus used to furnish SNF services.

A separate provider agreement and enrollment for the swing-bed unit is not required. (The hospital's provider agreement incorporates the swing-bed services.) The hospital can add the swing-bed unit as a practice location via the Form CMS-855A.

Additional data on "swing-bed" units can be found in Pub. 100-07, chapter 2, sections 2036 – 2040.

2. Psychiatric and Rehabilitation Units

Though these units receive a state survey, a separate provider agreement and enrollment is not required. (The hospital's provider agreement incorporates these units.) The hospital can add the unit as a practice location to the Form CMS-855A.

3. Multi-Campus Hospitals

A multi-campus hospital (MCH) has two or more hospital campuses operating under one CCN. The MCH would report its various units/campuses as practice locations on the Form CMS-855A. For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

4. Physician-Owned Hospitals

As defined in 42 CFR § 489.3, a physician-owned hospital (POH) means any participating hospital (as defined in 42 CFR §489.24) in which a physician or an immediate family member of a physician has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. (This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at 42 CFR § 411.356(a) or (b).)

Section 2(A)(4) of the Form CMS-855A asks the applicant to identify whether it is a physician-owned hospital. If the applicant indicates in Section 2(A)(2) that it is a hospital, it must complete Section 2(A)(4). Applicants that are not hospitals need not complete Section 2(A)(4).

At this time, POHs are not required to submit a completed Form CMS-855POH or a completed Attachment 1 of the Form CMS-855A. As stated in the March 12, 2015 announcement in MLN Connects Provider eNews, CMS has extended the deadline for the POH Initial Annual Ownership/Investment Report due to concerns about the accuracy of the data collected in the report. Future instruction regarding the reporting of POH ownership and investment will be provided on the CMS physician self-referral website.

5. Critical Access Hospitals

Critical access hospitals (CAHs) are not considered to be a hospital sub-type for enrollment purposes. CAHs instead must be enrolled as a separate, distinct provider type. Thus, if an existing hospital wishes to convert to a CAH, it must submit a Form CMS-855A as an initial enrollment.

6. Hospital Addition of Practice Location

In situations where a hospital is adding a practice location, the contractor shall notify the provider in writing that its recommendation for approval does not constitute approval of the facility or group as provider-based under 42 CFR § 413.65.

If the contractor makes a recommendation for approval of the provider's request to add a hospital unit, the contractor shall forward the package to the state agency as described in this chapter.

7. Transplant Programs

A transplant program is a component within a transplant hospital that provides transplantation of a particular type of organ to include: heart, lung, liver, kidney, pancreas, or intestine. All organ transplant programs must be located in a hospital that has a Medicare provider agreement. The transplant program will receive a CCN that is separate and distinct from the hospital.

For purposes of Medicare enrollment, a hospital transplant program is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant program, it must check the "other" box in Section 2A2 of the Form CMS-855A, write "transplant program" (and the type(s) thereof, such as liver transplant program, kidney transplant program, etc.) on the space provided, and follow the standard instructions for adding a hospital sub-unit. (If multiple types of transplant programs are listed, the contractor shall (a) treat each as a separate sub-unit for enrollment purposes and (b) process the application in the same fashion it would a hospital application that is reporting/adding multiple sub-units.) No separate enrollment in PECOS need or will be created for the transplant center.

D. Section 4 of the Form CMS-855A

Regarding Section 4 of the Form CMS-855A, the hospital must list all addresses where it - and not a separately enrolled provider or supplier it owns or operates, such as a nursing home - furnishes services. The hospital's primary practice location should be the first location identified in Section 4A and the contractor shall treat it as such – unless there is evidence indicating otherwise. NOTE: Hospital departments located at the same address as the main facility need not be listed as practice locations on the Form CMS-855A.

If an enrolled hospital seeks to add or delete a rehabilitation, psychiatric, or swing-bed unit, it should submit a Form CMS-855 change of information request and not, respectively, an initial enrollment application or a voluntary termination application.

E. Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals

Non-participating emergency hospitals, VA hospitals and DOD hospitals no longer need to complete a Form CMS-855A enrollment application in order to bill Medicare.

F. Form CMS-855B Applications Submitted by Hospitals

1. Group Practices

If an entity is enrolling via the Form CMS-855B as a hospital-owned clinic/physician practice, the contractor shall contact the applicant to determine whether the latter will be billing any of the

listed locations as provider-based. If the applicant will not be billing as provider-based, the contractor shall process the application normally. If, however, the applicant will bill as provider-based, the contractor shall notify the applicant that the hospital must report any changed practice locations to its contractor via the Form CMS-855A.

If the supplier is enrolling as a hospital department (under the "Clinic/Group Practice" category on the Form CMS-855B) or an existing hospital department is undergoing a change of ownership (CHOW), the contractor shall only issue the necessary billing numbers upon notification that a provider agreement has been issued – or, in the case of a CHOW, the provider agreement has been transferred to the new owner. If, however, the supplier is enrolling as a group practice that is merely owned by a hospital (as opposed to being a hospital department), the contractor need not wait until the provider agreement is issued before conveying billing privileges to the group.

2. Individual Billings

Assume an individual physician works for a hospital and will bill for services as an individual (i.e., not as part of the hospital service/payment). However, he/she wants to reassign these benefits to the hospital. The hospital will need to enroll with the contractor via the Form CMS-855B (e.g., as a hospital department, outpatient location).

10.2.1.8.1 – Rural Emergency Hospitals (REHs)

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

Section 125 of Division CC of the Consolidated Appropriations Act, 2021 added a new section 1861(kkk) to the Social Security Act (the Act) to establish REHs as a new Medicare provider type to address the growing concern over closures of rural hospitals. In accordance with section 1861(kkk), a facility is eligible to convert to an REH if it was a CAH or rural hospital with not more than 50 beds as of December 27, 2020. REHs must provide emergency services and observation care and are prohibited by the statute from providing inpatient services.

The CY 2023 OPPS/ASC fin4al rule (CMS-1772-F) established, among other things, requirements that REHs must meet to bill Medicare. These included enrollment requirements, addressed in part in new 42 CFR § 424.575. In short, the rule specified the following:

- A CAH or rural hospital wishing to convert to an REH must submit a Form CMS-855A change of information application, rather than an initial application
- No application fee need be paid
- REHs will be in the "limited" screening category under 42 CFR § 424.518
- REHs fall within 42 CFR § 424.520(a) in terms of establishing an effective date of billing privileges.

This section 10.2.1.8.1 instructs contractors on the processing of REH enrollment applications. Note that REHs (like CAHs) are not "transitioning" as that term is used in this chapter with respect to the survey and certification process.

A. Initial Process

(CMS will notify the contractors and the public as to when prospective REHs may begin to submit applications.)

1. Submission

In submitting a Form CMS-855A change of information (COI) application to convert to an REH, the facility must:

(a) Check the "You are changing your Medicare information" box in Section 1(A)

(b) Check the "Other" box in Section 2(A)(2) and write "Rural emergency hospital" or "REH" in the line next thereto

(c) Complete Sections 2(B) (with REH information), 3, and 15 and/or 16 (as applicable)

(d) Report any additions/deletions/changes to its current enrollment information (that is, its current CAH or rural hospital enrollment) that will stem from its conversion to an REH (e.g., new billing agency, adding/deleting two managing employees, deleting a 10 percent owner)

(e) Submit all required state licenses/certifications for operation as an REH (if available to the provider at the time)

(CMS will conduct outreach to the prospective REH community regarding the above requirements.)

However, the facility need not submit with its application:

- An application fee

- Any documentation related to its existing enrollment as a CAH or rural hospital (e.g., CAH licensure) except if a new adverse legal action is also being reported, in which case the contractor shall follow the instructions in section 10.6.6 of this chapter concerning documentation acquisition.

- Any other documentation that: (1) is specific to the survey and certification process; and (2) a non-transitioned, certified provider/supplier typically submits directly to the state or SOG Location pursuant to this process (e.g., a signed provider agreement). The state or SOG Location will, as applicable, collect this information. If the provider nonetheless submits these materials with its application, the contractor shall include them in any recommendation package it sends to the state; however, the contractor need not review them for compliance, signatures, etc.

2. Initial Contractor Review

In reviewing the application, the contractor shall adhere to the following:

(i) <u>Eligibility</u> -

- The contractor shall review PECOS to ascertain whether the enrolling REH was enrolled as a CAH or rural hospital as of December 27, 2020.

- If the contractor finds that the facility does not meet the above-referenced December 27, 2020, enrollment requirement, the contractor shall follow the procedures in section 10.2.1.8.1(A)(4)(ii) for denying the application without making a referral to the state/Survey & Operations Group Location.

- If the contractor is uncertain as to whether the facility qualified as a "rural hospital" as of December 27, 2020, it may contact its Provider Enrollment & Oversight Group Business Function Lead for assistance.

(ii) Submission of New/Initial Enrollment – In the highly unlikely event that the facility submits a full, initial REH enrollment application rather than a COI, the contractor shall nonetheless process the application. No fee is required. (See subsection (A)(3) below for more information.)

(iii) Application Fee – If the facility submits an application fee and/or hardship waiver, the contractor shall refund/return it consistent with the instructions in this chapter. However, if the facility seeks to add a new location pursuant to its application, the contractor in all cases shall contact its PEOG BFL for guidance.

(iv) Returns – If the contractor determines that a basis exists for returning the application under 42 CFR § 424.526 and section 10.4.1.4.2 of this chapter, the contractor shall contact its PEOG BFL for guidance.

(v) Authorized/Delegated Officials – The facility is not required to assign and utilize new authorized and delegated officials pursuant to the conversion. It may continue to use the officials who are part of its existing CAH or rural hospital enrollment. However, as with any other change of information stemming from the conversion, the facility must report any changes to its current authorized/delegated officials; this could occur, for example, if the facility will be under new leadership or management.

(vi) Voluntary Termination – The facility is not required to submit a voluntary termination application to terminate its existing CAH or rural hospital enrollment. Any termination will be effectuated upon the approval of the REH's enrollment. (See subsection (B) below.)

3. Processing and PECOS

Subject to the provisions in subsections 10.2.1.8.1(A)(1) and (2) above, the contractor shall process the COI consistent with the COI processing instructions in this chapter. This includes, but is not limited to, performing all required verifications (e.g., a new managing employee and/or delegated official is reported), developing for any missing or incomplete data, etc. It does not include, however, making determinations normally reserved to the state or SOG Location. For REHs, this includes, but is not limited to: (1) the number of beds; (2) whether emergency services, observation care, and inpatient services will be performed; (3) whether the facility is indeed in a rural area; and (4) whether CoPs are met.

Absent clear evidence to the contrary, the contractor can assume that any Form CMS-855A data that is not reported as changing per subsection (A)(1)(d) above is remaining intact. For instance, suppose the provider does not report any changes in Section 4 of the COI. The contractor can assume that the provider's practice location data will remain as is.

During the aforementioned process, the contractor shall create a new enrollment record in PECOS for the REH. The record shall include: (1) the data submitted on the COI; and (2) data that is currently part of the CAH's or rural hospital's enrollment record but is not changing on the COI. To illustrate, assume a CAH submits a COI to convert to an REH. Sections 6, 7, and 8 are blank, but Section 2(B) contains new REH licensure data. The new REH enrollment record shall include the Section 2(B) REH licensure information as well as the Section 6, 7, and 8 data that is in the CAH's current enrollment record. The CAH's enrollment record shall remain active and intact at this point.

For submitted initial applications:

- The contractor shall process the application consistent with this chapter's instructions for processing initial applications involving non-transitioning certified providers/suppliers.

- While the contractor shall create a new PECOS enrollment record for the REH, it need not (unlike with a COI) populate it with data from the facility's existing CAH or rural hospital record. It can simply use the data on the initial application; the application shall be designated as an initial application in PECOS.)

4. Recommendation/Disposition

i. Approval Recommended – If the contractor believes that a recommendation for approval is warranted, it shall forward its recommendation to the state consistent with the instructions for processing non-transitioned certified provider/supplier applications. The state will review the matter and thereafter refer it to the SOG Location for final review.

ii. Rejection or Denial – If the contractor believes the application should be rejected or denied, it shall send an e-mail to its PEOG BFL that: (1) identifies the provider (e.g., LBN); (2) explains the basis for the contractor's position; and (3) if a potential denial is involved, includes a copy of the draft denial letter for non-transitioned certified providers/suppliers. PEOG will review the matter. If PEOG approves the rejection or denial, the contractor shall --- within 3 business days of receiving said approval --- follow existing procedures for rejecting or denying an application; the state and SOG shall be copied on any denial letter.

B. ePost-SOG Location Procedures

1. Denial

If the SOG Location denies the REH's request for participation, it will notify the contractor thereof. The contractor shall accordingly follow the procedures in this chapter for denying non-

transitioned certified provider/supplier applications. (No prior PEOG approval of the denial is needed.) The facility's CAH or rural hospital enrollment, however, remains as is.

2. Approval

If the SOG Location notifies the contractor of its approval of the REH's request for participation, the contractor shall follow the procedures in this chapter for approving non-transitioned certified provider/supplier applications. As part of this, the contractor shall: (a) switch the REH's PECOS record to "Approved" (using the participation effective date on the SOG Location approval notice); and (b) deactivate the facility's CAH or rural hospital enrollment (with a status of "voluntary withdrawal"), as well as any CAH reassignments, effective the day before the REH's approval effective date.

C. Additional Considerations

1. Letters

- Denial – Any denial letter sent pursuant to this section 10.2.1.8.1 shall include the following language: "Your existing enrollment as a [insert critical access hospital or other hospital type, as applicable] is not affected by this determination."

The contractor shall use the denial letter applicable to the type of application submitted (e.g., a COI denial letter for a COI application).

- Approval – The approval letter shall include the following language: "With your enrollment as a rural emergency hospital, your existing enrollment as a [insert critical access hospital or other hospital type, as applicable] has been deactivated effective [insert date]. You will no longer be able to bill for [insert critical access hospital or other hospital type, as applicable] services under this enrollment." (No separate voluntary termination letter is required.)

The contractor shall use the approval letter applicable to the type of application submitted (e.g., an initial approval letter for an initial application).

The exact placement of the above-mentioned language in the letters lies within the contractor's discretion.

2. Processing Alternatives and Clock Stoppages – Except as otherwise indicated in this section 10.2.1.8.1, all processing alternatives and clock stoppages described in this chapter apply to REH enrollment applications.

D. Enrolled REHs

Once enrolled, the REH, like all providers and suppliers, must maintain compliance with the enrollment requirements in 42 CFR Part 424, subpart P. This includes, but is not limited to, reporting changes to its enrollment information, undergoing revalidation (and submitting the required fee with this application), etc. The contractor need not undertake any special actions

unique to enrolled REHs that are different from those applicable to all other provider/supplier types.

It is possible that an enrolled REH may seek to return to its former status as a CAH or rural hospital. To do so---and consistent with 42 CFR Part 424, subpart P and this chapter---it must submit an initial enrollment application and, for the REH enrollment, a voluntary termination application. It cannot do so via a change of information.

10.2.1.8.1.1 – Indian Health Service (IHS) Rural Emergency Hospital (REH)
(Rev. 12217; Issued: 08-24-23; Effective: 01-01-24; Implementation: 01-02-24)

Beginning January 1, 2024, a tribal or IHS operated hospital (as defined in 42 CFR § 413.65(m)) that converts to an REH (IHS-REH) that provides hospital outpatient services to a Medicare beneficiary may be paid for such services under the outpatient hospital All-Inclusive Rate (AIR) that is established and published annually by the IHS, rather than the rates for REH services described at 42 CFR § 419.92(a)(1).

A prospective IHS-REH must follow (and are subject to) the same provider enrollment requirements and procedures outlined in 42 CFR Part 424, subpart P (including 42 CFR § 424.575) and section 10.2.1.8.1 of this chapter as all other prospective REHs (e.g., submission of change of information rather than an initial application). Accordingly, the contractor shall process all IHS-REH applications in the same manner it would an REH application. There is no material difference between an IHS-REH and REH in terms of Form CMS-855A application completion, submission, and processing. With respect to identifying the provider type in Section 2 of the Form CMS-855A, the facility shall check the "Other" box and list "Indian Health Service – Rural Emergency Hospital." (An alternative identification, such as "IHS-REH," is acceptable so long as it is clear this is the type of facility involved, though the listing must be in Section 2(A).)

Concerning the REH letters mentioned in section 10.2.1.8.1(C), the contractor shall replace any reference therein to "rural emergency hospital" with "Indian Health Service rural emergency hospital" for IHS-REH applications.

As with other IHS enrollment applications, IHS-REH enrollment applications will be handled by Novitas Solutions. (See section 10.2.1.9 of this chapter for more information.) Though IHS-REHs may submit their applications via PECOS, the mailing address for IHS-REH paper applications is:

Novitas Solutions, Inc.
P.O. Box 3115
Mechanicsburg, PA 17055-1858

10.2.1.9 - Indian Health Services (IHS) Facilities
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A. General Background Information

For purposes of provider enrollment only, there are several types of IHS facilities: (1) those that are wholly owned and operated by the IHS; (2) facilities owned by the IHS but tribally operated; and (3) facilities wholly owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the Part A contractor, it may check in Section 2A of the Form CMS-855A either (a) "Indian Health Services Facility" or (b) the specific provider type it is. For instance, if an IHS hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will typically contain some type of reference to Indian Health Services. The contractor will therefore know that an IHS facility is involved.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, SNFs, CAHs, or ESRD facilities. The contractor processes IHS applications in the same manner (and via the same procedures) as it would with a hospital, SNF, etc. (This also applies to procedures for PECOS entry.)

As for CCNs, the IHS facility uses the same series that its concomitant provider type does. That is, an IHS hospital uses the same CCN series as a "regular" hospital, an IHS CAH utilizes the same series as a regular CAH, and so forth.

B. Enrollment Information

IHS facilities and tribal providers may use Internet-based PECOS or the paper Form CMS-855 enrollment application for their enrollment transactions. The designated Medicare contractor for IHS facilities and tribal providers is Novitas Solutions (Novitas).

If the IHS facility or tribal provider mails its Form CMS-855 to a Medicare contractor other than Novitas, that contractor shall forward the application directly to Novitas at the following address:

Novitas Solutions, Inc.
P.O. Box 3115
Mechanicsburg, PA 17055-1858

C. Licensure Requirements for Physicians and Practitioners Enrolling to Work in or Reassign Benefits to an Indian Tribe or Tribal Organization

The Affordable Care Act (Pub. L 111-148) amended Section 221 of the Indian Health Care Improvement Act such that licensed health professionals employed by a tribal health program are, if licensed in any state, exempt from the licensing requirements of the state in which the tribal program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 450, et seq.). Pursuant to this statutory provision, therefore, any physician or practitioner need only be licensed in one state – regardless of whether that state is the one in which the practitioner practices – if he or she is employed by a tribal health program performing services as permitted under the ISDEAA (see Pub. 100-04, chapter 19, section 10 for definitions).

The contractor shall apply this policy when processing applications from these individuals. In terms of the effective date of Medicare billing privileges, the contractor shall continue to apply the provisions of 42 CFR §§ 424.520(d) and 424.521(a) and section 10.6.2 of this chapter.

D. Additional Information

For additional general information on IHS facilities, see Pub. 100-04, chapter 19.

10.2.1.10 - Organ Procurement Organizations (OPOs)
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A. General Background Information

An OPO is an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs. An OPO must have been certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation. In order to be certified as a qualified OPO, an OPO must have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous four years as being a qualified OPO. Under the statute, no new OPOs can enroll into the Medicare program

B. Re-Certification

An OPO is designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. Re-certification must occur not more frequently than once every 4 years. The SOG Location is responsible for conducting the re-certification surveys every 4 years; the OPO must sign a new provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation Network. (See CMS Pub. 100-07, chapter 2, sections 2810 and 2811.)

C. Change in Control/Ownership or Service Area

OPOs can undergo a change in control or ownership or service area (§ 486.310). The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership. The OPO must notify CMS before implementing a change in ownership or control or a change in its service area. The OPO must provide the SOG Location with information that is specific to the board structure of the new organization, as well as operating budgets, financial information and other documentation that the SOG Location determines to be necessary. The OPO must also submit a revised Form CMS-855 to the MAC for review and a recommendation of approval from the SOG Location. When the SOG Location receives notification of a prospective change in control or ownership for a designated OPO, the SOG Location must determine (based upon the documents and information submitted) that the operation of the OPO will continue uninterrupted during and following the change. For any change of ownership or control, a new CMS Form-576 must be signed.

The instructions in the previous paragraph are in addition to, and not in lieu of, those pertaining to changes of ownership and referrals to SOG Locations in sections 10.6 and 10.6.1 et seq. of this chapter.

D. Additional Information

For more information on OPOs, refer to:

- Section 1138 of the Social Security Act
- 42 CFR § 486.301 - § 486.360
- Pub. 100-07, chapter 2, sections 2810 – 2821

For guidance on the appropriate contractor jurisdiction for incoming OPO applications, see CMS Pub. 100-04, chapter 1, section 20. Note that a hospital-based OPO must enroll separately, be separately certified, and sign its own provider agreement.

10.2.1.11 - Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)

(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

A. General Background Information

Physical therapists and speech pathologists provide therapy targeting a person's ability to move and perform functional activities in their daily lives typically inhibited by illness or injury. Care is typically coordinated by therapists in conjunction with a physician and is based on an agreed upon plan of care.

As explained in Pub. 100-07, chapter 2 section 2292, there are three types of organizations that may qualify as providers of OPT and OSP services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CCN. The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability and to tailor a rehabilitation program to meet the specific rehabilitation needs of each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. Social/vocational services are no longer a requirement.

Note that:

- If an OPT/OSP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. An initial Form CMS-855A enrollment application, state survey, and CMS program approval are also required.

- Only those OTP/OSP providers covered under 42 CFR Part 485, Subpart H that furnish OPT/OSP services (as listed above) have provider agreements under 42 CFR § 489.2. Part B physician groups – the supplier type that most people normally associate with the term "clinics" – do not have certified provider or certified supplier agreements.

- Occupational therapy cannot be substituted for the physical therapy requirement. It may, however, be provided in addition to physical therapy or speech pathology services. (See Pub. 100-07, chapter 2, section 2292A.)

There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider if they are not operating in the same space at the same time. (See Pub. 100-07, chapter 2, section 2304.)

B. Processing Instructions for OPT/OSP Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of an OPT/OSP initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the OPT/OSP has submitted all documentation otherwise required per this chapter. For OPT/OSP initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The OPT/OSP must complete, sign, date, and include the Form CMS-1561, though the OPT/OSP need not complete those sections of the form reserved for CMS. For organizational OPT/OSPs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.11(B) prohibits the contractor from returning or rejecting the OPT/OSP application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.11(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the OPT/OSP, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification the contractor shall commence the actions described in section 10.2.1.11(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the OPT/OSP; (2) send a copy of both the approval letter and the provider agreement to the state and/or AO (as applicable)); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Extension Locations

1. Background

As discussed in Pub. 100-07, chapter 2, sections 2298 and 2298A, an OPT/OSP provider can, in certain instances, furnish services from locations other than its primary site. (The provider must designate one location as its primary location on the Form CMS-855A, however.) These sites are called extension locations. An extension location is defined at 42 CFR § 485.703 as "a location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency." Per Pub. 100-07, chapter 2, section 2298A, only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations. These two providers must provide outpatient therapy services at their Medicare approved location.

An OPT/OSP provider may also furnish therapy services in a patient's home or in a patient's room in a SNF. (See Pub. 100-07, chapter 2, section 2300. Note that when the OPT provides services away from the primary site or extension location(s), this is referred to as "off-premises activity" at other locations. Section 2300 (referenced) above discusses such activities.) Because

these are not considered extension locations, neither the home nor the patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, chapter 2, section 2298B.)

OPT/OSP extension sites fall under the parent's Medicare provider agreement and CCN. They are assigned and identified by a unique 10-digit alphanumeric identification number (also sometimes referred to as a "Medicare Branch ID") linked to the parent CCN. PEOG is responsible for the assignment or termination of OPT/OSP extension site identifiers and for updating ASPEN accordingly.

2. Extension Site Changes

All extension site additions, deletions, changes, and relocations require a Form CMS-855A change of information application.

a. Additions

An addition or relocation/change of an extension site requires a referral to the state and thereafter to PEOG to review for final determination prior to approval. The approval letter sent to the OPT/OSP provider, with a copy to the state and/or AO, should include the assigned Medicare Branch ID and the effective date of the added or relocated extension site. The effective date of coverage for services provided from the extension site is the date CMS determines that the extension site meets all applicable federal requirements.

b. Deletions

Deletions do not require a referral to the state but do require post approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) per section 10.6.1.2(B) of this chapter.

D. CHOWs

For OPT/OSP CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter.

E. Additional Information

For more information on OPT/OSP providers, refer to:

- Section 1861(p) of the Social Security Act
- 42 CFR Part 485, subpart H
- Pub. 100-07, chapter 2, sections 2290 – 2308
- Pub. 100-07, Appendix E

10.2.1.12 - Religious Non-Medical Health Care Institutions (RNHCIs)
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A. General Background Information

RNHCIs furnish only nonmedical nursing services and items to people who choose to rely solely on obtaining a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious views. Such nonmedical services are performed exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients (e.g., caring for the physical needs such as assistance with activities of daily living; assistance in moving, positioning, and ambulation; nutritional needs; and comfort and support measures). RNHCIs do not perform any medical screenings, examinations, diagnoses, or treatments, including the administration of drugs. Each beneficiary who wishes to receive services in an RNHCI must make a valid and formal written statement (or "election") to do so. (The specific election requirements are discussed in 42 CFR § 403.724 and Pub. 100-07, chapter 2, section 2054.1B.)

CMS's Boston Northeast SOG Location (in coordination with the CMS Central Office) has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the state but must meet all of the conditions of coverage outlined in 42 CFR §403.720 as well as all conditions of participation. (See 42 CFR §§ 403.730 through 403.746 regarding RNCHI conditions of participation.) For purposes of provider enrollment, the three most important conditions are that the provider:

a. Must not be owned by, under common ownership with, or have an ownership interest of 5 percent or more in a provider of medical treatment or services.

b. Must not be affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services. (Permissible affiliations are described in 42 CFR § 403.738(c)).

c. Must be a non-profit organization per subsection (c)(3) of § 501 of the Internal Revenue Code of 1986, and exempt from taxes under subsection 501(a).

(See Pub. 100-07, chapter 2, section 2054.1 for additional conditions.)

To this end, the contractor shall (1) examine Sections 5 and 6 of the Form CMS-855A and (2) verify the provider's non-profit status to ensure that the aforementioned conditions are met.

B. Additional Information

For more information on RNCHIs, refer to:

- Section 1861(ss)(1) of the Social Security Act
- 42 CFR Part 403, subpart G

- Pub. 100-07, chapter 2, sections 2054, 2054.1, 2054.1A and 2054.1B

- Pub. 100-04, chapter 3, sections 170 - 180

- Pub. 100-02, chapter 1, sections 130 – 130.4.2

For guidance on the appropriate contractor jurisdiction for incoming RNCHI applications, please see Pub. 100-04, chapter 1, section 20.

10.2.1.13 - Rural Health Clinics (RHCs)
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A. General Background Information

An RHC is a facility located in a rural area designated as a shortage area and is neither a rehabilitation agency nor a facility primarily for the care and treatment of mental diseases. It must meet all other requirements of the RHC regulations at 42 CFR Part 491, subpart A. RHCs:

- Are considered to be Part B certified suppliers even though they enroll in Medicare via the Form CMS-855A.

- Are defined in section 1861(aa)(2) of the Social Security Act as facilities that are engaged primarily in providing services that are typically furnished in an outpatient clinic.

- Sign a supplier agreement with CMS (akin to those signed by certified providers). Specifically, RHCs sign the Health Insurance Benefit Agreement (Form CMS-1561A).

- Can be either mobile in nature or fixed/permanent locations.

- Can be freestanding or provider-based. (As stated in Pub. 100-07, provider-based RHCs are an integral and subordinate part of a hospital (including a critical access hospital (CAH), skilled nursing facility (SNF), or a home health agency (HHA)).

There are certain services performed by RHCs that do not actually qualify as RHC services. To bill for these services, the clinic must enroll as a Clinic/Group Practice via the Form CMS-855B. It is not uncommon to see RHCs simultaneously enrolled in Medicare via the Form CMS-855A (to bill for RHC services) and the Form CMS-855B (to bill for non-RHC services).

Note that a facility cannot be simultaneously enrolled as an FQHC and an RHC. Though there are similarities between these two supplier types, there are key differences as well. For instance, FQHCs can service rural or urban regions. To be eligible for certification as an RHC, however, a clinic must be located in a non-urbanized area, as determined by the U.S.

Census Bureau, and in an area designated or certified within the previous 4 years by the Secretary of Health and Human Services (HHS), in any one of the four types of shortage area designations that are accepted for RHC certification. (See Pub. 100-02, chapter 13, sections 10.1 and 20.) Also: (1) RHCs are surveyed by the state while FQHCs are not; and (2) FQHCs furnish preventive services while RHCs do not.

B. Additional Information

For more information on RHCs, refer to:

- Section 1861(aa)(1-2) of the Social Security Act
- 42 CFR Part 491, subpart A
- Pub. 100-07, chapter 2, sections 2240 – 2249
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, refer to Pub. 100-04, chapter 1, section 20.

10.2.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 11808; Issued: 01-24-23; Effective: 01-01-23; Implementation: 01-03-23)

A. General Background Information

As stated in Pub. 100-07, chapter 7, section 7004.2, a SNF is a facility that:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or
- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons; while the care and treatment of mental disease is not the primary action of SNFs, the ability to provide appropriate resources and support for these beneficiaries is necessary;
- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under § 1866 of the Social Security Act); and
- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.

Like other certified providers, SNFs receive a state survey and sign a provider agreement.

SNFs cannot have multiple practice locations under one Form CMS-855A enrollment.

Effective January 1, 2023, SNFs that are initially enrolling or undergoing a change in ownership (as described in sections 10.6.15 and 10.6.21(E)(3) of this chapter) fall within the “high” screening category under 42 CFR § 424.518. SNF revalidations are processed at the “moderate” screening level.

B. Processing Instructions for SNF Initial Form CMS-855A Applications

1. Receipt of Application

Upon receipt of a SNF initial Form CMS-855A application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(i) Perform all data validations otherwise required per this chapter.

(ii) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(iii) Ensure that the SNF has submitted all documentation otherwise required per this chapter. For SNF initial enrollment, this also includes the following:

- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")

- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

- A signed SNF patient transfer agreement. (See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Facility-Transfer-Agreement-Example.pdf for an example.)

(The SNF must complete, sign, date, and include the Form CMS-1561 and transfer agreement described above, though the SNF need not complete those sections of the forms reserved for CMS. For organizational SNFs, an authorized official (as defined in § 424.502) must sign the forms; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-1561, Form HHS-690 evidence, or SNF transfer agreement is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.14(B) prohibits the contractor from returning or rejecting the SNF application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

a. Approval Recommendation

If, consistent with the instructions in section 10.2.1.14(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. (This includes sending recommendations via hard copy mail if the state only accepts this method of transmission.) The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the SNF, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

b. Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

a. Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.14(B)(2)(b) above.

b. Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (D)(1) below.

If the SNF fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(b) above. If the SNF passes the site visit, the contractor shall (within 3

business days of completing its review of the results) send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state.
- A copy of the provider-signed Form CMS-1561.
- A copy of the provider-signed SNF transfer agreement.
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the provider agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

Within 5 business days of receiving from PEOG the signed provider agreement, transfer agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the SNF; (2) send a copy of both the letter and the provider agreement sent to the state and/or AO (as applicable)); (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions; and (3) retain the provider-signed transfer agreement (which CMS does not counter-sign) on file.

C. SNF Distinct Parts

A SNF can be a separate institution or a "distinct part" of an institution. The term "distinct part" means an area or portion of an institution (e.g., a hospital) that is certified to furnish SNF services. The hospital and the SNF distinct part will each receive a separate CCN. Also:

- A hospital may have only one SNF distinct part.

- "Distinct part" designation is not equivalent to being "provider-based."

A SNF distinct part unit must enroll separately (i.e., it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed, and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.)

D. Site Visits

1. Initial application - The scope of the site visit shall be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. Revalidation – If a SNF submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's

enrollment requirements. The scope of the site visit shall be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

(See sections 10.6.15 and 10.6.21(E)(3) for instructions regarding site visits for ownership changes.)

E. Additional Information

For more information on SNFs, refer to:

- Section 1819 of the Social Security Act
- Pub. 100-07, chapter 7
- Pub. 100-02, chapter 8

10.2.2 – Suppliers That Enroll Via the Form CMS-855B
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

10.2.2.1 – Ambulatory Surgical Centers (ASCs)
(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)

ASCs are a certified supplier type that enroll via the Form CMS-855B.

A. Background

An ASC is defined in 42 CFR § 416.2 as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission; the entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in 42 CFR Part 416, subparts B and C (The ASC supplier agreement (Form CMS-370) is similar to the provider agreement signed by Part A providers.)

An ASC satisfies the criterion of being a "distinct" entity when it is separate and clearly distinguishable from any other healthcare facility or office-based physician practice. Thus, distinct entity means that surgical services may only be provided at the single location listed in the Medicare supplier agreement. Medicare-certified ASCs are not permitted to have multiple locations under the same supplier agreement. If an entity owns multiple surgical locations and wishes them to participate in Medicare as an ASC, each location must seek separate participation and enrollment and must demonstrate independent compliance with the ASC conditions of coverage, for the regulations do not permit configurations of multiple ASC locations under one Medicare agreement. (Each location would be considered a new, initial enrollment; thus, if an enrolled ASC wishes to add a second practice location, the transaction would constitute a new, initial enrollment rather than the addition of a practice location to an existing enrollment.) ASCs

may only have one surgical location per CMS Certification Number (CCN). See also CMS Publication (Pub. 100-07), State Operations Manual, chapter 2, section 2210 for more information.

As stated in § 416.26(a), CMS may deem an ASC to be in compliance with any or all of the ASC conditions of coverage set forth in 42 CFR Part 416, subpart C if:

- The ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met;

- In the case of deemed status through accreditation by a national accrediting body, where state law requires licensure, the ASC complies with state licensure requirements; and

- The ASC authorizes the release to CMS of the findings of the accreditation survey.

Unless CMS deems the ASC to be in compliance with the ASC conditions of coverage in 42 CFR Part 416, subpart C, the state survey agency must survey the facility to ascertain compliance with those conditions. (See 42 CFR § 416.26(b).)

B. Processing Instructions for ASC Initial Form CMS-855B Applications

1. Receipt of Application

Upon receipt of an ASC initial Form CMS-855B application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the ASC has submitted all documentation otherwise required per this chapter. For ASC initial enrollment, this also includes the Form CMS-370 (ASC supplier agreement).

(The ASC must complete, sign, date, and include the Form CMS-370, though the ASC need not complete those sections of the form reserved for CMS. For organizational ASCs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-370 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.2.1(B) prohibits the contractor from returning or rejecting the ASC application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.2.1(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the ASC, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.2.1(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the supplier Form CMS-370
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

PEOG will countersign the supplier agreement. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the signed supplier agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned supplier agreement to the ASC; (2) send a copy of both the approval letter and the supplier agreement to the state and/or AO; and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Additional Enrollment Information

The contractor shall ensure that, as applicable, all licenses, certifications, and accreditations submitted by ASCs are included in the enrollment package that is forwarded to the state.

If the ASC applicant's address or telephone number cannot be verified, the contractor shall contact the applicant for further information. If the supplier states that the facility or its phone number is not yet operational, the contractor shall continue processing the application. However, it shall indicate in its recommendation letter to the state agency ("state")/SOG Location that the address and telephone number of the facility could not be verified.

When enrolling the ASC, and except as otherwise stated in this chapter or as otherwise instructed by PEOG, the contractor shall use the effective date indicated on the state approval notice/letter (e.g. CMS-1539). This is the date from which the supplier can bill for services.

D. ASCs and Reassignment

Physicians and non-physician practitioners who meet the reassignment exceptions in 42 CFR § 424.80, and CMS Pub. 100-04, Claims Processing Manual, chapter 1, sections 30.2.6 and 30.2.7 may reassign their benefits to an ASC. In such a reassignment, the individual and the ASC must sign the Form CMS-855R. However, the ASC need not separately and additionally enroll as a group practice in order to receive benefits. It can accept reassignment as an ASC.

E. ASCs Changes of Ownership (CHOWs) and Changes of Information

Though ASCs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving ASCs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For ASC CHOW processing instructions, see section 10.6.1.1 of this chapter.

The contractor shall process ASC changes of information in accordance with section 10.6.1.2 of this chapter.

F. Additional General ASC Information

For more information on ASCs, refer to:

- 42 CFR Part 416
- Pub. 100-07, chapter 2, section 2210 and Appendix L. (See Pub. 100-07, chapter 2, section 2210 for information regarding the sharing of space between ASCs and other providers and suppliers.)
- Pub. 100-02, Benefit Policy Manual, chapter 15, sections 260 – 260.5.3
- Pub. 100-04, chapter 14

G. ASCs and Hospitals

See the following instructions for guidance regarding hospital-operated/affiliated ASCs:

- Pub. 100-04, chapter 14, section 10.1
- Pub. 100-02, chapter 15, section 260.1

10.2.2.2 – Home Infusion Therapy Suppliers
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Home infusion therapy suppliers are a supplier type that enroll via the Form CMS-855B.

A. General Background Information

Section 5012 of the 21st Century Cures Act ("the Cures Act") (Pub. L. 114-255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 1861(iii)(3)(D)(i) of the Act defines a "qualified home infusion therapy supplier" as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. A qualified home infusion therapy supplier must: (1)furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) be accredited by an organization designated by the Secretary; and (4) meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under Part C and in the private sector.

B. Home Infusion Therapy Supplier Eligibility and Enrollment Requirements

An entity that wishes to furnish home infusion therapy services to Medicare beneficiaries must enroll as a home infusion therapy supplier. The supplier must meet the following requirements:

- Obtain and maintain a valid tax identification number and National Provider Identifier at the organizational level.

- Be currently and validly accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare. The CMS-recognized home infusion therapy supplier accreditation organizations include the Joint Commission (TJC), the Utilization Review Accreditation Commission (URAC), the Accreditation Commission for Health Care (ACHC), the Community Health Accreditation Partner (CHAP), the National Association Boards of Pharmacy (NABP), and the Compliance Team (TCT).

- Submit documentation containing an effective date of accreditation as well as the locations accredited for home infusion therapy with its application. (This may, but is not required to be, a copy of the accreditation certification and/or accreditation approval letter.)

- Be compliant with § 414.1515 and all provisions of 42 CFR Part 486, subpart I in order to enroll and maintain Medicare enrollment.

- Certify via the Form CMS-855B application that it meets and will continue to meet the specific requirements for enrollment described in 42 CFR § 424.68 and 42 CFR Part 424, subpart P.

- Successfully complete application screening at the limited categorical risk level per § 424.518(a).

- Pay an application fee at initial enrollment, revalidation, and when adding a practice location.

- Enroll in each state in which it has an accredited practice location. The supplier may provide services in patients' homes across state borders as long as it is appropriately licensed (if the state requires licensure); the supplier must be appropriately licensed (if

the state requires licensure) in each state in which it furnishes home infusion therapy services in patients' homes. (See section 10.3 of this chapter for certain PECOS application submission policies with respect to enrolling in multiple states within one contractor jurisdiction.)

The supplier completes Section 4D (Rendering Services in Patients Homes) of the Form CMS-855B application to report all locations where health care services are rendered in patients' homes. This includes locations across state borders. As an illustration, suppose the supplier has two accredited practice locations in Arkansas and furnishes home infusion therapy services in patients' homes in Arkansas and in Oklahoma; here, the supplier only needs to enroll in Arkansas. If, however, this same supplier wants to add another accredited practice location in Texas, it would have to enroll in in Texas.

10.2.2.3 – Independent Clinical Laboratory Improvement Act (CLIA) Labs

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Independent CLIA labs are a certified supplier type that enroll via the Form CMS-855B. In the context of provider enrollment, it is important to keep in mind when reviewing this section 10.2.2.3 the distinction between (1) a CLIA lab enrolling as an independent Medicare supplier and (2) a different provider/supplier type (e.g., physician group, rural health clinic) that has a CLIA certificate and whose laboratory services are under the same ownership and at the same location as the main provider/supplier.

A. General Background Information

As explained in CMS Publication (Pub.) 100-07, chapter 6, sections 6000 and 6002, the Clinical Laboratory Improvement Amendments of 1988 amended the Public Health Service Act (42 U.S.C. 263a) to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Except as provided at 42 CFR § 493.3, entities that meet the definition of a laboratory at 42 CFR § 493.2 must meet applicable federal requirements and have a CLIA certificate in order to operate.

Regulations implementing CLIA are codified under 42 CFR Part 493. These regulations require that all laboratories or entities performing laboratory testing:

- Pay user fees as assessed by CMS to finance the entire cost of administering the CLIA program;
- Submit specific information to HHS or its designee;
- Comply with specific administrative and program requirements;
- Submit to surveys to assess compliance with CLIA requirements;

- Be subject to specified enforcement actions; and

- (1) Apply for CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization, or (2) be licensed or approved in accordance with state requirements if located in a state with a CMS-approved state laboratory licensure program.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 requires that laboratories participating in the Medicare program comply with CLIA requirements. Therefore, all laboratories, with the exception of laboratories located in and licensed or approved by a state with a CMS-approved state laboratory licensure program (CLIA-exempt laboratories) must obtain a CLIA certificate to operate and to be eligible for payment under Medicare and Medicaid. Although CLIA-exempt laboratories do not need a CLIA certificate to operate, they are assigned a CLIA identification number for Medicare and Medicaid payment purposes.

As stated in Pub. 100-07, chapter 6, section 6002, certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. These include:

- Any facility or component of a facility that performs testing strictly for forensic purposes;

- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients;

- Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. (However, all other testing conducted by a SAMHSA certified laboratory is subject to this rule.);

- Laboratories under the jurisdiction of the Department of Veterans Affairs;

- Department of Defense (DoD) laboratories are subject to requirements that CMS has determined to be comparable to those in CLIA. The DoD is responsible for assuring compliance with these requirements and for oversight of its laboratories under a Memorandum of Understanding (MOU) between the Secretary of HHS and the Secretary of DoD;

- Laboratory testing conducted in conjunction with the provision of home health or hospice care in an individual's home, where the home health agency or hospice employee merely **assists** the individual in performing a test, since tests performed by individuals in the home are not subject to CLIA (see Pub. 100-7, chapter 6, section 6010.1.2.1);

- Laboratories located in and licensed or approved by a state with a CMS-approved laboratory licensure program is approved by CMS (i.e., CLIA exempt as approved under 42 CFR part 493, Subpart E);

- Facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostic tests;

- Radiological facilities that perform only imaging procedures (e.g., x-rays, ultrasounds, magnetic resonance imaging, computerized tomography);

- Facilities performing only physiological testing (e.g., spirometry, slit-lamp test for eyes, breath analysis, pulse oximetry); and

- Any facility or component of a facility that performs substance use disorder testing (such as for alcohol and/or drugs) solely for employment purposes (such as disciplinary, administrative, or legal action).

B. Certificates

See Pub. 100-07, chapter 6, sections 6006 through 6006.7, 6008, and 6014 for information regarding the various types of CLIA certificates.

C. Independent CLIA Lab Enrollment

1. Integrated Labs vs. Independent Labs

Labs that are "integrated" into an existing provider or supplier do not require a separate Form CMS-855B enrollment. "Integrated" labs typically are those that have exactly the same ownership and physical location as another enrolled supplier or provider. (Common examples include: (1) hospital labs and (2) a lab at a physician's office.) If a lab is considered "integrated," the parent provider/supplier shall identify the lab as a practice location in Section 4 of its Form CMS-855 and list the applicable CLIA number.

If the lab is not "integrated," the lab must enroll as an independent CLIA lab via the Form CMS-855B application. The contractor shall advise the lab that it must contact the applicable CLIA office; the lab cannot be enrolled until it receives a CLIA number. The contractor shall also ensure that the lab is CLIA-certified and, as applicable, state-licensed.

2. Additional Enrollment Policies

Unless stated otherwise in this chapter or in another CMS directive:

i. Practice Locations - Each practice location at which laboratory tests are performed must submit to the contractor a separate CLIA certificate for that location. (This includes applications submitted via PECOS.) The only exceptions to this requirement are: (1) laboratories within a hospital that are located at contiguous buildings, on the same campus, and under common direction; (2) non-profit or governmental laboratories that engage in limited public health testing; and (3) laboratories that are not at a fixed location (i.e., are mobile).

ii. States - The laboratory must submit to the contractor a separate certificate for each state in which testing is performed.

D. Procedure to Update CLIA Certificate for an Enrolled CLIA Lab

A Medicare-enrolled CLIA lab shall submit any updated CLIA certificate to its contractor with a Form CMS-855.

E. Site Visits of Independent CLIA Labs

1. Initial and revalidation applications – If an independent CLIA lab submits an initial or revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is (or is still) in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier (or, in the case of revalidation, make a final decision regarding the application) prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. New/changed location - If an independent CLIA lab is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS. This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

F. Additional Information

For additional data on CLIA laboratories, refer to:

- 42 CFR Part 493
- Pub. 100-07, chapter 6
- Pub. 100-04, chapter 16
- Form CMS-116 (CLIA Application for Certification)

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

IDTFs are a supplier type that enrolls via the Form CMS-855B.

A. Introduction

1. General Background

An IDTF is a facility that is independent both of an attending or consulting physician's office and of a hospital. However, IDTF general coverage and payment policy rules apply when an IDTF furnishes diagnostic procedures in a physician's office (see 42 CFR § 410.33(a)(1)).

Effective for diagnostic procedures performed on or after March 15, 1999, MACs pay for diagnostic procedures under the physician fee schedule when performed by an IDTF. An IDTF may be a fixed location or a mobile entity. It is independent of a physician's office or hospital.

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

IDTFs generally perform diagnostic tests on beneficiaries in, for instance, a health care facility, physician's office, or mobile setting. The IDTF standards at § 410.33(g) (as well as other provisions in § 410.33) were, in fact, designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. Yet some health care entities have developed or utilize diagnostic tests that do not require such interaction (hereafter occasionally referenced as "indirect IDTFs"). That is, certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. The service is often conducted by a technician who undertakes a computer analysis offsite or at another location at which the patient is not present. The physician then reviews the image to determine the appropriate course of action. In short, these entities generally, though not exclusively, have two overriding characteristics. First, the tests they perform do not involve direct patient interaction, meaning that the test is conducted away from the patient's physical presence and is non-invasive. Second, the test involves off-site computer modeling and analytics.

Despite the comparatively new and innovative forms of testing these entities undertake, they can still qualify as IDTFs (notwithstanding the offsite and indirect nature of the test) so long as they meet the applicable requirements of § 410.33. In the past, however, these entities have often been unable to meet certain IDTF requirements (and thus cannot enroll in Medicare) strictly because of the test's indirect nature. In other words, the types of tests at issue do not fall within the category of those to which several of the standards in § 410.33 were intended to apply (specifically, to in-person procedures).

ii. "Indirect IDTFs" – General Description, Exemptions, and Verification

To account for such technological advances in diagnostic testing, we revised § 410.33 in the CY 2022 Physician Fee Schedule final rule such that **IDTFs that have no beneficiary interaction, treatment, or testing whatsoever at their practice location are wholly exempt from the following requirements in § 410.33(g).**

- § 410.33(g)(6)) - The IDTF must have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF.

- § 410.33(g)(8)) - The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF.

- § 410.33(g)(9)) - The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public.

In addition. 42 CFR § 410.33(c) previously stated in full: "Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met." This requirement (now codified in § 410.33(c)(1)) remains intact for IDTFs that perform direct, in-person testing. For indirect IDTFs, however, new § 410.33(c)(2) states that---for services that do not require direct or in-person beneficiary interaction, treatment, or testing---any nonphysician personnel performing the test must meet all applicable state licensure requirements for doing so; if such state licensure requirements exist, the IDTF must maintain documentation available for review that these requirements have been met. If no state licensure requirements for such personnel exist, the contractor need not undertake additional verification activities under § 410.33(c)(2) concerning the technician in question; the contractor shall not establish its own additional certification, credentialing, or similar technician requirements (e.g., federal accreditation) above and beyond the requirements in § 410.33(c)(2).

The only complete or partial exemptions in § 410.33 that apply to indirect IDTFs are those described in this subsection (A)(2) (i.e., § 410.33(c)(2), (g)(6), (g)(8), and (g)(9)).

iii. Synopsis

In sum:

(A) IDTFs that perform direct, in-person testing on beneficiaries must still meet all requirements and standards in 42 CFR § 410.33. Also, the personnel performing these tests must comply with the requirements in § 410.33(c)(1).

(B) Indirect IDTFs need not meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). The personnel performing these tests must comply with the requirements in § 410.33(c)(2) rather than § 410.33(c)(1).

(C) If an IDTF performs both direct and indirect tests:

- It must meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). **An IDTF must exclusively and only perform tests involving no beneficiary interaction, treatment, or testing to be exempt from § 410.33(g)(6), (g)(8), and (g)(9). Thus, even if the overwhelming majority of the IDTF's tests are those described in the previous sentence, the above-mentioned exemptions are inapplicable if the IDTF conducts any tests requiring direct, in-person patient interaction.**

- Personnel performing direct patient interaction tests must meet the requirements of § 410.33(c)(1). Personnel conducting indirect, non-person tests must meet the requirements of § 410.33(c)(2). If a particular technician at an IDTF performs both categories of tests, he or she must meet § 410.33(c)(1)'s requirements for the direct, in-person tests and § 410.33(c)(2)'s requirements for the indirect, non-in-person tests.

(D) The contractor will typically be able to determine during application processing whether the IDTF is an "indirect IDTF." This can be done via, for instance, reviewing: (1) the site visit results; or (2) the tests reported in Attachment 2 of the Form CMS-855B. In this matter, the contractor shall abide by the following:

- Unless there is evidence that the IDTF only performs indirect tests, the contractor may assume that the supplier is not an "indirect IDTF."
- If the contractor determines that the IDTF performs both indirect and direct tests, it shall follow the instructions described in this subsection (A)(2).

Note that the contractor is not required to submit all potential indirect IDTF applications to PEOG for review or prior approval. The contractor need only contact its PEOG BFL if it: (1) is truly unsure if an indirect IDTF situation is involved; or (2) does not believe the supplier is an indirect IDTF but the supplier states that it is.

B. IDTF Standards

Consistent with 42 CFR § 410.33(g)—and excluding § 410.33(g)(6), (g)(8), and (g)(9) for indirect IDTFs---each IDTF must certify on its Form CMS-855B enrollment application that it meets the following standards and all other requirements:

1. Operates its business in compliance with all applicable federal and state licensure and regulatory requirements for the health and safety of patients (§ 410.33(g)(1)).

- The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by state and/or federal agencies to make certain that guidelines and regulations are being followed and to ensure that businesses are furnishing quality services to Medicare beneficiaries.

- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. No exemptions to applicable state licensing requirements are permitted, except when granted by the state.

- The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate state or federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.

2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and final adverse actions must be reported to the contractor within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days (§ 410.33(g)(2)).

(NOTE: This 30-day requirement takes precedence over the certification in Section 15 of the Form CMS-855B whereby the supplier agrees to notify Medicare of any changes to its enrollment data within 90 days of the effective date of the change. By signing the certification statement, the IDTF agrees to abide by all Medicare rules for its supplier type, including the 30-day rule in 42 CFR §410.33(g)(2)).

3. Maintain a physical facility on an appropriate site. (For purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.) (§410.33(g)(3)).

- IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

- The requirements in 42 CFR § 410.33(g)(3) take precedence over the guidelines in section 10.3.1(B)(1)(d) of this chapter pertaining to the supplier's practice location requirements.

- The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).

4. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request; and

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days. (§ 410.33(g)(4)).

5. Maintain a primary business phone under the name of the designated business. The IDTF must have its –

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance. (§ 410.33(g)(5)).

The requirements in 42 CFR § 410.33(g)(5) take precedence over the guidelines in section 10.3.1(B)(1)(d) of this chapter regarding the supplier's telephone requirements.

IDTFs may not use "call forwarding" or an answering service as their primary method of receiving calls from beneficiaries during posted operating hours.

6. Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a non-relative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must--

(i) Ensure that the insurance policy remains in force at all times and provide coverage of at least $300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations. (§ 410.33(g)(6))

7. Agree not to directly solicit patients; this includes - but is not limited to - a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician who: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem; and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in § 410.32(a)(3). (§ 410.33(g)(7))

- By the signature of the authorized official in Section 15 of the Form CMS-855B, the IDTF agrees to comply with 42 CFR § 410.33(g)(7).

- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.

- There is no prohibition on television, radio, or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. (§ 410.33(g)(8))

9. Openly post these standards for review by patients and the public. (§ 410.33(g)(9))

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change. (§ 410.33(g)(10))

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards. (§ 410.33(g)(11))

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable federal or state licenses or certifications of the individuals performing these services. (§ 410.33(g)(12))

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days. (§ 410.33(g)(13))

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours. (§ 410.33(g)(14))

15. With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (§ 410.33(g)(15))

16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed-base location. (§ 410.33(g)(16))

17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act (§ 410.33(g)(17)) (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as an agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

If the IDTF claims that it is furnishing services under arrangement as described in section 1861(w)(1), the IDTF must provide documentation of such with its initial or revalidation Form CMS-855 application.

The IDTF must meet all of the standards in 42 CFR § 410.33 – as well as all other federal and state statutory and regulatory requirements – in order to be enrolled in, and to maintain its enrollment in, the Medicare program. Failure to meet any standard in 42 CFR § 410.33 or any other applicable requirement will result in the denial of the supplier's Form CMS-855 application or, if the supplier is already enrolled in Medicare, the revocation of its Medicare billing privileges.

C. Leasing and Staffing

For purposes of the provisions in 42 CFR § 410.33, a "mobile IDTF" does not include entities that lease or contract with a Medicare enrolled provider or supplier to provide: (1) diagnostic testing equipment; (2) non-physician personnel described in 42 CFR § 410.33(c); or (3) diagnostic testing equipment and non-physician personnel described in 42 CFR § 410.33(c). This is because the provider/supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

An IDTF is not required to report equipment that the IDTF is leasing for a period less than 90 days unless the IDTF is leasing equipment for services that they have not already reported on a Form CMS-855B IDTF Attachment. For all new services being provided, IDTFs would need to complete a change of information to include the equipment and CPT/HCPCS codes that will be billed. Any accreditation for the services provided would need to be obtained by the IDTF.

D. Sharing of Space and Equipment

As previously noted, the standard in § 410.33(g)(15) states that, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF cannot: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

If the contractor determines that an IDTF is violating at least one of the three prohibitions in § 410.33(g)(15), the contractor shall revoke the supplier's Medicare billing privileges.

E. Multi-State IDTFs

As stated in 42 CFR § 410.33(e)(1), an IDTF that operates across state boundaries must:

a. Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the states in which it operates; and

b. Operate in compliance with all applicable federal, state, and local licensure and regulatory requirements with regard to the health and safety of patients.

Under § 410.33(e)(2), the point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

F. One Enrollment per Practice Location

An IDTF must separately enroll each of its practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that an enrolling IDTF can only have one practice location on its Form CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete Form CMS-855B application for that location and have that location undergo a separate site visit. Also, each of the IDTF's mobile units must enroll separately; if a fixed IDTF site also contains a mobile unit, the mobile unit must therefore enroll separately from the fixed location.

Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location's failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

If an IDTF adds equipment for diagnostic testing that is mobile in nature but is fixed permanently to the IDTF's physical location (i.e., a CT scanner that is mounted in a bus or trailer but is parked at the IDTF's site for use by the IDTF), a second enrollment is not necessary. This equipment can be listed in the Form CMS-855B along with the services performed on the equipment. In these cases, the contractor shall indicate the use of a fixed mobile unit is in use at the IDTF's site in the site visit request so the site inspector will know to view the fixed mobile equipment as part of the IDTF.

G. Interpreting Physicians

1. Reporting Interpreting Physicians on the Form CMS-855B

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who will provide interpretations subject to the anti-markup payment limitation as detailed in CMS Pub. 100-04, chapter 1, § 30.2.9 - whether the service is provided to the IDTF on a contract basis or is reassigned.

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare

- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so

- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The contractor may need to contact another contractor to obtain this information.) If the applicant does not list any interpreting physicians, the contractor need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

If an interpreting physician has been recently added or changed, the new interpreting physician must have met all of the interpreting physician requirements at the time any tests were performed.

A Form CMS-855R need not accompany a Form CMS-855B application submitted by an IDTF that employs or contracts with an interpreting physician.

2. Changes of Interpreting Physicians

If an interpreting physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. To perform services as an interpreting physician, the new interpreting physician must have met all requirements at the time any tests were performed.

If the contractor receives notification from an interpreting physician that he/she is no longer interpreting tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information to end date the interpreting physician from the enrollment.

H. Effective Date of IDTF Billing Privileges

As stated in 42 CFR § 410.33(i), the filing date of an IDTF Medicare enrollment application is the date the contractor receives a signed application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by the contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

A newly-enrolled IDTF, therefore, may not receive reimbursement for services furnished before the effective date of billing privileges.

The contractor shall note that if it rejects an IDTF application under 42 CFR § 424.525 and a new application is later submitted, the date of filing is the date the contractor receives the new enrollment application.

If an IDTF undergoes an ownership change that results in a new enrollment (e.g., a new federal tax information number (TIN) results from this change), the contractor should use the transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

I. IDTF Technicians Must Be Listed on the Form CMS-855B

Each non-physician who performs IDTF diagnostic tests must be listed. These persons are often referred to as technicians.

J. IDTF Technician Licensure and Certification Requirements

All technicians must meet state licensure or state certification standards at the time of the IDTF's enrollment. The contractor may not grant temporary exemptions from such requirements.

In lieu of requiring a copy of the technician's certification card, the contractor may validate a technician's credentials online via organizations such as the American Registry for Diagnostic Medical Sonography (ARDMS), the American Registry of Radiology Technologists (ARRT), and the Nuclear Medicine Technology Certification Board (NMTCB). If online verification is not available or cannot be made, the contractor shall request a copy of the technician's certification card.

K. IDTF - Changes of Technicians

If a technician is being added or changed, the updated information must be reported via a Form CMS-855B change request. The new technician must have met all of the necessary credentialing requirements at the time any tests were performed.

If the contractor receives notification from a technician that he/she is no longer performing tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the supplier did not have another technician qualified to perform the tests listed on the current application, the supplier must submit significant documentation in the form of payroll records, etc. to substantiate the performance of the test by a properly qualified technician after the date the original technician was no longer performing procedures at the IDTF.

L. IDTF Supervising Physicians – General Principles

An IDTF must have one or more supervising physicians who are responsible for:

- The direct and ongoing oversight of the quality of the testing performed;
- The proper operation and calibration of equipment used to perform tests; and
- The qualifications of non-physician IDTF personnel who use the equipment.

Not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications

of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

Under 42 CFR § 410.33(b)(1), each supervising physician must be limited to providing general supervision at no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

M. IDTF - Information about Supervising Physicians

The contractor shall ensure and document in PECOS that each supervising physician is: (1) licensed to practice in the state(s) where the diagnostic tests he or she supervises will be performed; (2) Medicare-enrolled; and (3) not currently excluded or debarred. The physician(s) need not necessarily be Medicare-enrolled in the state where the IDTF is enrolled; moreover, the physician need not be furnishing medical services outside of his/her role as a supervising physician (i.e., he/she need not have his/her own medical practice separate from the IDTF). If the physician is enrolled in another state or with another contractor, however, the contractor shall ensure that he or she is appropriately licensed in that state.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.

- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.

- If the contractor knows that a reported supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.

- If the supervising physician is enrolling in Medicare and does not intend to perform medical services outside of his/her role as a supervising physician: (1) the contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a PTAN; (2) the physician shall list the IDTF's address as a practice location; and (3) the space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

Section 410.33(b)(2) states that if a procedure requires the direct or personal supervision of a physician as set forth in, respectively, 42 CFR § 410.32(b)(3)(ii) or (iii), the contractor shall ensure that the IDTF's supervising physician furnishes this level of supervision.

The contractor shall: (a) be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR § 410.32(b)(3); and (b) ensure that the applicant has checked the highest required level of supervision for the tests being performed.

Each box that begins with "Assumes responsibility" must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

O. IDTF - Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervising physician listed. If Question E2 is not completed, the contractor may assume – unless it has reason to suspect otherwise - that the supervising physician in question supervises for all codes listed in Section 2 of the IDTF attachment. If Question E2 is completed, the contractor shall ensure that all codes listed in Section 2 are covered through the use of multiple supervising physicians.

With respect to physician verification, the contractor shall contact each supervisory physician by telephone to verify that the physician: (1) actually exists (e.g., is not using a false or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities.

If the physician is enrolled with a different contractor, the contractor shall contact the latter contractor and obtain the listed telephone number of the physician.

P. IDTF - Changes of Supervising Physicians

If a supervising physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. To perform services as a supervising physician, the new supervising physician must have met all requirements at the time any tests were performed.

If the contractor receives notification from a supervising physician that he/she is no longer supervising tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the IDTF did not have another supervising physician listed on the current application, the IDTF must submit a change of information adding a new supervising physician. If the IDTF does not provide this information, the contractor shall proceed with non-compliance revocation procedures as noted in section 10.4(M) of this chapter.

Q. Desk and Site Reviews

All initial and revalidating IDTF applicants shall receive: (1) a thorough desk review; and (2) a mandatory site visit prior to the contractor's approval of the application. The general purposes of these reviews are to determine whether:

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.

- To the extent applicable, the IDTF meets the criteria outlined in sections 10.6.20(A) and 10.6.20(B) of this chapter.

- The IDTF meets the supplier standards in 42 CFR § 410.33.

The contractor shall order the site visit through PECOS. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

R. Mobile Units

Mobile units must list their geographic service areas in Section 4 of the Form CMS-855B. Based on the information furnished therein, the NSVC will generally perform the site visit via one of the following methods: (1) the mobile unit visits the office of the NSVC (or some other agreed-to location) for inspection; (2) the NSVC visits the mobile unit's base of operations to inspect the unit; or (3) the NSVC obtains an advance schedule of the locations at which the IDTF will be performing services and conducts the site visit at one of those locations.

Units performing CPT-4 or HCPCS code procedures that require direct or personal supervision mandate special attention. To this end, the contractor shall maintain a listing of all mobile IDTFs that perform procedure codes that require such levels of supervision. The contractor shall also discuss with the applicant and all supervising physicians listed:

- How they will perform these types of supervision on a mobile basis;

- What their responsibilities are; and

- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

S. Addition of Codes

An enrolled IDTF that wants to perform additional CPT-4 or HCPCS codes must submit a Form CMS-855B change request. If the additional procedures are of a type and supervision level similar to those previously reported (e.g., an IDTF that performs MRIs for shoulders wants to perform MRIs for hips), a new site visit is typically not required, though the contractor reserves the right to request that the NSVC perform one.

If, however, the enrolled IDTF wants to perform additional procedures that are <u>not</u> similar to those previously reported (e.g., an IDTF that conducts sleep studies wants to perform ultrasound tests or skeletal x-rays), the contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

If the enrolled IDTF (1) originally listed only general supervision codes, (2) was only reviewed for general supervision tests, and (3) now wants to perform tests that require direct or personal supervision, the contractor shall promptly suspend all payments for all codes other than those requiring general supervision. The contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

In the situations described in the two previous paragraphs, the contractor shall not approve the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

T. IDTF That Performs Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration certification to perform the mammography. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography screening center.

U. IDTF Ownership of CLIA Laboratory

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number may own both an IDTF and an independent CLIA laboratory. In such a situation, they should be separately enrolled and advised to bill separately. The contractor shall also advise its claims unit to ensure that the CLIA codes are not being billed under the IDTF provider number.

V. Denials and Revocations for Non-Compliance with IDTF Supplier Standards

Pursuant to 42 CFR §§ 424.530(a)(1)/(18) and 424.535(a)(1)/(23), an IDTF's enrollment may be denied or revoked if it violates any applicable standard in § 410.33(g). The contractor shall abide by the following in such situations:

1. <u>(a)(1) – Prior approval unnecessary</u>

For violations of any of the following supplier standards in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(1). Prior PEOG approval is unnecessary. Corrective action plan (CAP) rights under §§ 424.530(a)(1) or 424.535(a)(1) apply.

- § 410.33(g)(1) through (g)(6) as well as (g)(8) through (17).

2. <u>(a)(1) and (a)(23) – Prior approval unnecessary</u>

For violations of the following supplier standard in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(23). Prior PEOG

approval is unnecessary. CAP rights under §§ 424.530(a)(1) apply but no CAP rights apply for § 424.535(a)(23) revocations.

- § 410.33(g)(7)

10.2.2.5 – Intensive Cardiac Rehabilitation (ICR)
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

ICR suppliers are a supplier type that enrolls via the Form CMS-855B.

A. Background

Under 42 CFR § 410.49(a), an intensive cardiac rehabilitation (ICR) program is defined as a physician or non-physician practitioner-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c). (Nonphysician practitioners are eligible to supervise an ICR effective January 1, 2024.)

ICR programs must be approved by CMS through the national coverage determination (NCD) process and must meet certain criteria for approval. Individual sites seeking to provide ICR services via an approved ICR program must enroll with their local Medicare contractor as an ICR program supplier.

B. ICR Enrollment

To enroll as an ICR site, a supplier must complete a Form CMS-855B with the supplier type of "Intensive Cardiac Rehabilitation" selected. The contractor shall verify that CMS has approved the ICR program through the NCD process. A list of approved ICR programs will be identified through the NCD listings, the CMS Web site, and the Federal Register. The contractor shall use one of these options to verify that the ICR program has met CMS approval.

An ICR supplier must separately and individually enroll each of its practice locations. The supplier can therefore only have one practice location (which shall receive its own Provider Transaction Access Number (PTAN)) on its Form CMS-855B enrollment application. The contractor shall use specialty code 31 for these enrollments.

The contractor may accept and process reassignments to ICRs from physicians and nonphysicians who are otherwise authorized to reassign benefits under existing law and policy.

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of ICR suppliers:

- 42 CFR § 410.49

- Pub. 100-04, chapter 32, sections 140.2.2 - 140.2.2.6

- Pub. 100-02, chapter 15, section 232

10.2.2.6 – Mammography Screening Centers (MSCs)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

MSCs are a certified supplier type that enroll via the Form CMS-855B.

A. General Background Information

As defined in 42 CFR § 410.34(a)(2), a screening mammography is a radiologic procedure "furnished to a woman without signs or symptoms of breast disease for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure." Section 410.34(a)(4) defines a "supplier of screening mammography" as a "facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in § 410.34(c) and (d)."

B. Enrollment of MSCs

Consistent with § 410.34(a)(7), in order to qualify for coverage of its services under the Medicare program (and to thus enroll in Medicare), an MSC supplier must meet the following requirements:

1. Must have a valid provisional certificate, or a valid certificate, that has been issued by the Food and Drug Administration (FDA) indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

2. Has not been issued a written notification by the FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

3. Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by the FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(The FDA is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic).)

Unless stated otherwise in this chapter or in another CMS directive, the MSC shall submit a copy of its FDA certificate with its application. If the supplier fails to submit the FDA certificate within 30 days of the MAC's request, the MAC shall reject the application consistent with section 10.4(H)(2) of this chapter.

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of MSCs:

- 42 CFR § 410.34
- Pub. 100-04, chapter 18, sections 20 through 20.1.2
- Pub. 100-02, chapter 15, section 280.3

10.2.2.7 – Pharmacies
(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

Pharmacies are a supplier type that---depending upon the circumstances involved and as discussed below---enroll via the Form CMS-855S or Form CMS-855B.

A. General Background Information

Pharmacies typically enroll via the Form CMS-855S. However, there are certain covered drugs that are billed through the physician fee schedule and not the schedule for durable medical equipment, prosthetics, orthotics and supplies. These drugs must be billed to the Part A/B Medicare Administrative Contractor (MAC), meaning that the pharmacy must enroll via the Form CMS-855B.

B. Additional Information

For more information on the billing and coverage policies for Part B drugs, see:

- Pub. 100-04, chapter 17
- Pub. 100-02, chapter 15, sections 50 through 50.6

10.2.2.8 – Portable X-Ray Suppliers (PXRSs)
(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

PXRSs are a certified supplier type that enroll via the Form CMS-855B.

A. Background

To qualify as a PXRS, an entity must meet the conditions for coverage discussed in 42 CFR § 486.100-110.

A PXRS can be simultaneously enrolled as a mobile independent diagnostic testing facility (IDTF), though they cannot bill for the same service. A PXRS requires a state survey, while a mobile IDTF does not (although an IDTF requires a site visit).

A PXRS does not have a supplier agreement.

B. Processing Instructions for PXRS Initial Form CMS-855B Applications

1. Receipt of Application

Upon receipt of a PXRS initial Form CMS-855B application, the contractor shall undertake the following (in whichever order the contractor prefers unless directed otherwise in this chapter):

(A) Perform all data validations otherwise required per this chapter.

(B) Ensure that the application(s) is complete consistent with the instructions in this chapter.

(C) Ensure that the PXRS has submitted all documentation otherwise required per this chapter. For PXRS initial enrollment, this includes the Form CMS-1880 (Request for Certification as Supplier of Portable X-Ray Suppliers)

If the Form CMS-1880 is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.2.8(B) prohibits the contractor from returning or rejecting the PXRS application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.2.8(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the PXRS, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

If the contractor determines that a denial is warranted, it shall follow the denial procedures outlined in this chapter. This includes: (1) using the appropriate denial letter format in section 10.7.8 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

The state will notify the contractor once it has completed its review. There are two potential outcomes:

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) A site visit need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.2.8(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.)

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order a site visit as described in this chapter.

If the PXRS fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(B) above. If the PXRS passes the site visit, the contractor shall (within 3 business days of completing its review of the results) send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments.
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the supplier-signed Form CMS-1880
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

Based on the information received from the contractor, PEOG will (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

Within 5 business days of receiving from PEOG the effective date, and CCN, the contractor shall: (1) send the approval letter to the PXRS; (2) send a copy of the approval letter to the state

and/or AO (as applicable); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Site Visits

1. Initial application –The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. New/changed location - If a PXRS is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information. This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Reassignment

PXRSs may receive reassigned benefits. A PXRS need not separately enroll as a group practice in order to receive them.

E. Practice Location Information

In Section 4 of the Form CMS-855B, the PXRS must furnish certain information, including:

- Whether it furnishes services from a "mobile facility" or "portable unit." (A PXRS can be either, though it usually is a portable unit.) A "mobile facility" typically describes a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile homes and trailers. A portable unit involves a supplier transporting medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.

- Its base of operations. This is from where personnel are dispatched and where equipment is stored. It may or may not be the same address as the practice location.

- All geographic locations at which services will be rendered.

- Vehicle information if the services will be performed inside or from the vehicle. Unless stated otherwise in this chapter or in another CMS directive, copies of all licenses and registrations must be submitted as well.

F. Additional Enrollment Information

The contractor shall include any licenses, certifications, and accreditations submitted by PXRSs in the enrollment package that is forwarded to the state.

If the PXRS's address or telephone number cannot be verified, the contractor shall contact the applicant for further information. If the supplier states that the facility or its phone number is not yet operational, the contractor shall continue processing the application. However, it shall indicate in its recommendation letter to the state that the address and telephone number of the facility could not be verified.

When enrolling the PXRS, and except as otherwise stated in this chapter or as otherwise instructed by PEOG, the contractor shall use the effective date that is indicated on the state approval letter/notice. This is the date from which the supplier can bill for services.

G. PXRS Changes of Ownership (CHOWs) and Changes of Information

Though PXRSs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving PXRSs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For PXRS CHOW processing instructions, see section 10.6.1.1 of this chapter.

The contractor shall process PXRS changes of information in accordance with section 10.6.1.2 of this chapter.

H. Additional Information

For more information on PXRSs, refer to:

- 42 CFR §§ 486.100 – 486.110
- Pub. 100-07, chapter 2, sections 2420 – 2424B
- Pub. 100-02, chapter 15, sections 80.4 - 80.4.4
- Pub. 100-04, chapter 13, sections 90 - 90.5

10.2.2.9 – Radiation Therapy Centers (RTCs)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

RTCs are a supplier type that enroll via the Form CMS-855B.

A. General Background Information

Under 42 CFR § 410.35, Medicare Part B pays for x-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

RTCs may receive reassigned benefits. An RTC need not separately enroll as a group practice in order to receive them.

B. Additional Information

For additional background on radiation therapy services, see:

- 42 CFR § 410.35
- Pub. 100-04, chapter 13
- Pub. 100-02, chapter 15, section 90

10.2.2.10 – Suppliers of Ambulance Services
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Suppliers of ambulance services are supplier types that enroll via the Form CMS-855B.

A. General Background Information

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of ambulance suppliers:

- 42 CFR §§ 410.40 and 410.41
- 42 CFR Part 414, subpart H
- Pub. 100-02, chapter 10
- Pub. 100-04, chapter 15

B. Types of Ambulance Services

As stated in 42 CFR § 410.40(c), there are several levels of ambulance services covered by Medicare. They are generally defined in § 414.605 and in Pub. 100-02, chapter 10, section 30.1 as follows:

1. Advanced Life Support, level 1 (ALS1) - Transportation by ground ambulance vehicle, medically necessary supplies and services, and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

2. Advanced Life Support, level 2 (ALS2) - Either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three separate administrations of one or more medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or ground ambulance transport, medically necessary supplies and services, and

the provision of at least one of the seven ALS procedures specified in the definition of "Advanced Life Support, level 2" in § 414.605.

3. Air Ambulance (Fixed-Wing and Rotary-Wing) (See § 414.605 and Pub. 100-02, chapter 10, section 30.1.1.for specific definitions of fixed-wing and rotary-wing.)

4. Basic Life Support (BLS) - Transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished and where at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the state or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

5. Paramedic ALS Intercept Services (PI) - Per § 414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in § 410.40(d). In general, PI involves an arrangement between a BLS ambulance supplier and an ALS ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. Under § 410.40(d)(1) through (3), respectively, PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area (see § 410.40(d)(1) for more information on this requirement).

- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions: (1) are certified to furnish ambulance services as required under § 410.41; (2) furnish services only at the BLS level; and (3) be prohibited by state law from billing for any service.

- Be furnished by a paramedic ALS intercept supplier that meets the following conditions: (1) is certified to furnish ALS services as required in § 410.41(b)(2); and (2) bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.

6. Specialty Care Transport (SCT) - Inter-facility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (e.g., emergency or critical care nursing, emergency medicine, respiratory care, cardiovascular care, or an EMT-Paramedic with additional training).

C. Ambulance Qualifications

1. Vehicle Design and Equipment

Section 410.41(a) states that a vehicle used as an ambulance must meet the following requirements:

- Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all state and local laws governing an emergency transportation vehicle.

- Be equipped with emergency warning lights and sirens, as required by state or local laws.

- Be equipped with telecommunications equipment as required by state or local law to include, at a minimum, one two-way voice radio or wireless telephone.

- Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by state or local laws.

2. Vehicle Personnel

Per 42 CFR § 410.41(b)(1), a BLS vehicle must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must be: (i) certified at a minimum as an emergency medical technician-basic by the state or local authority where the services are furnished; and (ii) legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

Per 42 CFR § 410.41(b)(2), an ALS vehicle must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must: (i) meet the BLS vehicle staff requirements described in 42 CFR § 410.41(b)(1); and (ii) must also have one of the two staff members be certified as a paramedic or an emergency medical technician by the state or local authority where the services are being furnished to perform one or more ALS services.

D. Completion of the Form CMS-855B

Pub. 100-02, chapter 10, section 10.1.3 states that, in determining whether the vehicles and personnel of the ambulance supplier meet all of the above requirements, the contractor may accept the supplier's statement (absent information to the contrary) that its vehicles and personnel meet all of the requirements if the statement itself meets the requirements of section 10.1.3. However, section 10.1.3 does not obviate the need for the supplier to complete and submit to the contractor the Form CMS-855B (including Attachment 1 and all supporting documents), and does not excuse the contractor from having to verify the data on the Form CMS-855B in accordance with this chapter and all other applicable CMS instructions. In other words, the "statement" referred to in section 10.1.3 does not supplant or replace the Form CMS-855B enrollment process.

E. Geographic Area: Single Contractor Jurisdiction

If an ambulance supplier will furnish all of its services in the same contractor jurisdiction, the supplier should list:

- Each site at which its vehicles are garaged in Section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)

- Each site from which its personnel are dispatched in Section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)

- Its base of operations – which, for ambulance companies, is their primary headquarters – in Section 4E. (The supplier can only have one base of operations.)

If the supplier will furnish services in more than one contractor jurisdiction, the applicable instructions in sections 10.2.2.10(F) and (G) and 10.3.1(B)(1)(d)(iii) of this chapter apply.

F. Geographic Area: Multiple States

The supplier must list the geographic areas in which it provides services. If the supplier indicates that it furnishes services:

- In more than one contractor's jurisdiction, it must submit a separate Form CMS-855B to each contractor.

- In more than one state but within the same contractor jurisdiction, the contractor shall review sections 10.2.2(G)(7), 10.3, and 10.3.1(B)(1)(d)(iii) of this chapter to determine whether a separate enrollment for the additional state is required.

G. Practice Locations

For purposes of provider enrollment (and as indicated in section 10.2.2.10(E) above), the following are considered ambulance "practice locations":

- A site at which the supplier's vehicles are garaged

- A site from which the supplier's personnel are dispatched

- The supplier's base of operations (i.e., the supplier's primary headquarters). The supplier can only have one base of operations.

Hence, if an ambulance supplier submits a Form CMS-855B to add to its enrollment record a site at which the supplier's vehicles are garaged or from which personnel are dispatched, the supplier must pay an application fee.

Consider the following scenarios:

a. The ambulance supplier is enrolling and performing services in multiple states but within only one contractor jurisdiction: The supplier would have to list on its Form CMS-855B each city/state/zip code in which it performs services. Its base of operations and all other practice locations would also have to be listed, and all licensure/certification requirements would have to be met for each state in which it performs services. However, separate Form CMS-855B applications for each state would only be required if all five conditions described in section 10.3.1(B)(1)(d)(iii) of this chapter are met.

b. The ambulance supplier is enrolling (and has its base of operations) in Contractor Jurisdiction X. Its vehicles perform services in X and in adjacent Contractor Jurisdiction Y: The supplier would have to enroll with X and Y. For its Contractor X Form CMS-855B, the supplier would have to list all of the data mentioned in Example (a) above. For its Contractor Y Form CMS-855B, the supplier would have to (1) list the cities/zip codes in Y in which it performs services, (2) list its Jurisdiction X base of operations and any practice locations in Jurisdiction Y, and (3) meet all licensure/certification requirements for the state(s) in Y in which the supplier performs services.

H. Licensure Information

With respect to licensure:

- The contractor shall ensure that the supplier is appropriately licensed and/or certified, as applicable.

- An air ambulance supplier that is enrolling in a state to which it flies in order to pick up patients (that is, a state other than where its base of operations is located) is not required to have a practice location or place of business in that state. So long as the air ambulance supplier meets all other criteria for enrollment in Medicare, the contractor for that state may not deny the supplier's enrollment application solely on the grounds that the supplier does not have a practice location in that state. (This policy only applies to air ambulance suppliers.)

I. Paramedic Intercept Information

If the applicant indicates that it has a paramedic intercept arrangement, it must include a copy of the agreement/contract with its application.

J. Air Ambulances

Air ambulance suppliers must submit proof that it or its leasing company possesses a valid charter flight license (FAA Part 135 Certificate) for the aircraft being used as an air ambulance. Any of the following constitutes acceptable proof:

- If the air ambulance supplier or provider owns the aircraft, the owner's name on the FAA Part 135 certificate must be the same as the supplier's or provider’s name on the enrollment application.

- If the air ambulance supplier or provider owns the aircraft but contracts with an air services vendor to supply pilots, training, and/or vehicle maintenance, the FAA Part 135 certificate must be issued in the name of the air services vendor. A certification from the supplier or provider must also attest that it has an agreement with the air services vendor and must list the date of that agreement. A copy of the FAA Part 135 certificate must accompany the enrollment application.

- If the air ambulance supplier or provider leases the aircraft from another entity, a copy of the lease agreement must accompany the enrollment application. The name of the company leasing the aircraft from that other entity must be the same as the supplier's or provider's name on the enrollment application.

The air ambulance supplier shall maintain all applicable federal and state licenses and certifications, including pilot certifications, instrument and medical certifications, and air worthiness certifications.

In addition:

- The contractor shall access the following FAA Web site on a quarterly basis to validate all licenses/certifications of air ambulance operators that are enrolled with the contractor: https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/enforcement/reports/. This helps ensure that the supplier's licenses/certifications are active and in good-standing.

- The contractor shall deny or revoke the enrollment of an air ambulance supplier if the supplier does not maintain its FAA certification or any other applicable licenses.

- Section 424.516(e)(3) states that within 30 days of any revocation or suspension of a federal or state license or certification (including an FAA certification), an air ambulance supplier must report the revocation or suspension of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported: (i) specific pilot certifications including, but not limited to, instrument and medical certifications; and (2) airworthiness certification.

K. Hospital-Based Ambulances

An ambulance service that is owned and operated by a hospital need not complete a Form CMS-855B if:

- The ambulance services will appear on the hospital's cost-report; and

- The hospital possesses all licenses required by the state or locality to operate the ambulance service.

If the hospital decides to divest itself of the ambulance service, the latter will have to complete a Form CMS-855B if it wishes to bill Medicare.

10.2.3 - Individual Practitioners Who Enroll Via the Form CMS-855I

(Rev. 11020; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

This section provides background information on physicians and non-physician practitioners (NPPs). While Medicare has established federal standards governing these supplier types, these practitioners must also comply with all applicable state and local laws as a precondition of enrollment.

It is important that contractors review Publication (Pub). 100-02, Medicare Benefit Policy Manual, chapter 15 and Pub. 100-04, Claims Processing Manual, for specific information regarding the required qualifications of the suppliers listed in this section 10.2.3 et seq.

10.2.3.1 – Anesthesiology Assistants

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.69(b) define an anesthesiology assistant as a person who:

1. Works under the direction of an anesthesiologist;

2. Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on non-physician anesthetists; and

3. Is a graduate of a medical school-based anesthesiologist's assistant educational program that: (i) is accredited by the Committee on Allied Health Education and Accreditation; and (ii) includes approximately 2 years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

10.2.3.2 – Audiologists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Section 1861(ll)(3)(B) of the Social Security Act and Pub. 100-02, chapter 15, section 80.3.1 state that a qualified audiologist means an individual with a master's or doctoral degree in audiology who:

1. Is licensed as an audiologist by the state in which the individual furnishes such services; or

2. In the case of an individual who furnishes services in a state that does not license audiologists, has:

    - Successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), and

    - Performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and

    - Successfully completed a national examination in audiology approved by the Secretary.

Given these requirements (and as stated in the aforementioned section 80.3.1), a Doctor of Audiology (AuD) 4th year student with a provisional license from a state does not qualify unless he or she also holds a master's or doctoral degree in audiology.

See Pub. 100-04, chapter 12, section 30.3 for further information regarding audiologist billing.

10.2.3.3 – Certified Nurse-Midwives

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.77 list the Medicare qualifications for certified nurse-midwives (CNMs). These qualifications require that a CNM:

- Be a registered nurse who is legally authorized to practice as a nurse-midwife in the state where services are performed;

- Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and

- Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American Midwifery Certification Board.

For more information on CNMs, refer to:

- Section 1861(gg) of the Social Security Act

- Pub. 100-02, chapter 15, section 180

- Pub. 100-04, chapter 12, section 130.1

10.2.3.4 – Certified Registered Nurse Anesthetists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.69(b)(1) through (4) state that a Certified Registered Nurse Anesthetists (CRNA) is a registered nurse who:

(1) Is licensed as a registered professional nurse by the state in which the nurse practices;

(2) Meets any licensure requirements the state imposes with respect to non-physician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in § 410.69(b)(3) and within 24 months after that graduation meets the requirements of § 410.69(b)(4)(i).

For more information on CRNAs, refer to:

- Section 1861(bb) of the Social Security Act
- Pub. 100-04, chapter 12, section 140.1

10.2.3.5 – Clinical Nurse Specialists

(Rev. 11771; Issued:12-30-22; Effective:01-01-23; Implementation: 01-31-23)

Federal regulations at 42 CFR § 410.76 state that a clinical nurse specialist must meet all of the following requirements:

1. Be a registered nurse who is currently licensed to practice in the state where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with state law.

2. Have a master's degree in a defined clinical area of nursing from an accredited educational institution or a Doctor of Nursing Practice (DNP) doctoral degree; and

3. Be certified as a clinical nurse specialist by a recognized national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary.

Pub. 100-02, chapter 15, section 210 states that CMS recognizes the following organizations as national certifying bodies for clinical nurse specialists at the advanced practice level:

a. American Academy of Nurse Practitioners

b. American Nurses Credentialing Center

c. National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties

d. Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses)

e. Oncology Nurses Certification Corporation

f. AACN Certification Corporation

g. National Board on Certification of Hospice and Palliative Nurses

h. Nurses Portfolio Credentialing Commission (NPCC)

10.2.3.6 – Clinical Psychologists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.71(d) state that to qualify as a clinical psychologist, a practitioner must meet the following requirements:

1. Hold a doctoral degree in psychology (that is, a Ph.D., Ed.D., Psy.D.), and

2. Is licensed or certified, on the basis of the doctoral degree in psychology, by the state in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

A clinical psychologist must agree to meet the consultation requirements of 42 CFR § 410.71(e)(1) through (e)(3). Under 42 CFR § 410.71(e), the practitioner's signing of the Form CMS-855I indicates his or her agreement to adhere to the requirements of § 410.71(e)(1) through (e)(3).

For more information on clinical psychologists, refer to Pub. 100-02, chapter 15, section 160.

10.2.3.7 – Clinical Social Workers

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.73(a) define a clinical social worker as an individual who:

1. Possesses a master's or doctor's degree in social work;

2. After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

3. Either is licensed or certified as a clinical social worker by the state in which the services are performed or, in the case of an individual in a state that does not provide for licensure or certification as a clinical social worker—

    a. Is licensed or certified at the highest level of practice provided by the laws of the state in which the services are performed; and

    b. Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting, such as a hospital, skilled nursing facility (SNF), or clinic.

For more information on clinical social workers, refer to Pub. 100-02, chapter 15, section 170.

10.2.3.8 – Nurse Practitioners

(Rev. 11771; Issued: 12-30-2022; Effective:01-01-2023; Implementation: 01-31-23)

Federal regulations at 42 CFR § 410.75(b) state that a nurse practitioner must be a registered professional nurse who is authorized by the state in which the services are furnished to practice as a nurse practitioner in accordance with state law. The individual must also meet one of the following criteria:

1. Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

    a. Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

    b. Possesses a master’s degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

    (If the aforementioned master’s or doctoral degree is required to obtain a license as a

nurse practitioner in the state, the contractor need not separately verify the degree or require the practitioner to submit applicable documentation.)

2. Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in (1)(a) above.

3. Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

Pub. 100-02, chapter 15, section 200 lists the following organizations as CMS-recognized national certifying bodies for nurse practitioners at the advanced practice level:

- American Academy of Nurse Practitioners
- American Nurses Credentialing Center
    - National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties
    - Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses)
- Oncology Nurses Certification Corporation
- AACN Certification Corporation
- National Board on Certification of Hospice and Palliative Nurses
- Nurses Portfolio Credentialing Commission (NPCC)

10.2.3.9 – Occupational Therapists in Private Practice

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Regulatory Requirements - Occupational Therapist in Private Practice

Section 42 CFR § 410.59(c)(1)(i) through (iv) state that an occupational therapist in private practice must meet all the following:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the state in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: (A) solo practice; (B) a partnership; (C) group practice; or (D) as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. (A therapist's private practice office space refers to the location(s) where the practice is operated in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, such space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a critical access hospital, or a SNF.))

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

B. Qualified Occupational Therapist Requirements

Pub. 100-02, chapter 15, section 230.2(B) states that a qualified occupational therapist is an individual who meets the requirements in one of the four categories below:

Category #1 – The occupational therapist: (i) is licensed (if licensure applies) or otherwise regulated (if applicable) as an occupational therapist by the state in which practicing; (ii) graduated from an accredited education program for occupational therapists; and (iii) is eligible to take or has passed the examination for occupational therapists administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). The phrase "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is furnished (including temporary licensure), regardless of the location of the entity billing the services. The education program for U.S. trained occupational therapists is accredited by the Accreditation Council for Occupational Therapy Education (ACOTE).

The requirements above apply to all occupational therapists effective January 1, 2010 if the occupational therapist has not met any of the following requirements prior to January 1, 2010.

Category #2 - On or before December 31, 2009, the individual --

(a) Is licensed or otherwise regulated as an occupational therapist in the state in which practicing (regardless of the qualifications they met to obtain that licensure or regulation); or

(b) When licensure or other regulation does not apply--

(i) Graduated from an occupational therapist education program accredited by ACOTE; and

(ii) Is eligible to take, or has successfully completed, the NCBOT examination for occupational therapists.

Category #3 - On or before January 1, 2008 (and if the individual met the Medicare requirements for occupational therapists that were in 42 CFR § 484.4 prior to January 1, 2008), the individual--

(a) Graduated from an occupational therapy program approved jointly by the American Medical Association and the American Occupational Therapy Association (AOTA); or

(b) Is eligible for the National Registration Examination of AOTA or NBCOT.

Category #4 - On or before December 31, 1977, the individual--

(a) Had 2 years of appropriate experience as an occupational therapist; and

(b) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

C. Occupational Therapist Educated Outside the United States

Pub. 100-02, chapter 15, section 230.2(B) states that individuals educated outside the U.S. may meet the same qualifications as domestic trained occupational therapists. For example, the individual qualifies if he or she was licensed or otherwise regulated by the state in which practicing on or before December 31, 2009. The individual also qualifies if he or she:

- Graduated from an occupational therapy education program accredited as substantially equivalent to a U.S. occupational therapy education program by ACOTE, the World Federation of Occupational Therapists, or a credentialing body approved by AOTA;

- Passed the NBCOT examination for occupational therapists; and

- Effective January 1, 2010, are licensed or otherwise regulated, if applicable, as an occupational therapy by the state in which practicing.

D. Occupational Therapists - Additional References

In Pub. 100-02, chapter 15, see section 230.2(B) for more information regarding the required qualifications of occupational therapists and section 230.4 for information regarding the term “private practice.”

E. Other Enrollment Information - Form CMS-855 Completion

All occupational therapists in private practice must respond to the questions in Section 2J of the Form CMS-855I. However, Section 2J does not apply if the occupational therapist: (1) plans to provide his/her services as a member of an established occupational therapist group, an employee of a physician-directed group, or an employee of a non-professional corporation; and (2) wishes to reassign his/her benefits to that group.

If the occupational therapist checks that he/she renders all his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be

the person's home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, Section 4B of the Form CMS-855I should indicate where services are rendered (e.g., county, state, city of the patients' homes). Post office boxes are not acceptable.

If the individual answers "Yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for occupational therapy services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

10.2.3.10 – Physical Therapists in Private Practice

A. Regulatory Requirements - Physical Therapist in Private Practice

Section 42 CFR § 410.60(c) states that to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

1. Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the state in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

2. Engage in the private practice of physical therapy on a regular basis as an individual in one of the following practice types: (i) a solo practice; (ii) a partnership; (iii) a group practice; or (iv) as an employee of any of (i), (ii), or (iii).

3. Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, such space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

4. Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

B. Qualified Physical Therapist Definition

Pub. 100-02, chapter 15, section 230.1 states that a qualified physical therapist is a person who: (1) is licensed, if applicable, by the state in which he or she is practicing (unless licensure does not apply); (2) has graduated from an accredited physical therapist education program; and (3) passed an examination approved by the state in which physical therapy services are provided. The phrase "by the state in which practicing" includes any

authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The curriculum accreditation is provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or, for those who graduated before CAPTE, curriculum approval was provided by the American Physical Therapy Association (APTA). For internationally educated physical therapists, curricula are approved by a credentials evaluation organization either approved by the APTA or identified in 8 CFR 212.15(e) as it relates to physical therapists. For example, in 2007, 8 CFR 212.15(e) approved the credentials evaluation provided by the Federation of State Boards of Physical Therapy (FSBPT) and the Foreign Credentialing Commission on Physical Therapy (FCCPT).

The requirements above do not apply to a physical therapist effective January 1, 2010, if he or she has otherwise met the requirements outlined in Category #2, Category #3, Category #4, or Category #5 below. (Category #1 is outlined in the previous paragraph.)

Category #2 – A physical therapist whose current license was obtained on or prior to December 31, 2009, qualifies to provide physical therapy services to Medicare beneficiaries if he or she:

(a) Graduated from a CAPTE approved program in physical therapy on or before December 31, 2009 (examination is not required); or

(b) Meets both of the following:

(i) Graduated on or before December 31, 2009, from a physical therapy program outside the U.S. that is determined to be substantially equivalent to a U.S. program by a credentialed evaluation organization approved by the APTA or identified in 8 CFR § 212.15(e).

(ii) Passed an examination for physical therapists approved by the state in which he or she is practicing.

Category #3 – A physical therapist whose current license was obtained before January 1, 2008, may meet the requirements in place on that date (i.e., graduation from a curriculum approved by either the APTA, the American Medical Association, or both).

Category #4 – A physical therapist meets the requirements if he or she (a) is currently licensed as a physical therapist, (b) was licensed or qualified as a physical therapist on or before December 31, 1977, (c) had 2 years of appropriate experience as a physical therapist, and (d) passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Category #5 – A physical therapist meets the requirements if he or she is currently licensed and before January 1, 1966, he or she was:

- Admitted to membership by the APTA; or
- Admitted to registration by the American Registry of Physical Therapists; or

- Graduated from a 4-year physical therapist curriculum approved by a state Department of Education; or

- Licensed or registered and prior to January 1, 1970, he/she had 15 years of full-time experience in physical therapy under the order and direction of attending and referring doctors of medicine or osteopathy.

C. Physical Therapist Trained Outside the United States

Pub. 100-02, chapter 15, section 230.1(B) states that a physical therapist meets the requirements if he or she: (a) is currently licensed; (b) was trained outside the U.S. before January 1, 2008; (c) after 1928 graduated from a physical therapy curriculum approved in the country in which the curriculum was located and that country had an organization that was a member of the World Confederation for Physical Therapy; and (d) he/she qualified as a member of that organization.

D. Physical Therapists - Additional References

In Pub. 100-02, chapter 15, see section 230.2(B) for more information regarding the required qualifications of physical therapists and section 230.4 for detailed information regarding the term "private practice."

E. Site Visits of Physical Therapists in Private Practice

(This site visit requirement is pursuant to 42 CFR § 424.518(b).)

Unless otherwise stated in this chapter or another CMS directive, site visits will be performed in accordance with the following:

i. Initial application – If a physical therapist or physical therapist group submits an initial application for private practice, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

ii. Revalidation – If a private practice physical therapist or physical therapist group submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

iii. New/changed location – Unless CMS has directed otherwise, if a private practice physical therapist or physical therapist group is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the

new/changed location through PECOS. This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

Note that if the PT (being a moderate-risk provider under § 424.518) has multiple practice locations, the SVC will conduct a site visit of each location rather than simply one selected location.

F. Physical Therapists: Additional Site Visit Information

The contractor is also advised of the following:

- In Section 2B of the Form CMS-855B application, physical and occupational therapy groups are denoted as "Physical/Occupational Therapy Group in Private Practice." If a supplier that checks this box in Section 2B is exclusively an occupational therapy group in private practice – that is, there are no physical therapists in the group – the contractor shall process the application using the procedures in the "limited" screening category. No site visit is necessary. If there is at least one physical therapist in the group, however, the application shall be processed using the procedures in the "moderate" screening category. A site visit by the NSVC is required unless CMS has directed otherwise.

- If an entity is enrolled as a physician practice and employs a physical therapist within the practice, the practice itself falls within the "limited" screening category. This is because the entity is enrolled as a physician practice and not a physical therapy group in private practice. However, this does not exempt the physical therapist from the screening required at the "moderate" risk level.

- Unless CMS has directed otherwise, a site visit by the NSVC is required when a physical therapist submits an application for private practice initial enrollment and reassignment of benefits (Form CMS-855I). However, a site visit is not required for an enrolled private practice physical therapist who is reassigning his or her benefits only.

- If the private practice physical therapist's practice location is his or her home address and it exclusively performs services in patients' homes, nursing homes, etc., no site visit is necessary.

G. Other Enrollment Information

All physical therapists in private practice must respond to the questions in Section 2J of the Form CMS-855I. However, Section 2J does not apply if the physical therapist: (1) plans to provide his/her services as a member of an established PT group, an employee of a physician-directed group, or an employee of a non-professional corporation; and (2) the

person wishes to reassign his/her benefits to that group. Such information will be captured on the group's Form CMS-855B application.

If the physical therapist checks that he/she renders all his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be the person's home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, Section 4E of the Form CMS-855I should indicate where services are rendered (e.g., county, state, city of the patients' homes). Post office boxes are not acceptable.

If the individual answers "Yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for physical therapist services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

10.2.3.10 – Physical Therapists in Private Practice

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

A. Regulatory Requirements - Physical Therapist in Private Practice

Section 42 CFR § 410.60(c) states that to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

1. Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the state in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

2. Engage in the private practice of physical therapy on a regular basis as an individual in one of the following practice types: (i) a solo practice; (ii) a partnership; (iii) a group practice; or (iv) as an employee of any of (i), (ii), or (iii).

3. Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, such space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

4. Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

B. Qualified Physical Therapist Definition

Pub. 100-02, chapter 15, section 230.1 states that a qualified physical therapist is a person who: (1) is licensed, if applicable, by the state in which he or she is practicing (unless licensure does not apply); (2) has graduated from an accredited physical therapist education program; and (3) passed an examination approved by the state in which physical therapy services are provided. The phrase "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The curriculum accreditation is provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or, for those who graduated before CAPTE, curriculum approval was provided by the American Physical Therapy Association (APTA). For internationally educated physical therapists, curricula are approved by a credentials evaluation organization either approved by the APTA or identified in 8 CFR 212.15(e) as it relates to physical therapists. For example, in 2007, 8 CFR 212.15(e) approved the credentials evaluation provided by the Federation of State Boards of Physical Therapy (FSBPT) and the Foreign Credentialing Commission on Physical Therapy (FCCPT).

The requirements above do not apply to a physical therapist effective January 1, 2010 if he or she has otherwise met the requirements outlined in Category #2, Category #3, Category #4, or Category #5 below. (Category #1 is outlined in the previous paragraph.)

Category #2 – A physical therapist whose current license was obtained on or prior to December 31, 2009 qualifies to provide physical therapy services to Medicare beneficiaries if he or she:

(a) Graduated from a CAPTE approved program in physical therapy on or before December 31, 2009 (examination is not required); or

(b) Meets both of the following:

(i) Graduated on or before December 31, 2009, from a physical therapy program outside the U.S. that is determined to be substantially equivalent to a U.S. program by a credentialed evaluation organization approved by the APTA or identified in 8 CFR § 212.15(e).

(ii) Passed an examination for physical therapists approved by the state in which he or she is practicing.

Category #3 – A physical therapist whose current license was obtained before January 1, 2008, may meet the requirements in place on that date (i.e., graduation from a curriculum approved by either the APTA, the American Medical Association, or both).

Category #4 – A physical therapist meets the requirements if he or she (a) is currently licensed as a physical therapist, (b) was licensed or qualified as a physical therapist on or before December 31, 1977, (c) had 2 years of appropriate experience as a physical therapist, and (d) passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Category #5 – A physical therapist meets the requirements if he or she is currently licensed and before January 1, 1966, he or she was:

- Admitted to membership by the APTA; or
- Admitted to registration by the American Registry of Physical Therapists; or
    - Graduated from a 4-year physical therapist curriculum approved by a state Department of Education; or
- Licensed or registered and prior to January 1, 1970, he/she had 15 years of full-time experience in physical therapy under the order and direction of attending and referring doctors of medicine or osteopathy.

C. Physical Therapist Trained Outside the United States

Pub. 100-02, chapter 15, section 230.1(B) states that a physical therapist meets the requirements if he or she: (a) is currently licensed; (b) was trained outside the U.S. before January 1, 2008; (c) after 1928 graduated from a physical therapy curriculum approved in the country in which the curriculum was located and that country had an organization that was a member of the World Confederation for Physical Therapy; and (d) he/she qualified as a member of that organization.

D. Physical Therapists - Additional References

In Pub. 100-02, chapter 15, see section 230.2(B) for more information regarding the required qualifications of physical therapists and section 230.4 for detailed information regarding the term "private practice."

E. Site Visits of Physical Therapists in Private Practice

(This site visit requirement is pursuant to 42 CFR § 424.518(b).)

Unless otherwise stated in this chapter or another CMS directive, site visits will be performed in accordance with the following:

1. Initial application – If a physical therapist or physical therapist group submits an initial application for private practice, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is compliant with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. Revalidation – If a private practice physical therapist or physical therapist group submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this

chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. New/changed location – Unless CMS has directed otherwise, if a private practice physical therapist or physical therapist group is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS. This is to ensure that the new/changed location is compliant with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

F. Physical Therapists: Additional Site Visit Information

The contractor is also advised of the following:

- In Section 2B of the Form CMS-855B application, physical and occupational therapy groups are denoted as "Physical/Occupational Therapy Group(s) in Private Practice." If a supplier that checks this box in Section 2B is *predominantly* an occupational therapy group in private practice, the contractor shall process the application using the procedures in the "limited" screening category. No site visit is necessary, *though each and any physical therapist in the group – being in the "moderate" screening category – will be subject to a site visit. If the supplier is predominantly a physical therapist* group, the application shall be processed using the procedures in the "moderate" screening category. A site visit by the NSVC is required, unless CMS has directed otherwise. *If the supplier is, to the best of the contractor's determination, a physical therapist and occupational therapist group in reasonably equal measure, the supplier shall be screened at the "moderate" screening level.*

- If an entity is enrolled as a physician practice and employs a physical therapist within the practice, the practice itself falls within the "limited" screening category. This is because the entity is enrolled as a physician practice and not a physical therapy group in private practice. However, *the physical therapist himself/herself will be screened* at the "moderate" risk level *and will receive a site visit.*

- If a newly-enrolling private practice physical therapist lists several practice locations, the enrollment contractor has the discretion to determine the location at which the NSVC will perform the required site visit.

- Unless CMS has directed otherwise, a site visit by the NSVC is required when a physical therapist submits an application for private practice initial enrollment and reassignment of benefits. However, a site visit is not required for an enrolled private practice physical therapist who is reassigning his or her benefits only.

- If the private practice physical therapist's practice location is his or her home address and it exclusively performs services in patients' homes, nursing homes, etc., no site visit is necessary.

G. Other Enrollment Information

All physical therapists in private practice must respond to the questions in Section 2K of the Form CMS-855I. However, Section 2K does not apply if the physical therapist: (1) plans to provide his/her services as a member of an established PT group, an employee of a physician-directed group, or an employee of a non-professional corporation; and (2) the person wishes to reassign his/her benefits to that group. Such information will be captured on the group's Form CMS-855B application.

If the physical therapist checks that he/she renders all of his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be the person's home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, Section 4E of the Form CMS-855I should indicate where services are rendered (e.g., county, state, city of the patients' homes). Post office boxes are not acceptable.

If the individual answers "yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for physical therapist services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

10.2.3.11 – Physicians

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

As described in § 1861(r)(1) of the Social Security Act and in 42 CFR § 410.20(b), a physician must be legally authorized to practice medicine by the state in which he/she performs such services in order to enroll in the Medicare program and to retain Medicare billing privileges. Such individuals include: (1) doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, or optometry; and (2) a chiropractor who meets the qualifications specified in 42 CFR § 410.22.

See Pub. 100-04, chapter 19, section 40.1.2 for special licensure rules regarding practitioners who work in or reassign benefits to hospitals or freestanding ambulatory care clinics operated by the Indian Health Service or by an Indian tribe or tribal organization.

10.2.3.12 – Physician Assistants

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

(The physician assistant (PA) enrollment instructions in this section 10.2.3.12 supersede all other PA-specific instructions in this chapter.)

A. PA Requirements Under § 410.74

Current federal regulations at 42 CFR §§ 410.74 discuss the requirements that a PA must meet.

Among the requirements for coverage of PA services outlined in 42 CFR §§ 410.74(a) are that the PA (as listed in §§ 410.74(a)(2)):

(i) Meets the qualifications set forth in § 410.74(c);

(ii) Is legally authorized to perform the services in the state in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and PAs (including explicit supervisory or collaborative practice requirements) describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Social Security Act. For states with no explicit state law and scope of practice rules regarding physician supervision of a PA's services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physician(s) when furnishing professional services; and

(v) Performs the services: (A) in all settings in either rural and urban areas; or (B) as an assistant at surgery.

Section 410.74(c), meanwhile, states that for Medicare Part B coverage of his or her services, a PA must meet all the following conditions:

- (1) Have graduated from a PA educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; OR (2) have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA);

  AND

- Be licensed by the state to practice as a PA. (The PA need not be currently NCCPA-certified.)

(In other words, either (1) or (2) in the first bullet must be met, and the licensure requirement in the second bullet must always be met.)

B. PA Employer

Prior to January 1, 2022, payment for the PA's services could only be made to the PA's employer, not to the PA himself/herself. That is, the PA could not individually enroll in Medicare to receive direct payment for his or her services. This also meant that the PA could not reassign his or her benefits to the employer, for the employer must receive direct payment anyway. Pursuant to the CY 2022 Physician Fee Schedule Final Rule, however, a PA may:

- Individually enroll in Medicare (e.g., as a sole proprietorship, professional corporation)
- Receive direct payment for his/her services
- Establish PA groups (e.g., LLCs)
- Reassign his/her benefits to his/her employer.

The previous requirement that the PA's employer must bill for his/her services has hence been eliminated.

C. PA Enrollment Information

With the above-mentioned change concerning PA employers (and except as stated in this subsection (C)), the contractor is advised of and/or shall adhere to the below policies, which are effective January 1, 2022. Note that reassignments of benefits are now captured via the Form CMS-855I, for the Form CMS-855R has been discontinued.

1. Newly enrolling, revalidating, and reactivating PAs shall complete the applicable Form CMS-855I sections to the same extent as would any other individual practitioner who is able to individually enroll in and bill Medicare.

2. Transactions

a. Initial Enrollment - If a PA is initially enrolling in Medicare and does not intend to reassign his/her benefits, he/she need not complete Sections 4(F)(1) and (2) of the Form CMS-855I. (The PA may, but is not required to, furnish the primary and secondary practice location information in Section 4(F)(3).)

b. Initial Enrollment - If a PA is initially enrolling in Medicare and intends to reassign his/her benefits, the PA shall complete Sections 4(F)(1) and (2) of the Form CMS-855I. (Section 4(F)(3) is optional.)

See section 10.3.1.4 of this chapter for more information on reassignments.

10.2.3.13 – Psychologists Practicing Independently

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Pub. 100-02, chapter 15, section 80.2 states that a psychologist practices independently when:

- He/she render services on his/her own responsibility, free of the administrative and professional control of an employer, such as a physician, institution, or agency;

- The persons he/she treats are his/her own patients;

- He/she has the right to bill directly, collect and retain the fee for his/her services; and

- The psychologist is state-licensed or certified in the state where furnishing services.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions are met: (1) the office is confined to a separately-identified part of the facility that is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and (2) the psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).

Independently practicing psychologists have a more limited benefit under the Medicare program than clinical psychologists. With a degree starting at the master's level of psychology, independently practicing psychologists are authorized to bill the program directly solely for diagnostic psychological and neuropsychological tests that have been ordered by a physician, clinical psychologist, or non-physician practitioner who is authorized to order diagnostic tests. Independently practicing psychologists are not authorized to supervise diagnostic psychological and neuropsychological tests. Any tests performed by an independently practicing psychologist must fall under the psychologist's state scope of practice.

The contractor shall ensure that all persons who check "Psychologist Billing Independently" in Section 2H of the Form CMS-855I answer all questions in Section 2J2. If the supplier answers "no" to question 1, 2, 3, 4a, or 4b, the contractor shall deny the application.

See Pub. 100-04, chapter 12, sections 160 and 160.1 for more information on psychologists billing independently.

10.2.3.14 – Registered Dietitians/Nutrition Professionals

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.134(a) through (c) state that a registered dietitian (or nutrition professional) is an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose;

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(c) Is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian"' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) above.

There are two exceptions to these requirements (as stated in 42 CFR § 410.134(d)(i) and (ii)):

(i) A dietitian or nutritionist licensed or certified in a state as of December 21, 2000, is not required to meet the requirements of (a) and (b) above.

(ii) A registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) above.

10.2.3.15 – Speech Language Pathologists in Private Practice

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Consistent with 42 CFR § 410.62(c), in order to qualify as an outpatient speech-language pathologist in private practice, an individual must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the state in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual in one of the following practice types: a solo practice, partnership, group practice, or as an employee of one of these.

(iii) Bill Medicare only for services furnished in one of the following:

(A) A speech-language pathologist's private practice office space that meets all of the following: (1) the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services and during the hours that the therapist engages in practice at that location; and (2) the space must be owned, leased, or rented by the practice, and used for the exclusive purpose of operating the practice; or

(B) A patient's home not including any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

For more information on speech language pathologists in private practice, refer to Pub. 100-02, chapter 15, section 230.

10.2.3.16 – Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an Ambulatory Surgical Center (ASC)

(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

Part A/B MACs make payments for implantable prosthetics and DME to hospitals, physicians, or ASCs. A manufacturer of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may enroll in the Medicare program as a DMEPOS supplier via the Form CMS-855S if it meets the definition of a supplier as well as the requirements of 42 CFR § 424.57.

10.2.3.17 – Marriage and Family Therapists (MFTs)

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Definition and Requirements

Effective January 1, 2024, Medicare covers services furnished by MFTs. An MFT is defined in CFR § 410.53(a)(1)-(3) as an individual who:

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to state law of the state in which such individual furnishes the services defined as MFT services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as an MFT by the state in which the services are performed.

Under 42 CFR § 410.53(b)(1), MFT services means services furnished by an MFT (as defined in § 410.53(a)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under state law (or the state regulatory mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service and must meet the requirements of § 410.53(b)(1).

Per 42 CFR § 410.53(b)(2), MFT services furnished by an MFT to an inpatient of a Medicare-participating hospital are not MFT services for purposes of billing Medicare Part B under the MFT benefit category.

B. Verification

As it does with Medicare supplier types, the contractor shall familiarize itself with the applicable state licensure and associated education requirements for MFTs. This will assist the contractor in ascertaining whether the MFT meets all state requirements.

In verifying the supplier's compliance with:

1. § 410.53(a)(1) – Except as stated in the discussion of § 410.53(a)(3) below, the contractor shall require the supplier to submit a copy of their master's or doctor's degree. Whether a master's or, instead, a doctor's degree is required will depend on the applicable state's requirements.

2. § 410.53(a)(2) – Except as stated in the discussion of § 410.53(a)(3) below, the contractor shall require the supplier to submit documentation verifying that they have performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in marriage and family therapy in an appropriate setting, such as a hospital, SNF, private practice, or clinic. (The supplier need only meet the 2-year or the 3,000-hour standard, not both.) Such documentation shall be one of the following:

   (i) A statement from the provider/supplier at which the MFT performed the services in question (e.g., hospital, clinic) verifying that the MFT performed services at that setting for the required number of years or hours. The statement shall:

   (a) Be on the provider's/supplier's letterhead (e-mail is not acceptable); and

   (b) Be signed by: (1) the provider/supplier supervisor under whom the MFT performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO has already been approved as such in the provider/supplier's enrollment record) if the provider/supplier is Medicare-enrolled.

   The statement need not contain standard, boilerplate language. It need only confirm to the contractor's satisfaction that the year or hour requirement was met. Also, the contractor may accept statements from multiple providers/suppliers if the year or hour requirement was met by performing services at more than one setting. For instance, suppose Dr. Smith earned her MFT experience by performing 1,000 hours at Hospital X and 2,000 hours at Hospital Y. The contractor can accept one statement from Hospital X concerning the 1,000 hours and another from Hospital Y regarding the remaining 2,000 hours so long as each statement meets the requirements of subsections (B)(2)(i)(a) and (B)(2)(i)(b) above. Put otherwise, the MFT can combine years and hours from multiple providers/suppliers to meet § 410.53(a)(2).

   In addition:

   - A statement from the MFT's current employer that the MFT met the year or time requirement at other settings besides the employer is not acceptable. All statements must be from the provider/supplier in which setting(s) the MFT performed the services. Using our example above, suppose Dr. Smith's supervisor at Hospital X was Dr. Jones. Dr. Jones is no longer with Hospital X, however. Dr. Smith submits a

statement from Dr. Jones stating that Dr. Smith performed 1,000 hours of MFT services at Hospital X. This statement cannot be accepted because it is not from Hospital X.

- The setting can be any provider/supplier at which MFT services are furnished. It need not be one of the four provider/supplier types listed in § 410.53(a)(2). Moreover, the provider/supplier need not have been (or currently be) enrolled in Medicare at the time the MFT performed the services there.

OR

(ii) A statement verifying that the MFT meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MFT is enrolling; or (2) national MFT credentialing organization. The statement can be signed by any official of the state licensing/credentialing or national credentialing body. It must, however, be on the body's letterhead.

If the MFT fails to furnish the above documentation, the contractor shall develop for it consistent with the instructions in this chapter.

3. § 410.53(a)(3) – The contractor shall verify state licensure or certification consistent with existing policies for doing so in this chapter.

If the contractor confirms to its satisfaction that the state already requires, as a condition of licensure or credentialing, the MFT to have:

- Performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic, the contractor can forgo verifying separate compliance with the § 410.53(a)(2) requirement described above; the MFT need not submit the documentation specified in subsection (B)(2). (This is because the licensure/credentialing already includes the year/hour requirement.)

- A master's or doctor's degree (as applicable), the MFT need not submit a copy of his or her degree nor need the contractor verify that the MFT received said degree.

C. Additional Information

1. Pre/Post Degree - As indicated above, all 2 years/3,000 hours of clinical supervised experience must have been performed post-degree. Pre-degree experience does not count towards the required time total under § 410.53(a)(2), even if the state permits pre-degree experience to be counted towards meeting state requirements. For example, suppose State X requires 1,000 hours of supervised experience for licensure. The hours can be performed pre-degree or post-degree. Jones, who is licensed by X, performed her 1,000 hours before receiving her degree. Jones cannot apply these hours towards the § 410.53(a)(2) time requirement – even though she is licensed – and must furnish evidence of 2 years/3,000 hours post-degree

experience. If, however, Jones had performed 500 hours pre-degree and 500 hours post-degree, she could apply the latter (but not the former) to the § 410.53(a)(2) time requirement.

2. Additional Policies

Like certain other individual practitioners, MFTs may opt-out of Medicare, form groups, reassign their benefits under § 424.80, receive reassigned benefits, and order/certify services to the extent otherwise permitted by law. They will complete the Form CMS-855I to bill for services and be subject to limited-risk screening (except as described in § 424.518(c)(3)).

Until the Form CMS-855I is revised to include MFTs, the MFT shall check the "Undefined Non-Physician Practitioner Specialty" box and state "marriage and family therapist" in the line next thereto.

10.2.3.18 – Mental Health Counselors (MHCs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Definitions and Requirements

Effective January 1, 2024, Medicare covers services furnished by MHCs. An MHC is defined in 42 CFR § 410.54(a) as an individual who:

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as an MHC, clinical professional counselor, or professional counselor under the state law of the state in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as an MHC, clinical professional counselor, professional counselor, addiction counselor, or alcohol and drug counselor (ADC) by the state in which the services are performed.

Under 42 CFR § 410.54(b)(1), MHC services means services furnished by an MHC (as defined in § 410.54(a)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under state law (or the state regulatory 1417 mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service and must meet the requirements of § 410.54.

Per 42 CFR § 410.54(c)(2), MHC services furnished by an MHC to an inpatient of a Medicare-participating hospital are not MHC services for purposes of billing Medicare Part B:

B. Verification

As it does with Medicare supplier types, the contractor shall familiarize itself with the state licensure and associated education requirements for MHCs. This will assist the contractor in ascertaining whether the MHC meets all state requirements.

In verifying the supplier's compliance with:

1. § 410.54(a)(1) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit a copy of their master's or doctor's degree. Whether a master's or, instead, a doctor's degree is required will depend on the applicable state's requirements.

2. § 410.54(a)(2) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit documentation verifying that they have performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic. (The supplier need only meet the 2-year or the 3,000-hour standard, not both.) Such documentation shall be one of the following:

   (i) A statement from the provider/supplier at which the MHC performed the services in question (e.g., hospital, clinic) verifying that the MHC performed services at that setting for the required number of years or hours. The statement shall:

   (a) Be on the provider's/supplier's letterhead (e-mail is not acceptable); and

   (b) Be signed by: (1) the supervisor under whom the MHC performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO has already been approved as such in the provider/supplier's enrollment record) if the provider/supplier is Medicare-enrolled.

   The statement need not contain standard, boilerplate language. It need only confirm to the contractor's satisfaction that the year or hour requirement was met. Also, the contractor may accept statements from multiple providers/suppliers if the year or hour requirement was met by performing services at more than one setting. For instance, suppose Dr. Smith earned her MHC experience by performing 1,000 hours at Hospital X and 2,000 hours at Hospital Y. The contractor can accept one statement from Hospital X concerning the 1,000 hours and another from Hospital Y regarding the remaining 2,000 hours so long as each statement meets the requirements of subsections (B)(2)(i)(a) and (B)(2)(i)(b) above. Put otherwise, the MHC can combine years and hours from multiple providers/suppliers to meet the requirements in § 410.54(a)(2).

   In addition:

   - A statement from the MHC's current employer that the MHC met the year or time requirement at other settings besides the employer is not acceptable. All statements must be from the provider/supplier in which setting(s) the MHC performed the

services. Using our example above, suppose Dr. Smith's supervisor at Hospital X was Dr. Jones. Dr. Jones is no longer with Hospital X, however. Dr. Smith submits a statement from Dr. Jones stating that Dr. Smith performed 1,000 hours of MHC service at Hospital X. This statement cannot be accepted because it is not from Hospital X.

- The setting can be any provider/supplier at which MHC services are furnished. It need not be one of the four provider/supplier types listed in § 410.54(a)(2). Moreover, the provider/supplier need not have been (or currently be) enrolled in Medicare at the time the MHC performed the services there; or

(ii) A statement verifying that the MHC meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MHC is enrolling; or (2) national MHC credentialing organization. The statement can be signed by any official of the state licensing/credentialing or national credentialing body. It must, however, be on the body's letterhead.

If the MHC fails to furnish the above documentation, the contractor shall develop for it consistent with the instructions in this chapter.

3. § 410.54(a)(3) – The contractor shall verify state licensure or certification consistent with existing policies for doing so in this chapter.

   If the contractor confirms to its satisfaction that the state already requires, as a condition of licensure or credentialing, the MHC to have:

   - Performed, at a minimum, either 2 years or 3,000 hours of clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic, the contractor can forgo verifying separate compliance with the § 410.54(a)(2) requirement described above; the MHC need not submit the documentation specified in subsection (B)(2). (This is because the licensure/credentialing already includes the year/hour requirement.)

   - A master's or doctor's degree (as applicable), the MHC need not submit a copy of his or her degree nor need the contractor verify that the MHC received said degree.

C. Further Information

1. Other Titles - Individuals who meet all applicable statutory and regulatory qualifications to be an MHC --- even though they may be licensed or certified by their state under a different title to furnish mental health counseling --- may enroll as an MHC. This includes mental health professionals who otherwise meet the requirements of § 410.54(a). (While a clinical psychologist, for instance, must possess a doctoral degree in psychology to enroll as such in Medicare, only a master's degree is required for MHC enrollment.) In short, the individual's specific title under state law for purposes of mental health counseling is less important than whether the requirements of § 410.54(a) are met.

As an example, addiction counselors, ADCs, and licensed professional counselors (LPCs) may enroll as MHCs if they meet the MHC requirements. They cannot, however, enroll as addiction counselors, ADCs, or LPCs, for Medicare does not recognize such supplier types.

2. Pre/Post Degree – As indicated above, all 2 years/3,000 hours of clinical supervised experience must have been performed post-degree. Pre-degree experience does not count towards the required time total under § 410.53(a)(2), even if the state permits pre-degree experience to be counted towards meeting state requirements. For example, suppose State X requires 1,000 hours of supervised experience for licensure. The hours can be performed pre-degree or post-degree. Jones, who is licensed by X, performed her 1,000 hours before receiving her degree. Jones cannot apply these hours towards the § 410.53(a)(2) time requirement – even though she is licensed – and must furnish evidence of 2 years/3,000 hours post-degree experience. If, however, Jones had performed 500 hours pre-degree and 500 hours post-degree, she could apply the latter (but not the former) to the § 410.53(a)(2) time requirement.

3. Additional Policies - Like certain other individual practitioners, MHCs may opt-out of Medicare, form groups, reassign their benefits under § 424.80, receive reassigned benefits, and order/certify services to the extent otherwise permitted by law. They will complete the Form CMS-855I to bill for services and be subject to limited-risk screening (except as described in § 424.518(c)(3)).

   Until the Form CMS-855I is revised to include MHCs, the MHC shall check the "Undefined Non-Physician Practitioner Specialty" box and state "mental health counselor" in the line next thereto.

10.2.4 - Other Medicare Part B Services

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Residents and Interns

1. General Background Information

If the applicant is a "resident" in an "approved medical residency program" (as these two terms are defined at 42 CFR § 413.75(b)), the contractor shall refer to Pub. 100-02, chapter 15, section 30.3 for further instructions. (The contractor can also refer to 42 CFR § 415.200, which states that services furnished by residents in approved programs are not "physician services.")

The physician should indicate the exact date on which its residency program, internship, or fellowship was completed, so that the appropriate effective date can be issued.

2. Interns are Ineligible to Enroll in the Medicare Program

An intern cannot enroll in the Medicare program. (For purposes of this requirement, the term "intern" means an individual who is not licensed by the state because he/she is still in post-graduate year (PGY) 1.)

B. Diabetes Self-Management Training

Diabetes self-management training (DSMT) is not a separately recognized provider type, such as a physician or nurse practitioner. A person or entity cannot enroll in Medicare for the sole purpose of performing DSMT. Rather, DSMT is an extra service that an enrolled provider or supplier can bill for, assuming it meets all of the necessary DSMT requirements. If the person or entity enrolls as a provider type (i.e., pharmacy, mass immunizer) that requires the submission of an application fee, the fee shall be submitted with the application.

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. CMS recognizes the American Diabetes Association (ADA) and the Association of Diabetes Care & Education Specialists (ADCES) (formerly known as the American Association of Diabetes Educators or AADE) as approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the appropriate accreditation certificate to its contractor. No Form CMS-855 is required unless the provider or supplier is not in the Provider Enrollment, Chain and Ownership System (PECOS), in which case a complete Form CMS-855 application must be submitted.

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local Part A/B MAC. This is because A/B MACs, rather than Durable Medical Equipment Medicare Administrative Contractors, pay DSMT claims. Thus, the DMEPOS supplier must separately enroll with its A/B MAC even if it has already completed a Form CMS-855S. If an A/B MAC receives an application from a DMEPOS supplier that would like to bill for DMST, it shall verify with the applicable NPE contractor that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- 42 CFR Part 410 (subpart H)

- Publication 100-02, Medicare Benefit Policy Manual, chapter 15, sections 300 – 300.5.1

C. Mass Immunizers Who Roster Bill

An entity or individual who wishes to furnish mass immunization services - but may not otherwise qualify as a Medicare provider - may be eligible to enroll as a “Mass Immunizer” via the Form CMS-855I (individuals) or the Form CMS-855B (entities). Such suppliers must meet the following requirements:

1. They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.

2. They must submit claims through the roster billing process.

3. The supplier, as well as all personnel who administer the shots, must meet all applicable state and local licensure or certification requirements.

The roster billing process was developed to enable Medicare beneficiaries to participate in mass PPV and influenza virus vaccination programs offered by public health clinics and other organizations.

In addition:

- See 42 CFR §§ 424.520(d) and 424.521(a) for information regarding mass immunizer effective dates.

- In Section 4 of the Form CMS-855, the supplier need not list each off-site location (e.g., county fair, shopping mall) at which it furnishes services. It need only list its base of operations (e.g., county health department headquarters, drug store location).

For more information on mass immunization roster billing, refer to:

- Publication 100-02, Benefit Policy Manual, chapter 15, section 50.4.4.2

- Publication 100-04, Claims Processing Manual, chapter 18, sections 10 through 10.3.2.3

D. Advanced Diagnostic Imaging

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1834(e) of the Social Security Act. It required the Secretary to designate organizations to accredit suppliers – including, but not limited to, physicians, non-physician practitioners, and independent diagnostic testing facilities - that furnish the technical component (TC) of advanced diagnostic imaging services. MIPPA specifically defined advanced diagnostic imaging procedures as including diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging, such as positron emission tomography (PET). The law also authorizes the Secretary to specify other diagnostic imaging services in consultation with physician specialty organizations and other stakeholders.

The CMS has approved four national accreditation organizations (AOs) – the American College of Radiology, the Inter-societal Accreditation Commission, the Joint Commission, and Rad Site - to provide accreditation services for suppliers of the TC of advanced diagnostic imaging procedures. The accreditation applies only to: (1) the suppliers of the images, not to the physician's interpretation of the image; and (2) those who are paid under the Physician Fee Schedule. All AOs have quality standards that address the safety of the equipment as well as the safety of the patients and staff. Each of these designated AOs submits monthly reports to CMS that list the suppliers who have been or are accredited, as well as the beginning and end-dates of the accreditation and the respective modalities for which they receive accreditation.

Newly enrolling physicians and non-physician practitioners described above do not need to complete the appropriate boxes for Advanced Diagnostic Imaging (ADI) on Internet-based PECOS or the appropriate Form CMS-855. Information for all ADI accredited suppliers is provided to CMS by the approved ADI AOs. The contractor need not verify ADI information submitted on the application.

10.2.5 – Suppliers That Enroll Via the Form CMS-855S
(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

Section 10.2.5, et al. instructs the contractor on the appropriate handling of certain situations involving DMEPOS suppliers.

10.2.5.1 – DMEPOS Supplier Accreditation
(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

A. General Requirement

DMEPOS suppliers must be accredited prior to submitting an application to the contractor. The contractor shall deny any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt.

The contractor shall revoke an enrolled DMEPOS supplier's billing privileges if the supplier fails to: (1) obtain and submit supporting documentation that it has been accredited; or (2) maintain its required accreditation.

In the future, Medicare will deny claims for DMEPOS suppliers that fail to maintain accreditation information on file with the contractor.

B. Exemptions

Individual medical practitioners, inclusive of group practices of same, do not require accreditation as a condition of enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security Act. In addition, the practitioner categories of physicians, orthotists, prosthetists, optometrists, opticians, audiologists, occupational therapists, physical therapists, and suppliers who provide drugs and pharmaceuticals (only) do not require accreditation as a condition of enrollment.

Although suppliers that provide only drugs and pharmaceuticals are exempt from the accreditation requirement, suppliers that provide equipment to administer drugs or pharmaceuticals must be accredited.

C. Changes of Ownership

A DMEPOS supplier undergoing a change of ownership for an existing supplier location with a new tax identification number (TIN) must submit an initial Form CMS-855S enrollment application to enroll as a new supplier. The supplier's application shall be denied (consistent with 42 CFR § 424.57) if the new owner does not have an accreditation that covers all of its locations. If the old owner has such an accreditation, the new owner can be enrolled as of the date of sale if the accreditor determines that the accreditation should remain in effect as of the date of sale. (This, however, is only applicable when the new owner also meets all other enrollment criteria found at 42 CFR § 424.57).

Some ownership changes do not result in a complete change of ownership, since the business entity remains the same with no change in TIN. However, in cases where more than 5 percent of the ownership has changed, the following principles apply:

(i) If the change in ownership has not been reported to the contractor within the required 30-day period, the contractor shall proceed with revocation action.

(ii) If the change has been received within the required 30-day period and the supplier has been accredited, the contractor shall immediately notify the accreditor of the ownership change and request that the latter advise the contractor if the accreditation should still remain in effect.

D. Accreditation and Deactivation/Revocation

A non-exempt DMEPOS supplier requesting reactivation after a deactivation (regardless of the deactivation reason) is required to be accredited.

A revoked DMEPOS supplier that has submitted an acceptable corrective action plan can be reinstated without accreditation unless the accreditation was already required prior to revocation.

10.2.5.2 – Fraud Level Indicators for DMEPOS Suppliers - Development and Use

(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

A. General Information

The contractor shall perform a fraud potential analysis of all DMEPOS applicants and current DMEPOS suppliers. The fraud level indicator shall represent the potential for fraud and/or abuse. The contractor shall use four fraud level indicator codes as follows:

- Low Risk (e.g., national drug store chains)
- Limited Risk (e.g., prosthetist in a low fraud area)
- Medium Risk (e.g., midsize general medical supplier in a high fraud area)
- High Risk (e.g., very small space diabetic supplier with low inventory in a high fraud area whose owner has previously had a chapter 7 bankruptcy). High fraud areas shall be determined by contractor analysis with concurrence of the contractor project officer.

(**NOTE:** These risk categories are in addition to, and not in lieu of, those specified in 42 CFR § 424.518.)

In assessing a fraud level indicator, the contractor shall consider such factors as:

- Experience as a DMEPOS supplier with other payers
- Prior Medicare experience
- The geographic area

- Fraud potential of products and services listed
- Site visit results
- Inventory observed and contracted
- Accreditation of the supplier

After a fraud level indicator is assigned and the DMEPOS supplier is enrolled, the contractor shall establish a DMEPOS Review Plan based on the fraud level assessment. The DMEPOS Review Plan shall contain information regarding:

- Frequency of unscheduled site visits
- Maximum billing amounts before recommendation for prepay medical review
- Maximum billing spike amounts before recommendation for payment suspensions/prepay medical review, etc.

The fraud level indicator shall be updated based upon information obtained through the Medicare enrollment process, such as reported changes of information.

Information obtained by the Office of Inspector General (OIG), CMS (including CMS satellite office), and/or a Unified Program Integrity Contractor (UPIC) shall be reported to the contractor project officer. The contractor shall update the fraud level indicator based on information obtained by the OIG, CMS (including CMS satellite office), and/or a UPIC only after the review and concurrence of the contractor project officer.

In addition, the contractor shall monitor and assess geographic trends that indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.

B. When a DMEPOS Fraud Level Indicator Differs from Risk Screening Category under 42 CFR § 424.518

The fraud level indicator described in this subsection is unrelated to the risk screening categories required under 42 CFR § 424.518. Under § 424.518(c)(1)(ii), for example, newly enrolling DMEPOS suppliers are assigned to the "high" risk screening category. Such DMEPOS suppliers are therefore subject to screening activities that correspond to the "high" risk screening category, including an on-site visit and a fingerprint-based criminal background check for all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the supplier. (See § 424.518(c)(2).) The on-site visits that the contractor conducts are responsive to the requirement at § 424.518(c)(2)(i) for a site visit and include gathering information concerning fraud level indicator assignment as required in this subsection. A DMEPOS supplier therefore has both a risk-based screening category assignment pursuant to requirements under § 424.518, and a separate fraud level indicator based upon the guidance in this subsection.

C. Fraud Level Indicator Standards

The contractor shall have documented evidence that it has, at a minimum, met the following requirements:

- Assigned an appropriate fraud level indicator for at least 95 percent of all DMEPOS suppliers upon initial enrollment or revalidation. The fraud level indicator shall accurately reflect the risk the supplier poses to the Medicare program based on pre-defined criteria above.

- Updated the DMEPOS fraud level indicator for each enrolled DMEPOS supplier on an annual basis.

D. Alert Codes for DMEPOS Suppliers

The contractor shall receive and maintain the following "alert indicators" from the DME MACs and UPICs:

Alert Code and Definition

A - Possible fraudulent or abusive claims identified
B - Overpayments
D - Violations of disclosure of ownership requirements
E - Violations of participation agreements
L - Suspended by contractor outside alert code process
M - Supplier is going through claims appeal process

The contractor shall append the supplier file and transfer to the DME-MACs and/or UPICs the following alert codes in the following circumstances:

Alert Code and Definition

C - Violations of supplier standards
F - Excluded by the OIG or debarred per the System for Award Management
H - Meets supplier standards; however, the contractor recommends increased scrutiny by the contractor (initiated by the contractor only)
N - Supplier being investigated under the "Do Not Forward" initiative (initiated by contractor only)
Q - Low Risk Fraud Level Indicator

R - Limited Risk Fraud Level Indicator
S - Medium Risk Fraud Level Indicator
T - High Risk Fraud Level Indicator

The contractor shall append an Alert Code "H" for any supplier that meets present supplier standards but appears suspect in one of the areas that are verified by the contractor. This alert code notifies the contractors that a supplier may be inclined to submit a high percentage of questionable claims.

The contractor shall share the above information with the DME MACs and/or UPICs by sending alerts within 7 calendar days after identification of a supplier having common ownership or business ties with a sanctioned or suspect supplier for their research and/or action. The

contractor also shall forward alert codes submitted by the contractors with the other contractors within 7 calendar days after receipt.

10.2.5.3 – Surety Bonds
(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

10.2.5.3.1 – Basics of the Surety Bond Requirement
(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

A. Parties Subject and Not Subject to Surety Bond Requirement

All DMEPOS suppliers are subject to the surety bond requirement except:

(1) Government-operated DMEPOS suppliers are exempted if the supplier has provided CMS with a comparable surety bond under state law.

(2) State-licensed orthotic and prosthetic personnel (which, for purposes of the surety bond requirement, does not include pedorthists) in private practice making custom- made orthotics and prosthetics are exempted if—

- The business is solely-owned and operated by the orthotic and prosthetic personnel, and
- The business is only billing for orthotic, prosthetics, and supplies.

(3) Physicians and non-physician practitioners, as defined in section 1842(b)(18) of the Social Security Act, are exempted if the items are furnished only to the physician or non-physician practitioner's own patients as part of his or her physician service. The non-physicians covered under this exception are: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals.

(4) Physical and occupational therapists in private practice are exempted if—

- The business is solely-owned and operated by the physical or occupational therapist;
- The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and
- The business is only billing for orthotics, prosthetics, and supplies.

If a previously-exempted supplier no longer qualifies for an exception, it must submit a surety bond to the contractor - in accordance with the requirements in 42 CFR § 424.57 - within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

B. Bond Submission

Effective May 4, 2009, DMEPOS suppliers submitting: (1) an initial enrollment application to enroll in the Medicare program for the first time, (2) an initial application to establish a new practice location, or (3) an enrollment application to change the ownership of an existing supplier, are required to obtain and submit a copy of its required surety bond to the contractor with their Form CMS-855S enrollment application. (**NOTE:** Ownership changes that do not involve a change in the status of the legal entity as evidenced by no change in the tax identification number (or changes that result in the same ownership at the level of individuals (corporate reorganizations and individuals incorporating)) are not considered to be "changes of ownership" for purposes of the May 4, 2009, effective date – meaning that such suppliers are considered "existing" suppliers).

For any Form CMS-855S application submitted on or after May 4, 2009 by a non-exempt supplier described in this subsection (B), the contractor shall reject the application if the supplier does not furnish a valid surety bond at the time it submits its application. The rejection shall be done in accordance with existing procedures (e.g., reject application after 30 days).

C. Amount and Basis

The surety bond must be in an amount of not less than $50,000 and is predicated on the NPI, not the tax identification number. Thus, if a supplier has two separately-enrolled DMEPOS locations, each with its own NPI, a $50,000 bond must be obtained for each site.

A supplier may obtain a single bond that encompasses multiple NPIs/locations. For instance, if a supplier has 10 separately-enrolled DMEPOS locations, it may obtain a $500,000 bond that covers all 10 locations.

As stated in 42 CFR § 424.57(d)(3), a supplier will be required to maintain an elevated surety bond amount of $50,000 for each final adverse action imposed against it within the 10 years preceding enrollment or reenrollment. This amount is in addition to, and not in lieu of, the base $50,000 amount that must be maintained. Thus, if a supplier has had two adverse actions imposed against it, the bond amount will be $150,000.

A final adverse action is one of the following:

- A Medicare-imposed revocation of Medicare billing privileges;
- Suspension or revocation of a license to provide health care by any State licensing authority;
- Revocation or suspension by an accreditation organization;
- A conviction of a federal or state felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment or re-enrollment; or
- An exclusion or debarment from participation in a federal or state health care program.

D. Bond Terms

The supplier is required to submit a copy of the bond that - on its face - reflects the requirements of 42 CFR §424.57(d). Specific terms that the bond must contain include:

- A guarantee that the surety will - within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, civil money penalties (CMPs), or assessments - pay CMS a total of up to the full penal amount of the bond in the following amounts:

a. The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible, and

b. The amount of any unpaid claims, CMPs, or assessments imposed by CMS or the OIG on the DMEPOS supplier, plus accrued interest.

- A statement that the surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

- A statement that actions under the bond may be brought by CMS or by CMS contractors.

- The surety's name, street address or post office box number, city, state, and zip code.

- Identification of the DMEPOS supplier as the Principal, CMS as the Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as the surety.

The term of the initial surety bond must be effective on the date that the application is submitted to the contractor. Moreover, the bond must be continuous.

E. List of Sureties

The list of sureties from which a bond can be secured is found at Department of the Treasury's "Listing of Certified (Surety Bond) Companies;" the Web site is https://www.fiscal.treasury.gov/fsreports/ref/suretyBnd/c570_a-z.htm. For purposes of the surety bond requirement, these sureties are considered "authorized" sureties, and are therefore the only sureties from which the supplier may obtain a bond.

F. Bond Cancellations and Gaps in Coverage

A DMEPOS supplier may cancel its surety bond, but it must provide written notice of such to the contractor and the surety at least 30 days before the effective date of the cancellation. Cancellation of a surety bond is grounds for revocation of the supplier's Medicare billing privileges unless the supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.

The contractor shall:

- Process post-dated surety bond cancellations within 45 calendar days from the date the contractor received the cancellation.
- Process future-dated surety bond cancellations within 45 calendar days from the effective date of cancellation.

(The contractor may apply a clock stoppage if a surety bond gap is involved and the case must be sent to PEOG for review. The clock stoppage remains in effect until the contractor receives PEOG's final determination.)

If a supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond. The previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.

Pursuant to 42 CFR § 424.57(d)(6)(iv), the surety must notify the contractor if there is a lapse in the surety's coverage of the DMEPOS supplier. This can be done via letter, fax, or e-mail to the contractor.

G. Reenrollment and Reactivation

The supplier must furnish the paperwork described above with any Form CMS-855S reenrollment or reactivation application it submits to the contractor unless it already has the information on file with the contractor. For example, if a supplier has submitted a continuous surety bond to the contractor prior to submission of its reenrollment application, a new copy of surety bond is not be required unless the contractor specifically requests it.

H. Surety Bond Changes

A DMEPOS supplier must submit an addendum to the existing bond (or, if the supplier prefers, a new bond) to the contractor in the following instances: (1) change in bond terms; (2) change in bond amount; or (3) a location on a bond covering multiple non-chain locations is being added or deleted.

10.2.5.3.2 – Claims against Surety Bonds

(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

(For purposes of this section, the term "contractor" means the enrollment contractor, unless otherwise indicated. Durable Medical Equipment Medicare Administrative Contractors will be referenced as "DME MACs.")

Pursuant to 42 CFR § 424.57(d)(5)(i), the surety must pay CMS - within 30 days of receiving written notice to do so - the following amounts up to the full penal sum of the bond:

1. The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.

2.. The amount of any unpaid claim, CMP, or assessment imposed by CMS or the OIG on the DMEPOS supplier, plus accrued interest.

This section 10.2.5.3.2 describes the procedures involved in making a claim against a surety bond.

A. Background

For purposes of the surety bond requirement, 42 CFR § 424.57(a) defines an "unpaid claim" as an overpayment (including accrued interest, as applicable) made by the Medicare program to the DMEPOS supplier for which the supplier is responsible.

The policies in this section 10.2.5.3.2 only apply to overpayment determinations relating to demands first made on or after March 3, 2009. A surety is liable for any overpayments based on dates of service occurring during the term of the surety bond. (For purposes of determining surety liability, the date of the initial demand letter was sent to the provider is the date on which the service was performed/furnished.) Even if the overpayment determination is made after the expiration of the surety bond, the surety remains liable if the date of service was within the surety bond coverage period. In short, the date of service – rather than the date of the overpayment determination or the date the overpayment demand letter was sent to the supplier--- is the principal factor in ascertaining surety liability.

As an illustration, assume that a supplier has a surety bond with Company X on August 1, 2015. It performs a service on October 1, 2015. The supplier ends its coverage with Company X effective January 1, 2016 and obtains a new surety bond with Company Y effective that same date. On February 1, 2016, CMS determines that the October 1, 2015 service resulted in an overpayment; on March 2, 2016, CMS sends an overpayment demand letter to the supplier. While the overpayment determination and the sending of the demand letter occurred during Company Y's coverage period, the date of service was within the Company X coverage period. Thus, liability (and responsibility for payment) rests with Company X, even though the supplier no longer has a surety bond with X.

B. Collections – Unpaid Claims

1. Delinquency Period

If the DME MAC determines – in accordance with CMS's existing procedures for making overpayment determinations - that (1) the DMEPOS supplier has an unpaid claim for which it is liable, and (2) no waiver of recovery under the provisions of section 1870 of the Social Security Act is warranted, the DME MAC shall attempt to recover the overpayment in accordance with the instructions in CMS Pub. 100-06, chapter 4.

If 80 days have passed since the initial demand letter was sent to the DMEPOS supplier and full payment has not been received, the DME MAC shall attempt to recover the overpayment. The DME MAC shall review the "List of Bonded Suppliers" the last week of each month to determine which suppliers that have exceeded this 80-day period have a surety bond. Said list:

- Will be electronically sent to the DME MACs by CMS' Provider Enrollment & Oversight Group on a monthly basis.

- Will be in the form of an Excel spreadsheet.

- Will contain the supplier's legal business name, tax identification number, NPI, surety bond amount, and other pertinent information.

If the supplier does not have a surety bond (i.e., is exempt from the surety bond requirement), the DME MAC shall continue to follow the instructions in Pub. 100-06, chapter 4 regarding collection of the overpayment.

2. Request for Payment from Surety – General Requirements

If, however, the supplier has a surety bond (and subject to situations (a) through (f) below), the DME MAC shall send an "Intent to Refer" (ITR) letter to the supplier and a copy thereof to the supplier's surety. The letter ITR and copy shall be sent to the supplier on day 66 after the initial demand letter was sent, and the surety notification shall be sent within 5 days. (The copy to the surety can be sent via mail, e-mail, or fax.)

(NOTE: Under federal law, a delinquent debt must be referred to the Department of Treasury within 120 days. (Per the chart below, this represents Day 150 of the entire collection cycle.) To ensure that the DME MAC meets this 120-day limit but has sufficient time to prepare the surety letter as described in the following paragraph, it is recommended that the DME MAC send the ITR letter several days prior to the 90-day limit referenced in the previous paragraph. This will give the DME MAC a few additional days beyond the 30-day deadline referenced in the next paragraph to send the surety letter.)

If the DME MAC does not receive full payment from the supplier within 30 days of sending the ITR letter (and subject to situations (a) through (f) below), the contractor shall notify the surety via letter that, in accordance with 42 CFR § 424.57(d)(5)(i)(A), the surety must make payment of the claim to CMS within 30 days from the date of the surety letter. (The DME MAC shall send a copy of the surety letter to the supplier on the same date.) The DME MAC shall send the surety letter no later than 30 days after sending the ITR letter (subject to the previous paragraph), depending on the facts of the case. Consider the following situations:

a. If a DMEPOS supplier has withdrawn from Medicare or has had its enrollment deactivated or revoked, the contractor shall send the ITR and the surety letter on the earliest possible day.

b. If the supplier has an extended repayment schedule (ERS) and is currently making payments, the DME MAC shall not send an ITR letter or a surety letter. If the DME MAC is currently reviewing an ERS application from the supplier, the contractor shall delay sending the ITR letter and the surety letter until after the ERS review is complete.

c. If the aggregated principal balance of the debt is less than $25, the DME MAC shall not send an ITR letter or a surety letter. It shall instead follow the instructions in CMS Pub. 100-06, chapter 4 regarding collection of the overpayment.

d. If the DME MAC believes the debt will be collected through recoupment, it shall not send an ITR letter or a surety letter. It shall instead follow the instructions in Pub. 100-06, chapter 4 regarding collection of the overpayment.

e. If the supplier has had a recent offset, the DME MAC may wait to see if future offsets will close the debt, without sending the surety a letter. If the debt is still not paid in full or an ERS has not been established, the DME MAC shall send the surety letter no later than the 115th day after the initial demand letter was sent.

f. A payment demand letter shall not be sent to the surety if the DME MAC is certain that the $50,000 surety bond amount in question has been completely exhausted.

(NOTE: The DME MAC may choose to aggregate debts from the same supplier into one surety letter, provided they are at least 30 days delinquent.)

3. Contents of Surety Letter

The surety letter shall:

a. Follow the format of the applicable model letter found in section 10.7.16 of this chapter.

b. Identify the specific amount to be paid and be accompanied by "sufficient evidence" of the unpaid claim. "Sufficient evidence" is defined in 42 CFR §424.57(a) as documents that CMS may supply to the DMEPOS supplier's surety to establish that the supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations.

c. Be accompanied by the following documents, which constitute "sufficient evidence" for purposes of §424.57(a):

(i) Overpayment Services Report - A computer-generated "Overpayment Services Report" containing the following information:

- Date of service (i.e., the date the service was furnished/performed, not the date of the overpayment determination or the date of the overpayment or demand letter)
- Date on which supplier was paid
- Paid Amount
- Overpayment Amount

(NOTE: The report shall not include HICN or any information otherwise protected under the Privacy Act.)

(ii) A copy of the overpayment determination letter that was sent to the supplier

(iii) A statement that payment shall be made via check or money order and that the Payee shall be the DME MAC

(iv) Identification of the address to which payment shall be sent

The DME MAC shall only seek repayment up to the full penal sum amount of the surety bond. Thus, if the supplier has a $60,000 unpaid claim and the amount of the supplier's bond coverage is $50,000, the DME MAC shall only seek the $50,000 amount. The remaining $10,000 will have to be obtained from the supplier via the existing overpayment collection process.

4. Follow-Up Contact

Between 8 and 12 calendar days after sending the surety letter, the DME MAC shall contact the surety by telephone or e-mail to determine whether the surety received the letter and, if it did, whether and when payment will be forthcoming.

If the surety indicates that it did not receive the letter, the DME MAC shall immediately fax or e-mail a copy of the letter to the surety. The surety will have 30 days from the original date of the letter – not 30 days from the date the letter was resent to the surety – to submit payment. To illustrate, suppose the DME MAC on April 1 sends the surety letter, which is also dated April 1. It places the follow-up call to the surety on April 11. The surety states that it never received the letter, so the contractor e-mails a copy of it to the surety that same day. Payment must be received by May 1, or 30 days from the original date of the letter.

If the surety cannot be reached (including situations where a voicemail message must be left) or if the surety indicates that it did receive the letter and that payment is forthcoming, no further action by the contractor is required. If the surety indicates that payment is not forthcoming, the contractor shall (1) attempt to ascertain the reason, and (2) follow the steps outlined below after the 30-day period expires.

The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

5. Verification of Payment

a. Full Payment of the Claim is Made

If full payment (including interest, as applicable) is made within the aforementioned 30-day period, the DME MAC shall, no later than 10 calendar days after payment was made:

(i) Update all applicable records to reflect that payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

(ii) Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the contractor shall be copied):

- Stating that payment has been made, the date the payment was received, and the amount of the payment

- Containing the following quoted verbiage:

  "You must, within 30 calendar days of the date of this letter, obtain and submit to the contractor additional surety bond coverage in the amount of (insert the amount that the surety paid) so as to ensure that your total coverage equals or exceeds the required $50,000 amount" (or higher if an elevated bond amount is involved due to a final adverse action). **Failure to timely do so will result in the revocation of your Medicare enrollment**.

"Additional surety bond coverage may be obtained by (1) adding to the amount of your existing surety bond so as to equal or exceed $50,000, or (2) cancelling your current surety bond and securing a new $50,000 surety bond. (Obtaining a separate (insert the amount the surety paid) surety bond is impermissible.) In either case, the effective date of the additional coverage must be on or before the date that you submit the additional coverage to the contractor."

If the contractor does not receive the additional bond coverage within this 30-day period, it shall revoke the DMEPOS supplier's Medicare enrollment under § 424.535(a)(1) in accordance with existing procedures. (The effective date of revocation shall be the date on which the DME MAC received payment from the surety.) It is important that the contractor: (1) monitor the supplier's surety bond status upon receiving a copy of the DME MAC's letter to the supplier; and (2) take prompt action against the supplier (consistent with existing procedures) if the supplier does not secure and timely submit the required additional coverage.

b. No Payment of the Claim Made

If the surety fails to make any payment within 30 calendar days of the date of the letter to the surety, the DME MAC shall:

(i) Refer the debt to the Department of Treasury (by HIGLAS on the 120-day deadline) immediately upon the expiration of said 30-day timeframe (i.e., preferably on the same day or the day after, but in all cases no later than the 120-day deadline for sending delinquent debts to the Department of Treasury) and as outlined in Pub. 100-06, chapter 4;

(ii) No later than 14 days after the 30-day period expires, contact the surety via e-mail or telephone to ascertain the reason for non-payment. Only one contact is necessary. A voice mail message may be left. The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

(iii) No later than 14 days after Step 2 has been completed – and if full payment still has not been received -- send the letter found in section 10.7.16 of this chapter.

(iv) Include information relating to the surety's non-payment in the report identified in section 10.2.5.3.2(D).

c. Partial Payment of the Claim is Made

If the surety pays part of the claim within the 30-day period and a balance is still due and owing, the DME MAC shall do the following:

(i) Refer the unpaid debt to the Department of Treasury (by HIGLAS on the 12-day deadline) immediately upon the expiration of said 30-day timeframe (i.e., preferably on the same day or the day after, but in all cases no later than the 120-day deadline for sending delinquent debts to the Department of Treasury) and as outlined in Pub. 100-06, chapter 4.

(ii) No later than 14 days after the 30-day period expires, contact the surety via e-mail or telephone to ascertain the reason for the partial non-payment. Only one contact is necessary. A voice mail message may be left. The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

(iii) No later than 14 days after Step (ii) has been completed – and if full payment still has not been received -- send the letter found in Section 10.7.16 of this chapter.

(iv) Include information relating to the surety's partial non-payment in the report identified in section 10.2.5.3.2(D).

(v) No later than 10 calendar days after the partial payment was made:

- Update all applicable records to reflect that partial payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

- Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the contractor shall be copied):

    - Stating that partial payment was made, the date the payment was received, and the amount of said payment

    - Containing the following quoted verbiage:

      "You must, within 30 calendar days of the date of this letter, obtain and submit to the contractor additional surety bond coverage in the amount of (insert the amount that the surety paid) so as to ensure that your total coverage equals or exceeds the required $50,000 amount" (or higher if an elevated bond amount is involved due to a final adverse action). **Failure to timely do so will result in the revocation of your Medicare enrollment**.

      Additional surety bond coverage may be obtained by (1) adding to the amount of your existing surety bond so as to equal or exceed $50,000, or (2) cancelling your current surety bond and securing a new $50,000 surety bond. (Obtaining a separate (insert the amount the surety paid) surety bond is impermissible.) In either case, the effective date of the additional coverage must be on or before the date that you submit the additional coverage to the contractor."

If the contractor does not receive the additional bond coverage within this 30-day period, it shall revoke the DMEPOS supplier's Medicare enrollment under § 424.535(a)(1) in accordance with existing procedures. (The effective date of revocation shall be the date on which the DME MAC received payment from the surety.) It is important that the contractor (1) monitor the supplier's surety bond status upon receiving a copy of the DME MAC's letter to the supplier and (2) take prompt action against the supplier (consistent with existing procedures) if the supplier does not secure and timely submit the required additional coverage.

6. Successful Appeal

If the supplier successfully appeals the overpayment and the surety has already made payment to the DME MAC on the overpayment, the DME MAC shall – within 30 calendar days of receiving notice of the successful appeal - notify the surety via letter of the successful appeal and repay the surety via check or money order.

7. Summary

The following chart outlines the timeframes involved in the surety bond collection process for overpayments:

Day 1	Initial Demand Letter Sent
Day 31	Debt is Delinquent/Interest Starts
Day 41	Recoupment Starts
Day 66	Intent to Refer Letter Sent
Day 115	Surety Bond Letter Sent
Day 150	Referral to Treasury

C. Claims Pertaining to Assessments and CMPs

1. Request for Payment from Surety

Per 42 CFR § 424.57(a), an assessment is defined as a "sum certain that CMS or the OIG may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act." Under 42 CFR § 424.57(a), a CMP is defined as a sum that CMS has the authority, as implemented by 42 CFR § 402.1(c) (or the OIG has the authority, under section 1128A of the Act or 42 CFR Part 1003) to impose on a supplier as a penalty.

The CMS will notify the DME MAC of the need for the latter to collect payment from the surety on an assessment or CMP imposed against a particular bonded DMEPOS supplier. Upon receipt of this notification, the DME MAC shall – regardless of the amount of the assessment or CMP - notify the surety via letter that, in accordance with 42 CFR § 424.57(d)(5)(i)(B), payment of the assessment or CMP must be made within 30 calendar days from the date of the letter. The letter (on which the contractor and the supplier/debtor shall be copied) shall:

- Follow the format of the applicable model letter found in Section 10.7.16 of this chapter.
- Identify the specific amount to be paid and be accompanied by "sufficient evidence." This includes all documentation that CMS (in its notification to the DME MAC as described above) requests the DME MAC to include with the letter (e.g., OIG letter).
- State that payment shall be made via check or money order and that the Payee shall be CMS.
- Identify the address to which payment shall be sent.

2. Follow-Up Contact

Between 8 and 12 calendar days after sending the surety letter, the DME MAC shall contact the surety by telephone or e-mail to determine whether the surety received the letter and, if it did, whether and when payment is forthcoming;

If the surety indicates that it did not receive the letter, the DME MAC shall immediately fax or e-mail a copy of the letter to the surety. The surety will have 30 days from the original date of the letter – not 30 days from the date the letter was resent to the surety – to submit payment. To illustrate, suppose the DME MAC on April 1 sends the surety letter, which is also dated April 1. It places the follow-up call to the surety on April 11. The surety states that it never received the letter, so the contractor e-mails a copy of it to the surety that same day. Payment must be received by May 1, or 30 days from the original date of the letter.

If the surety cannot be reached (including situations where a voicemail message must be left) or if the surety indicates that it received the letter and that payment is forthcoming, no further action by the contractor is required. If the surety indicates that payment is not forthcoming, the contractor shall (1) attempt to ascertain the reason and (2) follow the steps outlined below after the 30-day period expires.

The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

3. Verification of Payment

a. Full Payment of the Claim is Made

If full payment (including interest, as applicable) is made within 30 calendar days of the date of the letter to the surety, the DME MAC shall, no later than 10 calendar days after payment was made:

(i) Update all applicable records to reflect that payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

(ii) Notify the applicable CMS Location (formerly CMS Regional Office) via letter or e-mail that payment was made.

(iii) If the OIG imposed the CMP or assessment, notify the OIG via letter that payment was made.

(iv) Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the enrollment contractor shall be copied):

- Stating that payment has been made, the date the payment was received, and the amount of said payment

- Containing the following quoted verbiage:

"You must, within 30 calendar days of the date of this letter, obtain and submit to the contractor additional surety bond coverage in the amount of (insert the amount that the surety paid) so as to ensure that your total coverage equals or exceeds the required $50,000 amount" (or higher if an elevated bond amount is involved due to a final adverse action). **Failure to timely do so will result in the revocation of your Medicare enrollment**.

"Additional surety bond coverage may be obtained by (1) adding to the amount of your existing surety bond so as to equal or exceed $50,000, or (2) cancelling your current surety bond and securing a new $50,000 surety bond. (Obtaining a separate (insert the amount the surety paid) surety bond is impermissible.) In either case, the effective date of the additional coverage must be on or before the date that you submit the additional coverage to the contractor."

If the contractor does not receive the additional bond coverage within this 30-day period, it shall revoke the DMEPOS supplier's Medicare enrollment under § 424.535(a)(1) enrollment in accordance with existing procedures. (The effective date of revocation shall be the date on which the DME MAC received payment from the surety.) It is important that the contractor (1) monitor the supplier's surety bond status upon receiving a copy of the DME MAC's letter to the supplier and (2) take prompt action against the supplier (consistent with existing procedures) if the supplier does not secure and timely submit the required additional coverage.

b. No Payment of the Claim is Made

If the surety fails to make any payment within the aforementioned 30-day timeframe, the DME MAC shall:

(i) Continue collection efforts as outlined in Pub. 100-06, chapter 4;

(ii) No later than 14 days after the 30-day period expires, contact the surety via e-mail or telephone to ascertain the reason for non-payment. Only one contact is necessary. A voice mail message may be left. The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

(iii) No later than 14 days after Step 2 has been completed – and if full payment still has not been received -- send the letter found in Section 10.7.16 of this chapter.

(iv) Include information relating to the surety's non-payment in the report outlined in section 10.2.5.3.2(D).

c. Partial Payment of the Claim is Made

If the surety pays part of the claim within the 30-day period and a balance is still due and owing, the DME MAC shall do the following:

(i) Continue collection efforts as outlined in Pub. 100-06, chapter 4;

(ii) No later than 14 days after the 30-day period expires, contact the surety via e-mail or telephone to ascertain the reason for the partial non-payment. Only one contact is necessary. A

voice mail message may be left. The contractor shall document any attempts to contact the surety by telephone and the content of any resultant conversations with the surety.

(iii) No later than 14 days after Step (ii) has been completed – and if full payment still has not been received -- send the letter found in Section 10.7.16 of this chapter.

(iv) Include information relating to the surety's partial non-payment in the report identified in section 10.2.5.3.2(D).

(v) No later than 10 calendar days after the partial payment was made:

- Update all applicable records to reflect that partial payment was made. (Payment from the surety shall be treated as payment from the supplier for purposes of said record updates.)

- Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the contractor shall be copied):

    - Stating that partial payment was made, the date the payment was received, and the amount of said payment

    - Containing the following quoted verbiage:

    "You must, within 30 calendar days of the date of this letter, obtain and submit to the contractor additional surety bond coverage in the amount of (insert the amount that the surety paid) so as to ensure that your total coverage equals or exceeds the required $50,000 amount" (or higher if an elevated bond amount is involved due to a final adverse action). **Failure to timely do so will result in the revocation of your Medicare enrollment**.

    "Additional surety bond coverage may be obtained by (1) adding to the amount of your existing surety bond so as to equal or exceed $50,000, or (2) cancelling your current surety bond and securing a new $50,000 surety bond. (Obtaining a separate (insert the amount the surety paid) surety bond is impermissible.) In either case, the effective date of the additional coverage must be on or before the date that you submit the additional coverage to the contractor."

If the contractor does not receive the additional bond coverage within this 30-day period, it shall revoke the DMEPOS supplier's Medicare enrollment under § 424.535(a)(1) in accordance with existing procedures. (The effective date of revocation shall be the date on which the DME MAC received payment from the surety.) It is important that the contractor (1) monitor the supplier's surety bond status upon receiving a copy of the DME MAC's letter to the supplier and (2) take prompt action against the supplier (consistent with existing procedures) if the supplier does not secure and timely submit the required additional coverage.

4. Successful Appeal

If the DMEPOS supplier successfully appeals the CMP or assessment and the surety has already made payment, CMS will – within 30 days of receiving notice of the successful appeal - notify the surety via letter of the successful appeal and repay the surety.

D. Reporting Requirements

1. Contents

DME MACs shall compile a report on a quarterly basis in the format prescribed in existing CMS directives. The report will capture the following elements:

a. Number of account receivables (debts) reviewed for possible surety bond letter development

b. Number of debts sent to the surety for recovery

c. Amounts recovered directly from sureties (1) during the quarter in question, and (2) since March 3, 2009 (that is, the total/cumulative amount collected since the beginning of the surety bond collection process)

d. Amounts paid by suppliers after the debt was referred to the surety for collection. The report shall include the (1) amount for the quarter in question and (2) total/cumulative amount since March 3, 2009.

e. Names of suppliers and billing numbers for which letters were sent to the surety and/or surety bond recoveries were received

f. Names of suppliers on whose surety bond(s) the surety made payment in the last quarter and to whom the DME MAC consequently sent notice to the supplier that it must obtain additional surety bond coverage to reach the $50,000 threshold.

g. Names and addresses of sureties that have failed to make payment within the quarterly period. For each instance of non-payment, the report shall identify (a) the amount that was requested, (b) the amount that was paid (if any), (3) the name and tax identification number of the supplier in question, and (4) the reason the surety did not pay (to the extent this can be determined).

2. Timing

The quarterly reports shall encompass the following time periods: January through March, April through June, July through August, and September through December. Reports shall be submitted to PEOG (with a copy to the DME MAC COR) --- via the following e-mail address: XXXXXXXX@cms.hhs.gov --- by the 10th day of the month following the end of the reporting quarter. Information on surety collections shall be reported once for each demand letter. That action shall be reported only when the collection process has been fully completed for that specific identified overpayment, which may be comprised of multiple claims. For example, suppose the surety was sent a letter in December but its payment was not received until January. That action would be documented in the report encompassing the months of January, February, and March.

10.2.5.4 – Indian Health Services (IHS) Facilities' Enrollment as DMEPOS Suppliers

(Rev. 11682; Issued: 11-04-2022; Effective:1 2-05-2022; Implementation:12-05-2022)

A. Background

The contractor shall enroll IHS facilities as DMEPOS suppliers in accordance with: (a) the general enrollment procedures cited in chapter 10; (b) the statement of work contained in the contractor's contract with Medicare; and (c) the special procedures cited in this section.

For enrollment purposes, Medicare recognizes two types of IHS facilities: (1) facilities wholly owned and operated by the HIS; and (2) facilities owned by the IHS but tribally operated or totally owned and operated by a tribe. CMS will provide the contractor with a list of IHS facilities that distinguishes between these two types.

On the list, the contractor shall use the column entitled, "FAC OPERATED BY", for this purpose.

B. Enrollment

The supplier shall complete the Form CMS-855S in accordance with the instructions shown therein.

Facilities that are:

- Totally owned and operated by the IHS are considered governmental organizations. An Area Director of the IHS must sign Section 15 of the Form CMS–855S, be listed in Section 9 of the form, and sign the letter required under Section 8 of the form that attests that the IHS will be legally and financially responsible in the event there is any outstanding debt owed to CMS.

- Tribally operated are considered tribal organizations. Section 15 of the Form CMS–855S must be signed by a tribal official who meets the definition of an "authorized official" under 42 CFR § 424.502. The individual must also be listed in Section 9 of the form and must sign the letter required under Section 8 of the form that attests that the tribe will be legally and financially responsible in the event there is any outstanding debt owed to CMS.

C. Supplier Standards, Exceptions, and Site Visits

All IHS facilities, whether operated by the IHS or a tribe:

1. Shall meet all required standards, with the exception of the comprehensive liability insurance requirements under 42 CFR § 424.57(c)(10).

2. Need not meet the requirement to provide state licenses for their facility/business. For example, if the DMEPOS supplier indicates on its application that it will be providing hospital beds and is located in a state that requires a bedding license, such licensure is not

required. However, if it provides a DMEPOS item that requires a licensed professional in order to properly provide the item, it shall provide a copy of the professional license. The licensed professional can be licensed in any state or have a federal license (e.g., a pharmacy does not need a pharmacy license but shall have a licensed pharmacist).

3. Shall, like all other DMEPOS suppliers, undergo site visits in accordance with section 10.6.20(A) and 10.6.20(B) of this chapter. (This includes all hospitals and pharmacies enrolling as DMEPOS suppliers.)

D. Provider Education for IHS Facilities

The contractor shall ensure that its web site includes the information contained in this section 10.2.5.4) that is specific to enrollment of IHS facilities (whether operated by the IHS or a tribe).

E. Specialty Codes

The contractor shall apply the specialty code A9 (IHS) to all IHS enrollments (whether operated by the IHS or a tribe). However, the specialty code A9/A0 shall be applied to facilities that are IHS/tribal hospitals.

Other specialty codes should be applied as applicable (e.g., pharmacies).

10.2.5.5 – Pharmacy Enrollment as a DMEPOS Supplier - Accreditation

(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation: 12-05-2022)

(Refer to section 10.2.2.7 of this chapter for a discussion of pharmacy enrollment via the Form CMS-855B (i.e., pharmacy not enrolling as a DMEPOS supplier).)

The contractor shall not require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.

The contractor shall determine which enrolled suppliers are pharmacies that are not accredited and who will be enrolled for 5 calendar years prior to January 1 of the next calendar year. The contractor shall then send a notice of revocation by January 10, 2011, to all enrolled pharmacies that are not accredited and who will not be enrolled for 5 calendar years as of January 1, 2011.

The contractor shall prepare a letter which enables all individually enrolled practice locations of pharmacies who have been enrolled for 5 calendar years prior to January 1, 2011, to attest that they are exempt from the requirement to be accredited because their total durable medical equipment, prosthetics orthotics and supplies (DMEPOS) billings subject to accreditation are less than 5 percent of their total pharmacy sales, as determined based upon the total pharmacy sales of the pharmacy for the previous 3 calendar or fiscal years. The letter shall cite that the attestation requires the signature of the authorized or delegated official of the entity. The authorized and delegated officials are defined in Section 15, of the Medicare Enrollment Application (Form CMS-855S), and as described in the internet enrollment application version of PECOS. Before mailing the letters, contractor shall obtain the contractor project officer's approval of the letter. The mailing shall be in the form of an endorsement letter with an enclosed

stamped self-addressed envelope. The mailing should be performed between October 1, 2010 and October 31, 2010. For pharmacies with more than one practice location, the letters shall cite the need for each individually enrolled practice location to attest that they are exempt from the accreditation requirements. New locations of enrolled chain pharmacies shall not be considered to have been enrolled for 5 calendar years. Pharmacies that have had a change of ownership in the prior 5 years which resulted in a change in their legal business entity, including a change in their tax identification number (TIN), shall not qualify for an attestation accreditation exemption and therefore shall not be sent the attestation letter.

The contractor shall review the attestations received from pharmacies. Pharmacies that properly signed the attestation letter shall be given an accreditation status of exempt. The contractor shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations. The contractor shall send a notice of revocation by January 10, 2011, to all enrolled pharmacies who were sent an attestation letter and have not properly completed it as of the date of the notice of revocation. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

Between April 1, 2011 and April 30, 2011, the contractor shall compile a sample listing of at least 10 percent of the pharmacies that have submitted a contractor-accepted attestation exempting them from accreditation. The contractor shall develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct. The letter shall request submission of evidence substantiating that the validity of the pharmacy supplier's attestation. At a minimum, requested materials for this evidence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods. The contractor shall obtain contractor project officer approval of the letter. Within 45 days after project officer approval of the letter, the contractor shall mail a copy of the letter to the random sample of pharmacies that claimed exemption through an attestation. The contractor shall determine the acceptability of the replies received in response to the audit verification random sample mailing. The contractor shall use DMEPOS billing data for only products and services requiring accreditation to assist in the determination. The contractor shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications. The contractor shall consult with the contractor project officer in cases where it is uncertain as to the acceptability of the supplier's response to the audit request. By June 30, 2011, the contractor shall send a notice of revocation to all enrolled pharmacies that were sent an audit verification letter who did not submit satisfactory evidence that they were compliant with the requirements to obtain an accreditation exemption. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

The contractor shall follow the procedures shown above concerning issuance of attestation letters and audit survey letters for all succeeding years after they have been performed for the first time.

10.2.6 - Medicare Diabetes Prevention Program (MDPP) Suppliers

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. General Background Information

MDPP is a structured lifestyle intervention that includes dietary coaching, lifestyle intervention, and moderate physical activity, all with the goal of preventing the onset of diabetes in individuals who are pre-diabetic. An entity or individual seeking to furnish MDPP services to Medicare beneficiaries must enroll as an "MDPP supplier" via the Form CMS-20134. Such suppliers must meet the following enrollment requirements:

- Has: (1) MDPP preliminary recognition; (2) full recognition as determined by the Center for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP); or (3) full CDC recognition plus DPRP recognition.

- Maintains a valid TIN and NPI at the organizational level

- Passed screening requirements at a high categorical risk level per § 424.518(c) upon initial enrollment and revalidate at the moderate categorical risk level per § 424.518(b) and

- Complies with the supplier standards

MDPP supplier applicants do not require any licensure, accreditation, or certificates to be eligible to enroll as an MDPP supplier. Rather, the CDC administers the curriculum for the MDPP and monitors the organization's fidelity to and success with furnishing the services. Thus, organizations with preliminary or full recognition from the CDC's DPRP indicate that they are prepared to deliver MDPP services.

As a part of the expanded CMMI model, CMS will only accept in-person MDPP suppliers to enroll in Medicare. MDPP suppliers can provide any combination of in-person and distance learning sessions and they would still be considered in-person MDPP suppliers. In June 2024, CDC released the 2024 Diabetes Prevention Recognition Program (DPRP) Standards (https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures) that included five types of CDC DPRP organization recognition codes: "in-person", "in-person with a distance learning component", "distance learning", "online", and "combination with an online component". The contractor can approve MDPP applications for organizations that demonstrate an "in-person" or an "in-person with a distance learning component" CDC DPRP recognition code.

B. MDPP Supplier Standards

All MDPP suppliers must comply with MDPP supplier standards to obtain and retain Medicare billing privileges. Consistent with 42 CFR § 424.205(c), each MDPP supplier must certify on its Form CMS-20134 enrollment application that it meets and will continue to meet the following standards (listed in § 424.205(c)) and all other requirements:

(1) Must have and maintain: (1) MDPP preliminary recognition; (2) full CDC recognition; or (3) full CDC recognition plus DPRP recognition.
(2) Must not currently have its billing privileges terminated or be excluded by a state Medicaid agency
(3) Must not permit MDPP services to be furnished by or include on its roster any individual

coach who meets the ineligibility criteria in § 424.205(d)(1)

(4) Must maintain at least one administrative location on an appropriate site. All administrative locations, must be reported on their CMS-20134 form and may be subject to site visits. (See § 424.205(c)(4) for more information regarding site requirements.)

(5) Must update the enrollment application within 30 days for any change of ownership, change to the coach roster, change of practice location (including additions and deletions of locations), and final adverse legal action history, and update all other changes within 90 days

(6) Must maintain a primary business telephone that is operating at administrative locations or directly where services are furnished. The associated telephone number must be listed with the name of the business in public view.

(7) Must not convey or reassign a supplier billing number

(8) Must not deny an MDPP beneficiary access to MDPP services during the MDPP benefit period, including conditioning access to MDPP services on the basis of an MDPP beneficiary's weight, health status, or achievement of performance goals (with certain exceptions described in § 424.205(c)(8)(i))

(9) Must not---nor may other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf---directly or indirectly commit any act or omission, or adopt any policy that coerces or otherwise influences an MDPP beneficiary's decision to begin accessing MDPP services or change to a different MDPP supplier specifically

(10) Must offer an MDPP beneficiary no fewer than the services described in § 424.205(c)(10)

(11) Must disclose detailed information about the MDPP benefit to each beneficiary to whom it furnishes MDPP services before the initial core session is furnished, including the set of services, eligibility requirements, the once-per-lifetime nature of MDPP services, and the standards in § 424.205(c)

(12) Must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP related complaints. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. This information must be kept at each administrative location and made available to CMS or its contractors upon request

(13) Must maintain a crosswalk file which indicates how participant identifications for the purposes of CDC performance data correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary. The MDPP supplier must submit the crosswalk file to CMS or its contractor

(14) Must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core benefit

(15) Must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, as well as the documentation requirements outlined § 424.205(f)

The CMS will notify the contractor when an MDPP supplier within its jurisdiction has moved from preliminary or full recognition down to pending and therefore no longer maintains eligibility as an MDPP supplier.

For those suppliers that no longer have a valid recognition level to maintain their MDPP supplier enrollment, the contractor shall take the necessary steps to revoke the supplier's billing privileges.

Violations of the supplier standards are determined as non-compliance and the associated enrolment denial and revocation authorities would apply.

10.2.7 - Opioid Treatment Programs
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Legislative and Regulatory Background

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (hereafter referenced as the "SUPPORT Act") was designed to alleviate the nationwide opioid crisis by: (1) reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. Section 2005 of the SUPPORT Act attempted to fulfill these objectives, in part, by establishing a new Medicare benefit category for opioid treatment programs (OTPs).

An OTP is currently defined in 42 CFR § 8.2 as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. § 823(g)(1). There are three overarching (but not exclusive) requirements that an OTP must meet to bill for OTP services:

1. Accreditation

The OTP must have a current, valid accreditation by an accrediting body or other entity approved by the Substance Abuse and Mental Health Services Administration (SAMHSA), the federal agency that oversees OTPs. The accreditation process includes, but is not limited to, an accreditation survey, which involves an onsite review and evaluation of the OTP to determine compliance with applicable federal standards. There are currently six SAMHSA-approved accreditation bodies.

2. Certification

The OTP must have a current, full, valid certification by SAMHSA for such a program. The prerequisites for certification (as well as the certification process itself) are addressed in 42 CFR §8.11 and include, but are not restricted to, the following:

- Current and valid accreditation (described in subsection (A)(1) above)
- Adherence to the federal opioid treatment standards described in 42 CFR § 8.12
- Compliance with all pertinent state laws and regulations, as stated in § 8.11(f)(1)

Under 42 CFR §8.11(a)(3), certification is generally for a maximum 3-year period, though this may be extended by 1 year if an application for accreditation is pending. SAMHSA may revoke

or suspend an OTP's certification if any of the applicable grounds identified in 42 CFR § 8.14(a) or (b), respectively, exist.

3. Enrollment

The SUPPORT Act also required that an OTP be enrolled in the Medicare program under section 1866(j) of the Act to bill and receive payment from Medicare for opioid use disorder treatment services.

In the Calendar Year (CY) 2020 Physician Fee Schedule final rule (published in the **Federal Register** on November 15, 2019 (84 FR 62567)), CMS established a new 42 CFR § 424.67 containing requirements that OTPs must meet and continually adhere to in order to enroll (and remain enrolled) in Medicare effective January 1, 2020. Since this latter date, OTPs have enrolled in Medicare consistent with 42 CFR § 424.67 and the general provider enrollment requirements of 42 CFR Part 424, subpart P (42 CFR § 424.500 et seq.). This section 10.2.7 outlines the specific enrollment policies associated with OTP enrollment.

A. OTP Enrollment Process

The instructions in this section 10.2.7(B) are in addition to, and not in lieu of, those in CMS Pub. 100-08, Program Integrity Manual (PIM), chapter 10. To the extent there are conflicting instructions, the policies in this section 10.2.7 shall take precedence.

1. Applicable Form CMS-855

a. General Requirements

As of November 16, 2020, OTPs may enroll (and remain enrolled) via the Form CMS-855B or the Form CMS-855A, but not both. Some OTPs currently enrolled via the Form CMS-855B may accordingly seek to change their enrollment to a Form CMS-855A. To ensure that the OTP is at no time enrolled under both Form CMS-855 application types, the contractor shall do the following:

- Upon receipt of an initial Form CMS-855A or Form CMS 855B from an OTP, the contractor shall confirm that the OTP is not currently enrolled as such via another Form CMS-855 application type. (For example, if the contractor receives an initial Form CMS-855A from an OTP, the contractor shall verify that the OTP is not already enrolled via the Form CMS-855B.)

- If the contractor determines that the OTP is not already enrolled as such, the contractor shall process the application normally.

- If, however, the contractor determines that the OTP is already enrolled as such via a different Form CMS-855 application type, the contractor shall verify with an authorized or delegated official of the OTP (by telephone or e-mail) that the OTP is changing its enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa). The OTP in

this situation is not required to submit a Form CMS-855 application to voluntarily terminate its prior enrollment.

The Form CMS-855B has been updated to add "Opioid Treatment Program" as a listed provider type. (For the Form CMS-855A (at least until that form is updated), the OTP shall check the "Other" box in Section 2 and state "Opioid Treatment Program.")

An entity that is enrolling or is already enrolled in Medicare as another provider or supplier type may also seek enrollment as an OTP. It must, however, submit a separate Form CMS-855 application to do so; it cannot enroll or be enrolled as an OTP and another provider/supplier type via the same enrollment.

Note that the policies in this section 10.2.7 regarding an OTP's transition from a Form CMS-855B enrollment to a Form CMS-855A enrollment (or vice versa) only apply if the OTP is doing so in the same state in which it is currently enrolled as an OTP. If an OTP is enrolling under a different Form CMS-855 in a state different from that in which it is currently enrolled (e.g., a Form CMS-855B enrolled OTP in State X is enrolling via the Form CMS-855A in State Y), it is considered a brand new enrollment (and not merely a "switch" in OTP enrollment type); this would thus require, for instance, moderate or high-level screening as opposed to limited screening (as discussed further in section 10.2.7(B)(3) below).

2. Applicable Fee

An OTP is an "institutional provider" under 42 CFR § 424.502 and thus is required to pay an application fee pursuant to 42 CFR § 424.514. The contractor shall follow the application fee procedures outlined in chapter 10 of the PIM. A fee is required even when the OTP is changing its enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa.

3. Categorical Screening

Consistent with 42 CFR § 424.518, the contractor shall categorically screen OTP applications as follows:

a. Newly enrolling OTPs that **are not** changing their enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa -

- If the OTP has not been fully and continuously certified by SAMHSA since October 24, 2018, the contractor shall conduct high-risk level categorical screening.

- If the OTP has been fully and continuously certified by SAMHSA since October 24, 2018, the contractor shall conduct moderate-risk level categorical screening.

b. Newly enrolling OTPs that **are** changing their enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa - The contractor shall conduct limited-risk level categorical screening if the OTP had previously completed, as applicable, the moderate or high-risk level screening as part of its initial enrollment. Otherwise, moderate or high-risk level screening (as applicable under § 424.518) shall be conducted.

c. Revalidating OTPs – The contractor shall conduct moderate-risk level categorical screening.

d. Practice Location Addition – The contractor shall conduct moderate-risk level categorical screening (i.e., site visit of the new location consistent with the procedures outlined in this chapter 10).

4. Confirmation of Certification

When processing OTP initial applications (including those involving a change in Form CMS-855 application type) and revalidation applications, the contractor shall confirm and record in PECOS the OTP's SAMHSA certification status as follows:

a. Review the OTP directory at https://dpt2.samhsa.gov/treatment/directory.aspx. The OTP's certification must be full, current, and valid. ("Provisional" certification status is not acceptable.) The OTPs SAMHSA certificate (and the OTP's identification in the SAMHSA directory) need not have the exact same legal business name as that on the OTP's IRS document, though the contractor shall develop for clarification if it has questions as to whether the OTP on the application and in the directory are truly the same.

b. Verify that each location listed on the Form CMS-855 is separately and uniquely certified.

c. Enter into PECOS the OTP's relevant certification data obtained from the aforementioned OTP directory. This includes: (1) the OTP number; and (2) the certification effective date (which can be obtained from the OTP's renewal letter). The certification effective date is the date on which SAMHSA acknowledged notification from the accrediting organization and can be verified by reviewing the OTP's renewal letter information in the database. (The contractor need not obtain a copy of the letter from the OTP.)

The expiration date must be obtained via the SAMHSA operating certificate for the location in question; the OTP should submit said certificate with its application.

Irrespective of whether the OTP reported the data described in (4)(c) on the Form CMS-855, the contractor shall use the information in the OTP directory for purposes of data entry.

5. OTP Managing Employees

As with all enrolling providers and suppliers, the OTP must disclose all of its managing employees in Section 6 of the Form CMS-855. Such managing employees must include the OTP's medical director and program sponsor, which the OTP must have pursuant to 42 CFR §§ 8.12(b) and §§ 424.67(b)(5). The contractor shall verify that the medical director is a validly licensed physician or psychiatrist; he/she must be licensed by the state in which the OTP's primary practice location is situated. The contractor may develop with the OTP for any information it needs (and via any manner it chooses) to verify the person's licensure. If the contractor determines that the individual is not appropriately licensed, it shall contact its PEOG BFL for guidance.

The OTP must submit a copy of the organizational diagram required under Section 5 of the Form CMS-855 even if it merely changing its enrollment type from a Form CMS-855B to a Form CMS-855A (or vice versa).

6. OTP Personnel

i. Regulatory Background

Section 424.67 contains several important provisions concerning OTP personnel. These include:

- Completion of Attachment/Supplement (§ 424.67(b)(1)(i)) - Requires the OTP to maintain and submit to CMS (via the applicable Form CMS-855 supplement or attachment) a list of all physicians, other eligible professionals, and pharmacists (regardless of whether the individual is a W-2 employee of the OTP) who are legally authorized to prescribe, order, or dispense controlled substances on the OTP's behalf. The list must include the individual's (1) first and last name and middle initial, (2) social security number, (3) NPI, and (4) license number (if applicable).

- Felony Convictions (§ 424.67(b)(6)(i)(A)) - The OTP must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted of a federal or state felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. The applicable felonies are based on the same categories of detrimental felonies (as well as case-by-case detrimental determinations) found at § 424.535(a)(3). (It is immaterial whether the individual is (1) currently dispensing narcotics at or on behalf of the OTP or (2) a W-2 employee of the OTP.)

- Revoked/Preclusion List (§ 424.67(b)(6)(ii)) - The OTP must not employ or contract with any personnel (regardless of whether the individual is a W-2 employee of the OTP) who is (1) revoked from Medicare under § 424.535 or any other applicable section in Title 42 or (2) on the preclusion list.

- State Board Action (§ 424.67(b)(6)(iii)) - The OTP must not employ or contract with any personnel (W-2 or otherwise) who has a prior adverse action by a state oversight board (including, but not limited to, a reprimand, fine, or restriction) for a case involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

ii. Attachment and Verification

Attachment 3 of the Form CMS-855B and Section 10 of the Form CMS-855A (hereafter collectively referenced as "attachment") collect information on the individuals described in § 424.67(b)(1)(i) above. OTPs submitting the Form CMS-855B or the Form CMS-855A must complete this attachment as described in (and subject to) (ii)(A) below and --- once enrolled --- report any changes to the information thereon (e.g., new or deleted prescribers) consistent with 42 CFR § 424.516(e).

(A) When to Submit Attachment

(1) General Principles

The OTP need only submit the attachment for the first time as part of (i) an initial Form CMS-855B or Form CMS-855A enrollment, (ii) a Form CMS-855B or Form CMS-855A revalidation (periodic or off-cycle), or (iii) a change from a Form CMS-855A enrollment to a Form CMS-855B enrollment (or vice versa). The OTP is not required to complete it for the first time as part of a change of information request. Consider the following examples:

Example 1 - Smith OTP enrolled in Medicare via the Form CMS-855A in February 2023, prior to the Form CMS-855A being revised to include the attachment. Smith submits a change request in July 2024 to add a new billing agency. Smith need not complete the attachment at this time because Smith's application does not fall within any of the three categories in (A)(i) through (iii) above.

Example 2 - Using Example 1, suppose Smith submitted a Form CMS-855A revalidation application (rather than a change of information) in July 2024. Smith would have to complete the attachment at that time per (A)(1)(ii) above.

Example 3 - Again using Example 1, suppose Smith is currently enrolled via the Form CMS-855B, which it completed in July 2023. (The OTP attachment was completed, too.) Smith submits a Form CMS-855A in May 2024 to change its OTP enrollment to that form. Smith would have to complete the attachment on the CMS-855A form because (A)(1)(i) and (iii) above are met.

Example 4 - Again using Example 1, assume Smith enrolled via the Form CMS-855A in February 2023. Smith hires two pharmacists in March 2024. Smith need not report these persons on the attachment nor complete the attachment in full, for no category in (A)(i) through (iii) above applies. If, however, Smith enrolled via the Form CMS-855A in March 2024 (completing the attachment in the process) and hired the two pharmacists in June 2024, the latter would have to be reported on the attachment via a change of information.

(2) Submission When Not Required

Instances could occur where the OTP submits the Form CMS-855 attachment for the first time when it was not required to do so (i.e., no category in (6)(A)(i) through (iii) applies). The two most likely scenarios would involve: (a) a Form CMS-855A OTP application submission (e.g., initial, change request); or (b) a Form CMS-855B-enrolled OTP submitting a change request.

In the case of (a), the contractor shall not process the attachment and may either keep it in the provider file or return it to the OTP via the general procedures in this chapter for returning applications. Regardless of which of the latter two approaches the contractor takes, the contractor shall: (i) notify the OTP that the attachment was not processed; (ii) explain why; and (iii) state that the attachment will need to be submitted at a later time as determined by CMS. If the contractor elects to retain the attachment, the notification in (i)/(ii)/(iii) above may be given in any matter the contractor chooses.

For (b), the contractor shall process the attachment consistent with the instructions in this section (6)(ii).

(B) Owning/Managing Individuals - Notwithstanding (6)(ii)(A) above, any person otherwise required to be reported on the attachment must also be disclosed in Section 6 of the Form CMS-855B if he or she qualifies as a 5 percent or greater owner, managing employee, partner, etc. To illustrate, assume Dr. Jones prescribes controlled substances on the OTP's behalf. He is also a managing employee of the OTP. The OTP is initially enrolling in Medicare via the Form CMS-855B. Jones would have to be listed in Section 6 and on the attachment. If Jones left the OTP altogether, the OTP would have to report this in both Section 6 and the attachment; if Jones no longer prescribes drugs for the OTP but remains a managing employee, this would have to be reported via the attachment but not in Section 6.

(C) Timeframe for Changes - Additions/deletions/changes to the information in the attachment must be reported within 90 days of the change per 42 CFR § 424.516(e)(2).

(D) Missing Data - In general, the contractor shall develop (using the procedures outlined in this chapter) for any data that is missing or unverifiable on the attachment. (This includes individuals who the contractor learns (via any means) should be listed on the attachment but were not.) However, and excluding names and social security numbers, the contractor may forgo such development if the missing/unverifiable information can be located and validated via other means. This could include, for example: (i) the NPI of the individual (who is also a managing employee) is listed in Section 6 of the Form CMS-855B; or (ii) the person's license number can be obtained through PECOS.

Note that the specific processing exception addressed in (D) applies only to OTPs. Other processing exceptions applicable to other provider and supplier types (as well as to OTPs) can be found elsewhere in this chapter.

(E) Validation of Individuals on Attachment - The contractor shall review all individuals listed on the attachment against the MED and the SAM. (The contractor may combine this step with its check of the same individual if the latter is also listed in Section 6 of the form; it need not perform two separate reviews.) The contractor shall contact its PEOG BFL for further guidance if the contractor determines or learns during its screening that the individual:

- Is OIG excluded;
- Is debarred (per the SAM);
- Is on the preclusion list;
- Has one of the actions described in §§ 424.67(b)(6)(i)(A), 424.67(b)(6)(ii); or §§ 424.67(b)(6)(iii) above; or
- Does not meet applicable requirements to prescribe, order, or dispense controlled substances on the OTP's behalf.

In reviewing all individuals listed on the attachment (and absent a CMS directive to the contrary), the contractor is not required to perform any validation activities beyond those which it would ordinarily perform for persons listed in Section 6. (For example, the contractor need not

research each person to determine (i) whether he/she is licensed, (2) what his/her license number is, or (3) whether he/she has ever had a fine imposed against him/her related to patient harm.)

(F) Multiple Locations and Off-Site – All persons who meet the requirements of § 424.67(b)(1)(i) must be listed on the OTP's attachment regardless of where the individual is located (e.g., the primary practice location, one of the OTP's multiple locations, his/her home, etc.) The central issue is whether the individual is authorized to act on the OTP's behalf, not his/her location.

(G) Appropriate Attachment Sections

As there is no section on the Form CMS-855B attachment specific to prescribers, such persons should be listed in the "Ordering Personnel Identification" section rather than the "Dispensing Personnel Information" section. However, if the contractor determines that the prescriber was inadvertently listed in the "Dispensing" section, it need not require the OTP to move him/her to the "Ordering" section. In addition:

- If the person qualifies as both an ordering and dispensing individual but is only listed in one of the two sections of the attachment, the contractor need not require the OTP to list him/her in both.
- If the person qualifies as either an ordering or dispensing individual but is listed in the incorrect section (e.g., a dispenser is listed in the ordering section), the contractor need not require the OTP to move him/her to the other section.

iii. Person With Adverse Action but Need Not Be Listed on Attachment or in Section 6

There may be instances where the contractor learns (via any means) that an individual described in §§ 424.67(b)(6)(i)(A), 424.67(b)(6)(ii), or §§ 424.67(b)(6)(iii) has one of the actions described within those regulatory sections but was not required to be listed on the OTP's application (either on the attachment or elsewhere on the application). Examples could include the following:

- A W-2 nurse has restrictions on her license due to a patient harm case
- A non-prescribing/non-ordering physician under contract is currently on the preclusion list
- A physician assistant employee is currently revoked from Medicare.

These individuals may not have met the criteria under § 424.67(b)(1)(i) to be reported on the attachment or the OTP may not have yet been required to submit the attachment (e.g., the OTP is enrolled via the Form CMS-855A.) Regardless, if the contractor becomes aware of such an individual, it shall contact its PEOG BFL for guidance.

7. Provider Agreement

i. Basic Requirement

To enroll (and remain enrolled) in Medicare as an OTP, the OTP (including provider-based OTPs, as discussed in subsection (B)(9) below) must sign and adhere to the terms of the Form

CMS-1561 Provider Agreement. (This is the same agreement signed by certified providers such as hospitals, hospices, and home health agencies. See 42 CFR Part 489, Subparts A through E (as well as CMS Pub. 100-07, State Operational Manual) for general information on provider agreements.) Given this, the contractor shall verify that the OTP submitted a signed and dated Form CMS-1561 with its initial enrollment package. The provider agreement must be signed by an authorized or delegated official (as those terms are defined in § 424.502) of the OTP; the signature can be handwritten or digital. This form may be accepted via mail, fax, email, or document upload. The legal business name on the Form CMS-1561 must match that on the Form CMS-855.

If the OTP failed to submit the Form CMS-1561 as described in the previous paragraph, the contractor shall develop for the document (or any missing or inconsistent data thereon) consistent with the procedures outlined in chapter 10 of the PIM.

ii. Criteria for Inapplicability

The requirement to submit, sign, and date a new Form CMS-1561 does not apply if the OTP meets all of the following requirements: (1) the OTP is already enrolled as such in Medicare; (2) the OTP already has a valid Form CMS-1561 agreement in effect; and (3) the OTP is newly enrolling solely to change its existing Form CMS-855B enrollment to a Form CMS-855A, or vice versa.

8. Locations

An OTP may have multiple practice locations under a single enrollment so long as they all have the same legal business name and employer identification number. However, it may not split its locations between a Form CMS-855A enrollment and a Form CMS-855B enrollment. All locations must be under one enrollment. To illustrate, suppose an OTP is currently enrolled via the Form CMS-855B. It has four locations - W, X, Y, and Z. The OTP cannot keep W and X under its Form CMS-855B enrollment and switch Y and Z to a Form CMS-855A enrollment. It must retain all locations under the Form CMS-855B enrollment or move them all to a Form CMS-855A enrollment.

Instances might arise where an OTP lists multiple locations on its enrollment application, and one or more locations do not meet full status while one or more do. (For purposes of this situation, "full status" means that the location is separately and uniquely certified. See sections 10.2.7(a)(2) and (B)(4)(b) for more information.) Here, the contractor, in lieu of denying the entire application, may develop with the OTP to either: (1) update the location's status (if full status for it has since been obtained); or (2) remove the location from the enrollment application. Any such development---while encouraged, is not required---shall be performed consistent with the procedures and timeframes outlined in this chapter. The OTP's failure to fully and timely comply with the development request shall result in application's rejection. If the OTP does comply, the contractor can proceed as normal.

9. Provider-Based

As indicated in section 10.3.1.1.13(F)(1) of this chapter, an unenrolled OTP that wishes to become provider-based to a hospital cannot do so via the hospital's submission of a change of

information application that adds the OTP as a practice location. The OTP must first enroll as an OTP via an initial enrollment, sign a provider agreement, undergo screening, etc. Once the OTP is enrolled, the hospital may add the OTP as a practice location on its enrollment. The situation is akin to that described in section 10.3.1.1.3(F)(1) regarding provider-based HHAs; section 10.3.1.1.3(F)(1) emphasizes that the HHA must separately enroll as such.

If a hospital submits an application to add--

(i) An unenrolled OTP as a practice location, the contractor shall return the change request on the basis of § 424.526(a)(7); the OTP must submit an initial enrollment application.

(ii) An enrolled OTP as a practice location, the contractor shall process the application consistent with the instructions in this chapter. A separate PECOS record for the OTP site (in its capacity as a hospital practice location) need not be created. Moreover:

- The enrolled OTP need not sign a new/additional provider agreement.
- The hospital need not complete the attachment regarding ordering, prescribing, and dispensing personnel, for the attachment is only completed by OTPs. However, if the OTP's addition as a provider-based location results in a change to any of the individually enrolled OTP's existing attachment information (e.g., new prescribers), the OTP must submit a change of information consistent with 42 CFR § 424.516(e)(2). Likewise, any other change to the OTP's individual enrollment stemming from its provider-based status (e.g., new ownership, change in managing employees) must be reported consistent with this chapter's instructions as well as 42 CFR Part 424, subpart P, § 424.67, and any other applicable regulations.
- The contractor need not confirm that the OTP location is still SAMHSA-certified.
- The hospital must pay an application fee since it is adding a new location.
- The application shall be screened at the limited screening level per 42 CFR § 424.518.
- Notwithstanding any other instruction to the contrary in this chapter, the contractor shall follow the basic process in subsection (C)(2)(a) below with respect to referring the practice location addition to PEOG so that a CCN can be assigned to the OTP practice location (e.g., include in the e-mail the hospital's and OTP's respective names, the hospital's CCN and NPI, and the individually enrolled OTP's CCN and NPI)

C. Approval

1. No State Agency or CMS Survey & Operations Group (SOG) Location Involvement

Unlike with many entities that complete the Form CMS-855A, there is no state agency or SOG Location involvement with OTP Form CMS-855A enrollments. Accordingly, no recommendations for approval or other type of referral need be made to the state or SOG Location nor will the SOG Location send any tie-in notice to the contractor. Except as otherwise stated in this section 10.2.7, the application will be reviewed and handled entirely at the contractor level.

2. Process of Approval

If the contractor determines that the OTP's application should be approved, it shall undertake the following:

a. For Form CMS-855A applications only, request via PEMACReports@cms.hhs.gov that CMS assign a Form CMS-855A CCN to the enrollment. (This task is required even if the OTP is merely changing its existing enrollment from a Form CMS-855B to a Form CMS-855A.)

b. As applicable (and except as stated in section (B)(7)(ii) above), send the Form CMS-1561 to PEMACReports@cms.hhs.gov for CMS to execute the signature on behalf of the Secretary. CMS will return the executed provider agreement within 3 business days. (The tasks in 2(a) and 2(b) can be completed via the same e-mail.)

c. As applicable, send a copy of the executed provider agreement to the OTP along with the enrollment approval letter. (The contractor shall retain the original provider agreement.)

3. Effective Date of Billing

For newly enrolling OTPs that are not changing their enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa), the contractor shall apply the effective date policies outlined in 42 CFR §§ 424.520(d) and 424.521(a) and explained in chapter 10 of the PIM.

For newly enrolling OTPs that are changing their enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa), the contractor shall apply to the new/changed enrollment the same effective date of billing that was applied to the OTP's initial/former enrollment. (See 42 CFR § 424.67(c)(2).) To illustrate, suppose an OTP initially enrolled via the Form CMS-855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020, the OTP elects to end its Form CMS-855B enrollment and enroll via the Form CMS-855A pursuant. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS-855A enrollment would be retroactive to April 1, 2020 (though the time limits for filing claims found in § 424.44 would continue to apply).

4. In cases where the OTP is changing its Form CMS-855 enrollment type, the contractor shall do the following:

a. End-date/deactivate the prior enrollment effective: (1) the date following that on which the OTP submitted its last claim under its prior enrollment; or (2) the prior enrollment's effective date of billing if no claims were submitted under the prior enrollment. The PECOS L & T basis shall be "Voluntary Termination." The deactivation reason shall be "Voluntary withdrawal: Applicant voluntarily withdrew from Medicare program.

b. Notify the OTP in the approval letter that the OTP's prior enrollment has been end-dated/deactivated and specify said end-date.

10.2.8 - Providers/Suppliers Not Eligible to Enroll

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

Section 10.2.8 contains a non-exhaustive list of individuals and entities that frequently attempt to enroll in Medicare but are not eligible to enroll as one of the categories listed below. (For instance, an individual cannot enroll as a drug and alcohol rehabilitation counselor.) If the contractor receives an enrollment application from an individual/entity attempting to enroll as one of these categories below, the contractor shall deny the application -- with the exception of entities eligible to enroll using the Form CMS-20134, which is specific to the furnishing of MDPP services. An assisted living facility, for example, that also provides the DPP and is eligible to enroll as an MDPP supplier may enroll through the CMS-20134; however, this enrollment only pertains to the rendering of MDPP services.

- Acupuncturist
- Assisted Living Facility
- Birthing Center
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Intern (Graduate Medical Education)
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapist
- Licensed Practical Nurse
- Licensed Professional Counselor
- Master of Social Work
- Medicare Beneficiaries
- National Certified Counselor
- Naturopath
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse
- Speech and Hearing Center
- State Medicaid Agency (SMA)(SMAs do not have an NPI and are not eligible to enroll in the Medicare program. If an SMA is enrolled or seeks enrollment as a provider or supplier in the Medicare program, the contractor shall deny or revoke its Medicare billing privileges using, respectively, § 424.530(a)(5)(ii) (denials) and § 424.535(a)(5)(ii) (revocations) as the basis.)
- Substance Abuse Facility

10.3 – Medicare Enrollment Forms – Information, Processing, and PECOS 2.0

(Rev. 12514; Issued: 02-22-24; Effective: 03-25-24; Implementation: 03-25-24)

Sections 10.3, 10.3.1, 10.3.2 and 10.3.3 of this chapter provide guidance and information regarding the processing of provider enrollment forms. They also include new verification and operational instructions pertaining to the implementation of PECOS 2.0. Upon the implementation of PECOS 2.0 (and except as stated otherwise), said instructions in sections 10.3

through 10.3.3 take precedence over all other contrary guidance in this chapter. The contractor shall not follow the PECOS 2.0 instructions in this chapter prior to the system's implementation (or, as applicable, before PECOS 2.0 has been updated to include a certain feature to which the instruction applies). For more detailed information concerning the contractor's logistical navigation of the PECOS 2.0 system, the contractor can consult the PECOS 2.0 "Knowledge Base" (available within PECOS) and other technical direction.

Section 10.3 discusses the basic processes, capabilities, and policies associated with PECOS 2.0. The contractor shall adhere to the instructions in 10.3 when processing the applications described in sections 10.3.1 through 10.3.3.

A. Basic Function

Except as otherwise specified by CMS, PECOS 2.0 automatically processes all web-based applications upon submission as well as all paper applications after the contractor performs intake actions (e.g., entering the paper-submitted data into PECOS). (This includes all CMS-855, CMS-20134, CMS-588, and CMS-460 forms, and irrespective of the type of enrollment transaction involved (e.g., initial applications, change requests.) In general, PECOS 2.0 will only halt the automated process: (a) for more complex application situations (e.g., changes of ownership); or (b) if the contractor must manually perform certain verification activities (e.g., review of adverse action documentation). Upon this stoppage:

(i) The application exits the automatic process and requires the contractor to manually intervene.

(ii) PECOS 2.0 creates a list that outlines the verifications/checks performed and when they occurred.

For web-based applications, providers and suppliers must upload all required documentation, submit all signatures, and pay an application fee or submit a hardship request before submitting the application. PECOS requires the application (including the Form CMS-588 and Form CMS-460) to be 100% complete before the provider/supplier submits it. This reduces the amount of development the contractor must undertake. In addition, PECOS notifies the contractor of any change in the status of an application, which helps expedite processing.

(Note that PECOS 2.0 will also conduct certain validations/checks for paper applications after the contractor completes its data entry of the provider's or supplier's application information.)

B. Important Aspects of PECOS 2.0

This subsection (B) discusses various aspects of PECOS 2.0's capabilities and other concepts and instructions related thereto. (For purposes of the remainder of section 10.3 and of section 10.3.1, the term "PECOS" means "PECOS 2.0" (although PECOS 2.0 will still occasionally be used) and the term "PECOS applications" means "web-based applications.")

1. Verification

Some of the Form CMS-855/20134 application data elements and other enrollment functions that will be part of PECOS's verification/operational capabilities are:

(i) Validation of Social Security Numbers (SSN) (though PECOS will not verify employer identification numbers (EIN) with the IRS)

(ii) Validation of National Provider Identifiers (NPI)

(iii) Performing Delivery Point Verification

(iv) Review of the Death Master File (DMF)

(v) Reviewing for Office of Inspector General (OIG) exclusions per the Medicare Exclusions Database (MED) (Note that if the System for Award Management (SAM) is not part of PECOS's or APS's verifications, the contractor must perform SAM reviews manually.)

(vi) Checking whether an active reenrollment bar exists. (PECOS maintains the reenrollment bar list. For each individual or entity added to an application, PECOS will perform a processing check.))

(vii) Inclusion of high-risk screening list and all other CMS generated lists (e.g., overpayments, affiliations, Medicaid terminations)

(viii) Facilitation and verification of application fee payment

(ix) Ordering site visit and fingerprinting

(x) Reviewing licensure status via APS. (Note that the contractor may rely on APS licensure verification in limited scenarios, including revalidation and some changes of information. See subsection (B)(8) below for more information on licensure.) However, the contractor must still manually check for certifications, such as for non-physician practitioners.

(xi) Criminal background (e.g., the contractor need not click into APS)

(xii) Complete automated processing of revalidation applications that do not include any changed information and the application is e-signed

(xiii) Excluding CMS Certification Numbers (CCNs) for certified providers/suppliers, generation and management of provider transaction access numbers (PTANs) as needed. (PECOS can allocate locality information as well as determine how many PTANs are required for the enrollment situation in question and the associated effective date(s). The contractor can make edits as warranted and consistent with CMS policy. The contractor shall ensure that: (1) any PECOS-established effective date for a PECOS-issued PTAN is consistent with CMS regulations and policy; and (2) all PECOS-generated PTANs were issued consistent with CMS policy.

Except as otherwise specified in current or future CMS guidance, the contractor must manually handle all other validation and processing activities not referenced in (i) through (xiii) above. As

previously indicated, and after performing validations, PECOS will identify for the contractor those data elements requiring manual intervention because the data element (e.g., EIN, certain adverse actions, legal business name, certifications) is not one that PECOS checks. Moreover, automatic processing only occurs with applications for which PECOS has not identified errors (e.g., additional screening needed, unverified addresses, etc.). If errors exist and/or the application cannot otherwise be automatically processed further, PECOS reverts to manual processing and notifies the contractor thereof.

If the contractor manually corrects a data element that PECOS could not validate, PECOS attempts to reverify said data; the contractor need not manually perform this task.

All required data verification checks must be documented in PECOS (though some of these will be automatically recorded in PECOS if the system itself verifies the particular data element).

2. Documentation

a. Basic Principle

As a general rule (and for both web and paper applications), the provider/supplier need not submit documentation unless either of the following instances applies:

i. All other means the contractor is authorized to use (per this chapter) for validating the information have been exhausted (e.g., licensure web sites, state board web sites, APS, etc.) AND the supplier has not previously submitted said documentation in PECOS 1.0 or 2.0 (e.g., as part of a prior revalidation); OR

ii. The provider/supplier is furnishing or changing data for which this chapter specifically and unequivocally requires the submission of documentation to validate (e.g., adverse legal action documentation per section 10.6.6) AND the supplier has not previously submitted said documentation in PECOS 1.0 or 2.0.

The above principle applies to all application types and transactions and notwithstanding any other instruction to the contrary in this chapter.

Note that documents that have been uploaded into PECOS 1.0 will be migrated to PECOS 2.0.

b. Operational Procedures When Documentation Is Required

i. PECOS Applications – As mentioned earlier, providers/suppliers must upload required documentation before submitting the application. However, because PECOS cannot "read" documents or verify their exact contents, the contractor shall manually review and confirm the type and contents of the submitted document. Once this confirmation occurs, the contractor need not reverify the document when subsequent applications are submitted unless information relative to that document has changed.

Except as stated in subsection (2)(a) above, a provider/supplier submitting a web application need not upload required documentation if it has previously submitted that document. The

provider/supplier will be able to see the document in question in its PECOS record and select and apply that document to its current application.

ii. Paper Applications - The provider/supplier shall mail, fax, or e-mail such documentation (e.g., organizational charts per Section 5 of the Form CMS-855A) with its application. The contractor shall upload received documentation into PECOS when processing the application; each document, however, must be separately uploaded (e.g., the Form CMS-855 CHOW application must be uploaded separately from the sales agreement). For paper applications (including initial enrollments), if the provider failed to submit required documentation, the contractor shall review the provider/supplier's enrollment record to see if the provider/supplier previously submitted the document with a prior application. If it was previously submitted, the contractor shall apply the document to the current application without developing for it with the provider/supplier. If it was not previously submitted, the contractor shall develop for it.

iii. Documentation Classification

When documentation is uploaded into PECOS by the provider/supplier (PECOS applications) or the contractor (paper applications), the contractor shall ensure that, as applicable:

- Each document is uploaded in the application section with which it is most closely associated (e.g., criminal conviction documentation in the final adverse action section; IDTF technician certifications in the IDTF section).

- If the provider/supplier submits one file containing different document types (e.g., a CP-575, an ownership chart), each document type within said file is separated and uploaded in its appropriate application section (per the prior bullet).

If the provider/supplier does not submit its documents consistent with the practices in the two above bullets, the contractor shall remedy the issue itself without requesting the provider/supplier to do so.

Note that each page within a multi-page document need not be separately and individually uploaded in its own file. The document and all of the pages therein can be uploaded as a single, combined file.

3. Correspondence and Coordination – PECOS Applications Only

a. General Concept

Except as otherwise permitted or specified in sections 10.3.1 through 10.3.3, the contractor shall send written enrollment-related correspondence to the provider/supplier via PECOS (hereafter sometimes referenced as the PECOS Communication Vehicle (PCV)). This includes most types of provider-contractor correspondence, such as emails, revalidation requests, development requests, approval letters, etc. PECOS will store all such correspondence. Certain written communications, however, cannot be made through the PCV at this point; in such situations, the contractor shall: (1) follow current procedures for sending/receiving such communications; and (2) manually upload a copy of the written correspondence to the related application in PECOS.

Note that the "PCV" is not a separate system or module but is simply a term to describe PECOS's automated processes for sending correspondence, automatically e-mailing letters and/or generating letters for mailing, etc. It is not an interface the contractor will go to review incoming correspondence.

b. Telephonic Communications

It is emphasized that nothing in sections 10.3 through 10.3.3 precludes the use of telephonic communication/development (including for web applications) with the provider/supplier if it is otherwise permitted under these sections. However, the contractor shall document such telephonic communications in PECOS' Application Timeline with the same data elements as those required under section 10.6.19(L) of this chapter.

4. Party Relationships

a. Consolidated Applications and National Entity Profiles

In PECOS 2.0, individuals and organizations will have National Entity Profiles (hereafter "Profile(s)" or "National Profile(s)") that are unique by legal name, tax identification number, and ownership. (This is similar to the associate profile in legacy PECOS, the difference being that an entity's ownership information and other data unique to that organization is shared at the National Profile level in PECOS 2.0.) A party's National Profile will show Medicare enrollment record(s) for each of their provider/supplier types (e.g., ABC, Inc. will have one National Profile that includes 3 separate Medicare enrollment records: one for its clinic/group, one for its durable medical equipment (DME) enrollment, and one for its IDTF enrollment). All such records will be grouped by provider/supplier type due to differences in data collection and/or processing requirements.

Under PECOS 2.0, a provider/supplier can submit one "consolidated application" per provider/supplier type; said application will be split such that it results in the submission of one application to each contractor jurisdiction per provider/supplier type group. Consider the following examples:

EXAMPLE A: A group practice exists in Nebraska, Iowa, and Missouri, all of which are in the same contractor jurisdiction. Here: (1) only one application is submitted to the contractor as opposed to three (one for each state); and (2) for inventory purposes, this will constitute only one application (not three). (Note that the contractor need only send one determination letter (approval, denial, etc.) to the group practice even though three states are involved. This is because only one application was submitted.)

EXAMPLE B: A group practice exists in Ohio, Pennsylvania, and West Virginia, each of which are in separate contractor jurisdictions. Here, the group may submit a consolidated application for all three enrollments, which PECOS would then split into three separate applications because there are three separate contractor jurisdictions. (In this example, the fact that there are three separate states involved is largely irrelevant for application submission purposes. The central consideration is the number of contractor jurisdictions.)

EXAMPLE C: An organization has a group practice and an IDTF in one contractor jurisdiction. The entity must submit two applications because the clinic and IDTF are two distinct provider/supplier types and the enrollments are therefore grouped separately.

(Regarding Example C, note that a physician/practitioner can change a specialty within its broad supplier type category via PECOS 2.0 (e.g., changing from a nurse practitioner to a physician assistant). However (and as with the aforementioned group-IDTF scenario), a physician cannot change his/her enrollment to that of an NPP, or vice versa, by this means absent a new enrollment.)

National Profile (or "global") data is only screened when changed. This means that global information is not rescreened each time the provider/supplier submits an application pertaining to an enrollment record under/within that National Profile. In a similar vein, though, changes to National Profile information (e.g., legal business names (LBN), ownership) made on a single application are applied to all of the provider/supplier's enrollments. That is, an authorized or delegated official can make changes to National Profile information for numerous and associated providers/suppliers at one time, whereas data changes that are specific to a unique enrollment only apply to that enrollment. An illustration follows:

EXAMPLE D: Suppose 20 separately enrolled IDTFs have four common owners: W, X, Y, and Z. W sells its 25 percent interest to V. Under PECOS, this change can be reported via a single/consolidated application submission. Twenty separate submissions are unnecessary. Now assume that two of these group practices are changing their respective addresses. Here, the entity must submit an application that indicates the two separate change requests because the practice location data is unique to each enrollment.

Once the consolidated application has been processed and finalized, PECOS creates/updates all applicable individual enrollment records as though a single application had been submitted for each.

Though providers/suppliers may submit consolidated applications that update multiple enrollments of the same provider/supplier type or grouping, they still remain free to submit separate/individual applications for each enrollment.

When the provider/supplier is making a National Profile level change and that profile has multiple enrollments, the provider/supplier must check the box in PECOS confirming that it understands that this change: (1) is related to the National Profile for (XYY) with (TIN 123); and (2) will accordingly update all of the provider's/supplier's other active Medicare enrollments within PECOS, regardless of what is shown on this particular application. (This is sometimes labeled an "indirect enrollment record update" (IERU). With a National Profile level change that revises an enrollment record, PECOS may notify the provider/supplier (typically the contact person or the correspondence address) of the IERU.

b. Consolidated Application Exceptions

(i) Providers/suppliers may only submit one type of provider enrollment transaction in a consolidated application (e.g., the provider cannot submit a consolidated application to reactivate

the billing privileges of three of its enrolled suppliers and to report a CHOW involving two of its enrolled providers).

(ii) Initial enrollments for certain provider/supplier types (e.g., certified providers) cannot be submitted via a consolidated application.

(iii) DMEPOS suppliers may be limited in the number of individual enrollments than can be included in a consolidated application.

(iv) Consolidated applications are only for PECOS applications, not paper applications; that is, consolidated applications cannot be submitted via paper

c. Associations

Certain types of relationships (excluding ownership and management relationships) between enrolled persons and organizations in PECOS are labeled "associations." (This is not to be confused with the definition of "affiliation" in § 424.502 for purposes of § 424.519.) These associations/relationships frequently involve: (1) reassignors and reassignees; (2) IDTFs and supervising physicians; and (3) CAH II relationships. In all cases, both parties in the relationship must be enrolled for the affiliation to exist. The purpose of the "association" designation is to give a formal label to certain types of relationships for PECOS purposes.

d. Signatures

i. General Policy - If an application is submitted that will create multiple enrollments or enrollment records and the signer is authorized to sign all enrollments, the application's signature will be automatically applied to the other enrollments.

ii. Authorized Officials

In a consolidated application with multiple enrollments, an authorized official can only sign for those enrollments for which he/she is on record as an authorized official. To illustrate, suppose a consolidated application contains enrollments in Pennsylvania and Ohio. Ms. Smith is listed as an authorized official for the Pennsylvania enrollment but not the Ohio enrollment. Ms. Smith therefore cannot serve as an authorized official for the latter.

e. Multiple Contractor Involvement

As already referenced, situations will arise where a submitted consolidated application that changes National Profile information impacts multiple contractors. (To illustrate, a provider that is enrolled in three contractor jurisdictions (X, Y, Z) might submit a consolidated application to change its DBA name.) The contractor shall observe that:

(i) Each contractor is responsible for processing the application it receives. It cannot rely on one of the other affected contractors to process all of the applications. Using our above illustration, X must process the application it received that is unique to its jurisdiction, Y must process the application specific to its jurisdiction, and so forth.

(ii) The term "processing" in (i) above includes, but it not limited to, verifying data, developing for clarifying information, approving/denying the application, etc. Thus, for example, Contractor X cannot rely exclusively on Contractor Y's verifications without attempting to validate the same data concerning the Contractor X application. Nor can Contractor Y use Contractor X's development letter to solicit the same data. Each application in this situation stands alone on its own merits and must be handled separately (e.g., each contractor must: (a) make its own determination (approval, denial, etc.) regarding the application it is processing; (b) send its own approval/denial/rejection letter; (c) develop for clarifying data pertaining to its application; and (d) process its application consistent with applicable timeliness requirements).

5. Letter Generation

i. Automation

Except as stated in subsection (5)(ii) below and as otherwise stated in this section 10.3, PECOS generates and sends to the provider/supplier all required letters (e.g., approval letters under section 10.7 et seq. of this chapter), though the contractor must manually select which letter must be sent. Note that each letter will have an issue date that signifies both (1) the date of the letter and (2) the date it is sent. The contractor shall treat this issue date as the "date of letter" and "date sent" for purposes of establishing applicable effective dates, the conclusion of development periods, and other timeframes that are based on the letter date or sent date.

ii. Exceptions to Automated Letter Process

There may be isolated instances when the contractor has to produce and/or send letters outside of PECOS. This could include, for example:

- PECOS can produce most letters requiring certified mail, but the contractor must manually print and send them
- The letter type is not available in PECOS

(Note that the contractor can always override a particular automated letter creation and upload/use a different letter.)

For letters the contractor must prepare and/or send outside of PECOS, the contractor shall ensure that: (1) the letter has an "issue date" consistent with subsection (5)(i) above; and (2) it uploads a copy of the letter to PECOS. Except for certified letters (which must be mailed via hard-copy), the contractor may send the letter via mail, e-mail, fax, or the PCV, although the PCV is very highly preferred if the printed letter can be uploaded into PECOS and sent via this means.

The "date of the letter" is the date on which the letter was created. The "issue date" is the date on which the letter was sent. For letters that PECOS sends (see subsection (5)(i) above), the letter and issue dates will be the same. For the letters discussed in subsection (5)(ii), however, they may be different (i.e., the contractor may send the letter the day after it is created).

iii. Additional Information

- Editing - If the contractor must edit a letter after it has been sent, the contractor shall (a) edit it outside of PECOS and (b) upload it consistent with the document upload instructions described in this chapter and other CMS guidance.
- Verbiage Insertion – Any language the contractor must insert into a letter shall be entered using the language insertion feature in the letter module.
- Outside Letter - If CMS instructs the contractor to submit a letter that is typically not generated by PECOS (e.g., an educational letter to supplement an approval letter), the contractor shall create the letter outside of PECOS and upload it to the appropriate location.
- All opt-out letters (e.g., approval, denial) shall be created outside of PECOS.

6. Site Visits and Application Fees

a. Site Visits (SVs) -

i. General Principle

All SVs are ordered through PECOS, and all SV results (with photos) are entered/uploaded into said system. The National SV Contractor(s): (i) completes SV requests directly in PECOS; or (ii) receives the request from PECOS and sends the full SV record back to PECOS from its system when complete. They either are ordered for and attached to the relevant application or they occur ad-hoc. However, the contractor must still review the site visit results and indicate pass/fail, consistent with existing instructions.

PECOS can identify a completed/passed site visit within the previous 12 months so that a new site visit is unnecessary.

ii. Ordering

- PECOS Applications – PECOS will automatically order a site visit (if one is required) only in the following situations:

  (A) An initial application
  (B) Excluding certified providers/suppliers, a change of information or revalidation application if the provider/supplier is currently in the high or moderate screening level and the practice location in question has not passed a site visit within the previous 12 months.

Notwithstanding the foregoing, the contractor can manually intervene to postpone or cancel this site visit if warranted under the circumstances (and consistent with the instructions in this chapter).

For all other situations not referenced in subsection (ii)(A) and (B) above, the contractor must manually order the site visit.

- Paper Applications – The contractor must manually order the site visit if one is required.

b. Application Fees

Application fees can be combined if multiple enrollment records are implicated by the submission (e.g., consolidated application), but each application still requires a separate fee. To illustrate, suppose an entity is enrolling 5 different IDTFs, and the fee amount is $631 per IDTF. The provider can submit separate $631 fees or can combine them into a single $3,155 payment. In the case of hardship waivers, however, 5 separate hardship waivers – one for each enrollment – must be submitted; they cannot be combined into one waiver request.

In addition:

- If the provider/supplier is submitting an application requiring a fee, PECOS will automatically indicate the appropriate fee amount.
- For consolidated applications in which multiple fees are required, the provider/supplier can remove an enrollment record from its submission (e.g., the provider wishes to rescind its prospective enrollment because the fee amount is excessive), PECOS will correspondingly reduce the required total fee amount. If the provider/supplier does this after it has paid the fee, it can request a refund via the instructions in this chapter.
- If the provider/supplier makes an "out of bound" fee payment (that is, a payment outside of the application submission), the provider/supplier can apply the fee(s) to its application by entering Pay.gov tracking IDs.
- Providers/suppliers can request hardship waivers directly via PECOS.
- Fee refunds shall continue to be processed consistent with existing instructions.

7. Application Re-Routing and Returns

For web applications incorrectly sent to the contractor, the latter can re-route the application to the correct contractor via PECOS. For paper applications incorrectly sent to the contractor (and unless otherwise stated in this chapter or in another CMS directive), the contractor may return the application per 42 CFR § 424.526 without completing application intake.

PECOS cannot independently determine whether an application should be returned (e.g., initial Form CMS-855A application submitted more than 180 days prior to the effective date). The contractor must make this assessment.

8. Licensure

As already mentioned, APS will present to the contractor its review of the provider/supplier's licensure status. In some cases, however, the contractor will have to also manually verify the provider/supplier's licensure using an original source, such as a state licensing board website. In this regard, the contractor shall adhere to the following:

- Applications Other Than Initial Enrollments and Reactivations – The contractor need not review licensure original sources if all three of the following requirements are met: (1) all of the licensure information on the application (regardless of the data's materiality) matches that shown in APS (e.g., same name, active status); (2) the license contains no restrictions or

qualifiers insofar as the contractor can determine from the application and the APS review; and (3) it is otherwise clear to the contractor that the provider/supplier is appropriately licensed.

- Applications Other Than Initial Enrollments and Reactivations -- If any of the three criteria in the previous bullet are not met OR the contractor is in any way uncertain as to whether the provider/supplier is appropriately licensed, the contractor shall review an original source. (Note that the data match between APS and that on the application must be 100%, regardless of the materiality of the data or the extent of the discrepancy. Even if there is a slight difference in the individual's name, an original source must be reviewed.)
- Initial Enrollment Applications and Reactivations – The contractor shall use an original source to verify licensure notwithstanding the APS results.

In all cases, the contractor shall ensure that all licensure reviews required under this chapter are performed. If licensure is not required for the provider/supplier, the contractor shall treat this in PECOS as a situation where the provider/supplier passed the licensure review.

APS will display all licensure information relevant to the enrollment that the contractor is processing. It is possible, though, that licensure data may appear involving enrollments and parties other than those under review. The contractor need only take action based on licenses related to the specific enrollment being processed.

10. Development

Should a PECOS or paper application require development --- and unless this chapter permits telephonic development for the specific matter/info in question – the contractor shall issue the development request via PECOS's RFI functionality.

C. Impact on Application Transaction Types and Formats

This subsection (C) addresses certain PECOS functions, capabilities, and policies regarding specific enrollment-related transactions, application types, and application formats (e.g., web, paper), including associated signature requirements.

1. Revalidations

Except as otherwise described in this chapter, PECOS automatically handles revalidation requests, tracking, and correspondence. It also prevents the submission of web applications outside of the revalidation window. PECOS establishes timeframes and then queues mailings based on revalidation history and enrollment dates, although CMS can modify timeframes and request off-cycle revalidations at any time. Failure to respond to a revalidation request would result in, as applicable to the situation, an automatic pend, deactivation, etc.

2. Form CMS-588/Electronic Funds Transfer (EFT)/Multi-Carrier System (MCS)/Special Payment Addresses

Under PECOS:

a. All EFT information (including bank account data) must be entered, processed, and stored in PECOS. The contractor shall no longer use the shared system to enter bank information.

b. All MCS transactions related to provider enrollment shall be entered into and updated through PECOS. This includes provider codes, options, do not forward (DNF), effective periods, linkages to PTANs, banking, etc.

c. The contractor shall continue to follow the instructions in section 10.6.23 of this chapter 10.

d. Notwithstanding any other instruction in this subsection (C)(2), the contractor need not undertake pre-notification review of an EFT account if the latter already exists under the provider/supplier's TIN and the provider/supplier is merely adding it to a new enrollment under that same TIN.

e. EFT Processing Checks – The contractor shall document in PECOS: (1) its verification that the banking information is complete and correct; and (2) any required verification with the authorized official, delegated official, contact person, or the individual physician/practitioner.

3. Reassignments

a. General Principle

As stated earlier, PECOS automatically processes reassignments received online; this includes preventing a supplier from reassigning benefits to an ineligible party.

b. Location Group Assignment – When establishing a reassignment for PECOS applications, the provider/supplier must determine and select which "Locations Groups" of the clinic/group at which the provider/supplier will be performing services (i.e., billing from); this will help support proper PTAN assignment. For paper applications, however, the contractor must make the aforementioned determination based strictly on the information submitted (i.e., without development on this specific issue); such data could include, for instance, the reported primary and secondary practice locations and information that the group submitted.

4. Form CMS-855O and Form CMS-855I Conversions and Terminations

If a supplier who is enrolled via the Form CMS-855I or Form CMS-855O submits, respectively, a web Form CMS-855O or a web Form CMS-855I to change his/her enrollment, the supplier need not terminate his/her prior enrollment. PECOS 2.0 performs this function. (This only applies to web applications.)

5. Certified Provider/Supplier Application – State Involvement

The contractor cannot send/email documents, approval recommendation packages, etc., to the states, accrediting organizations (AO), and SOG Locations via PECOS. Said materials shall continue to be sent via the Box system consistent with existing policy. (States, AOs, and the SOG Locations do not have access to PECOS.) However, certain other components of the survey/certification process are handled/managed through PECOS. This includes, but is not

limited to: (1) tracking applications sent to the state; and (2) storing and/or generating approval letters to and from the state.

6. Appeals and Rebuttals

Appeals and rebuttals are stored in PECOS. The contractor can process the appeal/rebuttal via PECOS and, as applicable, revise the enrollment record based on the appeal/rebuttal decision.

If the contractor receives an appeal that should have instead been sent to CMS, the contractor shall enter the appeals data into PECOS and forward the appeal to CMS consistent with existing instructions.

The provider cannot submit appeals and rebuttals via PECOS.

7. Web vs. Paper Applications

a. Paper Applications

The contractor shall: (i) enter into PECOS the basic information about a received application (a process called "intake") such that PECOS can send a confirmation correspondence and, if applicable, associate the application with an existing enrollment; and (ii) upload into PECOS any images of the paper application and/or all supporting documentation. Note that these tasks do not constitute the creation of a web-based application. Providers/suppliers submitting paper applications:

- Must use fillable versions thereof, meaning the information cannot be handwritten. (This includes situations where the provider/supplier is submitting an application page pursuant to a development request; the page must be from a fillable application. If the provider/supplier submits a handwritten application or page, the contractor shall develop for a fillable one rather than return the application, though intake shall still be completed.) Note that this requirement applies:
    - To all CMS applications for which a fillable version thereof is available (e.g., CMS-588), including situations where the provider must submit corrected/revised pages of the application pursuant to a development request
    - Only to CMS form applications and not to (i) supporting documentation or (ii) responses to development requests not involving the submission of corrected/revised application pages (e.g., supporting documentation need not be in a fillable format).
- Must submit the application via mail
- Will receive correspondence via the PCV. (However, the provider/supplier must still submit any additional materials related to its application (e.g., application pages, supporting documents) via paper.)

One hundred percent (100%) of paper applications and appeals/rebuttals/CAPs (regardless of type (A/B/I) or transaction (initial/change of information)) must be entered into PECOS within

two business days of receipt. This includes uploading all hard copies of received applications/appeals/rebuttals and attachments into PECOS.

The minimum data elements that must be part of the contractor's "intake" are:

- Type of document (application or supporting document)
- Date of Receipt
- Method of receipt (mail, email, fax, upload)
- Application type
- Submission reason (initial, change, revalidation)
- State
- Name
- TIN
- DCN

(Regarding the intake of attachments and supporting documentation, the contractor need not separate the documents (or pages of documents) within the 2-business day period if they are submitted in bulk. Only the bulk document need be uploaded.)

At a minimum, the contractor shall upload the image of the entire application submission package (i.e., the application and all supporting documentation) as a single document at application intake, though the contractor may upload each document separately (i.e., application, EFT, PAR, license, etc.). The effective date of the document upload/received date is the same as the date of contractor entry/intake.

If the application fails to include all the information needed to perform intake, the application shall not be considered a submission. No action is required in PECOS, and the contractor shall handle the document consistent with the document retention polices in the contractor's internal document control system.

b. Signatures

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options, such as Adobe) are acceptable. For web applications, electronic signatures (which can be uploaded) are required.

Given the advent of PECOS 2.0, certain previous certification statement instructions pertaining to Internet-based PECOS applications are no longer applicable (e.g., the ability to submit paper certification statements after submission). In addition, because certification statements must be signed before the application is submitted, there will be much less need for the contractor to develop for them. Nevertheless, the contractor must still verify signatures consistent with the instructions in this chapter; this includes documenting the validity of an uploaded signature via the PECOS signature upload processing check.

c. Web and Paper Usage

A provider/supplier that submits a web application is not prohibited from submitting future enrollment applications via paper. Likewise, a provider/supplier that submitted its initial application via paper may always submit future applications via web. In each scenario, the contractor shall follow the instructions in this section 10.3 et seq. that are applicable to the type of application (PECOS vs. paper) that was submitted. For instance, suppose a provider previously submitted its initial application via web and now submits a paper change of information request. The contractor shall upload the submission into PECOS, develop for any missing or unsigned/undated certification statement, avail itself of any processing alternatives that are applicable to paper applications, etc.

Notwithstanding the above, when the provider/supplier submits a web application, any updates to the application---such as, for example, pursuant to a development request or the submission of additional documentation---before the application is processed to conclusion (e.g., approved, denied, rejected) must be via PECOS. The provider/supplier cannot submit its update via paper.

d. Documents Received Outside of Application Submissions

(1) General Guidance - The contractor may receive documents unrelated to a particular application submission, appeal, or rebuttal. This could include, for example, a W-9, a new CLIA certificate, an updated license, a surety bond cancellation notice, an FDA certification, a CMS-460, insurance documents, etc. These documents must be uploaded into PECOS consistent with the instructions in this section 10.3 et al. and the timeframe described in section 10.3(C)(7)(a).

(2) Special Situations

- For submitted stand-alone paper Form CMS-588s and CMS-460s, the contractor shall intake the document as the application type that corresponds to the enrollment record that will be impacted by the submission (e.g., Form CMS-855I, CMS-855A).
- When paper Form CMS-855I and Form CMS-855B applications are submitted concurrently pursuant to a reassignment, the contractor shall intake the two applications separately and individually.

8. Business and Practice Location Names/Assignments

The "DBA name" and "Other name" data fields are not required in PECOS. If the provider/supplier nevertheless submits this data, the other name/DBA name should be at the organization level while the name at the practice location level should be, in effect, the name on the location's "front door."

In reassignment situations, providers/suppliers can assign in PECOS multiple primary practice locations (PPLs), one PPL, or none at all. If the provider/supplier wishes to add, change, or remove a PPL designation, no signature is necessary.

9. Contact Persons/Parties for PECOS Applications

(The instructions in this subsection (C)(9) supersede those in section 10.6.9 of this chapter with respect to PECOS applications.)

For PECOS applications only, there are three types of contacts:

a. "Enrollment Representatives" (ER): These are persons whom the provider/supplier may designate in its PECOS application submission as having the authority to contact the contractor about the provider/supplier's enrollment once the provider/supplier is enrolled. ERs will not be contacted by CMS (except in response to an ER's inquiry) either by mail, e-mail, telephone, the PCV, etc., and their contact information will not be part of the official application or be shown on the PECOS screens. Moreover, the provider/supplier need not have any ERs if it so chooses.

b. "Application Contacts" (AC): These individuals are somewhat akin to the longstanding category of "contact persons." They are: (1) optional for the provider/supplier; (2) valid contacts only for the application in question; and (3) neither added to the formal enrollment record nor contacted by CMS on any matter other than the application. If the provider/supplier chooses to list ACs, it must also designate a "Primary AC" from this list; this person will receive any physical letters the contractor sends while the other ACs will receive e-mails.

(In addition:

- If the provider/supplier submits a paper application -- which does not differentiate between an ER and an AC -- the contractor can leave the ER field in PECOS blank.
- If a provider/supplier submitting a PECOS application chooses not to have an ER, the contractor shall follow current guidance regarding with whom it can discuss post-enrollment matters if no contact person is listed (e.g., with authorized and delegated officials).
- If an ER requests information regarding a pending application, the contractor shall follow current guidance regarding with whom it can discuss matters concerning pending applications.)

c. Correspondence Address – This is the same address that has long been used for provider enrollment applications. Its meaning and use will not change with the advent of PECOS 2.0.

Except as otherwise stated in subsections 9(a) through (c) above, the contractor shall:

- Continue to use the correspondence address as normal
- Use ACs (as opposed to ERs) for communications regarding the application in question
- Respond to any ER questions if they are related to a matter outside of the contractor's current processing of an application. (If the question is not related to the present application, the contractor shall notify the ER that it cannot respond to the query.)

10. Contacting CMS

For matters that require CMS/PEOG BFL input or decision --- and unless otherwise instructed in this chapter --- the contractor shall request CMS 'review' using the 'assignment' functionality in PECOS. The contractor shall include the pertinent data/question/note in the section provided

during the assignment/review process and attach any pertinent documentation (e.g., review of adverse legal action documentation).

D. Additional Guidance

1. Revocations – Except as otherwise instructed by CMS, all CMS-directed revocations will be processed in their entirety by CMS within PECOS.

2. Screening Levels – PECOS will automatically set the provider/supplier's correct screening level. Should the screening level nonetheless need to be adjusted, the contractor shall seek CMS approval via PECOS.

E. Chapter 10 Applicability

1. Except as otherwise noted, the PECOS instructions in section 10.3 et seq. take precedence over all others in this chapter pertaining to the same issue or operational procedure.

2. Certain existing instructions in chapter 10 (including those in section 10.3 et seq.) require (or, in a few cases, do not require) particular data elements on the application to be completed. The contractor shall observe that PECOS may or may not mandate that the provider complete particular data fields before proceeding to succeeding fields. This might render moot some of the processing alternatives and exemptions discussed in this chapter. The contractor may therefore disregard those alternatives/exemptions that are immaterial to the situation.

3. Certain existing data elements on the applications and which are listed in this chapter 10 may not be reflected in PECOS. In such cases, the contractor may disregard the instructions in this chapter pertaining thereto.

4. Except as otherwise stated, the term "PECOS" in this chapter refers to PECOS 2.0 and incorporates the phrase "Internet-based PECOS."

5. All instances in section 10.3 et seq. in which the contractor must now document a data element verification or a telephonic communication in PECOS rather than in the provider file shall include the applicable information required under section 10.6.19(L). Note that the contractor may document such communications in PECOS even for paper applications.

6. In cases where use of the PCV is not required but permissible, the contractor is very strongly encouraged to utilize that mechanism.

7. All clock stoppages otherwise permitted under this chapter can be applied with respect to the policies in this section 10.3.

10.3.1 - CMS-855 Series Enrollment Forms: Information and Processing

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Each CMS-855 Series form is used to enroll a specific provider or supplier type for a specific purpose. This section 10.3.1 et seq, discusses various data elements on the Form CMS-855 applications. Not every data element on the forms is discussed in section 10.3.1 et seq.; only those elements that warrant additional instructions are mentioned. Except as stated otherwise, the instructions in 10.3.1 et seq.: (1) support and do not supplant the instructions and information within the applications themselves; and (2) do not supersede federal regulations concerning Medicare provider screening and enrollment.

Regardless of whether the data element in question is discussed in this section, the contractor shall adhere to all instructions in this chapter 10 in terms of the collection, processing, and verification of all data elements on the Form CMS-855 applications, unless stated otherwise in this chapter or in another CMS directive. (This includes processing alternatives and clock stoppages.) CMS reiterates, however, that in the event of any inconsistency or conflicting direction between an instruction in section 10.3.1 et seq. and an instruction in section 10.3, the latter takes precedence; this includes, for example, guidance pertaining to: (1) enrollment data submission, acquisition, development, processing, and validation; and (2) communicating with the provider/supplier).

For purposes of these sections, and unless otherwise indicated, the term "approval" includes recommendations for approval.

In addition:

- The contractor is advised that the Form CMS-855 section numbers outlined in this section 10.3 et seq. may not be reflected (or may be different) in PECOS 2.0. However, the instructions for each denoted application section in 10.3 et seq. apply to the concomitant enrollment information in PECOS 2.0. For instance, if certain practice location information in Section 4 of the current Form CMS-855B is captured in a different section of PECOS 2.0, the contractor shall still follow the Section 4 practice location instructions. Chapter 10 will eventually be restructured to more closely align with the process of a provider/supplier's completion of a PECOS application.
- In situations where the contractor may capture or develop for information via several means, one of which is the PCV, the contractor is strongly encouraged to use the latter as its information acquisition or development vehicle.

If the contractor needs additional information concerning the forms or the processing thereof, it may contact its PEOG BFL.

10.3.1.1 – Form CMS-855A – Medicare Enrollment Application for Institutional Providers

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Institutional providers (e.g., hospitals) that will furnish Medicare Part A services to beneficiaries must complete the Form CMS-855A. For purposes of this section 10.3.1.1 et seq. (and except as otherwise stated), the term "provider" includes certified suppliers that must complete the Form CMS-855B.

10.3.1.1.1 – Section 1 (Basic Information) - Form CMS-855A
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In Section 1, the provider indicates the reason for submittal of the application. Unless otherwise stated in this chapter or in another CMS directive, or as permitted by PECOS, the provider can only check one reason for submittal.

With the exception of (1) the voluntary termination checkbox and (2) the effective date of termination---and except as stated in section 10.6.1.3 of this chapter---any blank data/checkboxes in the Basic Information section can be verified through any means (e.g., e-mail, the PCV, telephone, fax).

10.3.1.1.2 – Section 2 (Identifying Information) - Form CMS-855A
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Licenses, Certification, and Accreditation Information

The extent to which the provider must furnish licensure, certification, or accreditation information in Section 2 depends upon the provider type involved. Requirements vary by provider type and by location; for instance, some states may require a particular provider to be "certified" but not "licensed," or vice versa.

The only licenses the provider must submit with the application are those required by Medicare or the state to function as the provider type in question. Licenses and permits that are not of a medical nature are not required. If the contractor knows that a particular state does not require licensure/certification and the "Not Applicable" boxes in the Identifying Information section of the Form CMS-855A are not checked, no further development is needed.

Regarding accreditation under the Identifying Information section of the Form CMS-855A, if the provider checks "Yes," the contractor shall ensure that the listed accrediting body is one that CMS recognizes in lieu of a state survey or other certification for the provider type in question. If CMS does not recognize the accrediting body, the contractor shall advise the provider accordingly. (Note, however, that the provider may not intend to use the listed accreditation in lieu of the state survey; it may have merely furnished the accrediting body in response to the question.)

Documents that are attainable only after state surveys or accreditation need not be included as part of the application, and the provider need not furnish the data requested in the Identifying Information section of the Form CMS-855A. However, the provider shall furnish those documents it can submit prior to the survey/accreditation. The contractor shall include all submitted licenses, certifications, and accreditations in the enrollment package it sends to the state.

(See section 10.3.1.1.14 of this chapter for information about processing alternatives involving licensure submissions.)

B. Correspondence Address and Telephone Number

The correspondence address must be one at which the contractor can directly contact the provider to resolve any issues once the provider is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, chain home office, or the provider's representative (e.g., attorney, financial advisor); however, it can be a P.O. Box. The contractor need not verify the correspondence address.

The provider may list any telephone number it wishes as the correspondence phone number. The number need not link to the listed correspondence address. If the provider fails to list a correspondence telephone number and it is required for the application submission, the contractor shall develop for this information via the procedures outlined in this chapter (e.g., the PCV for PECOS applications). The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the provider. The contractor is not required to verify the telephone number.

Unless CMS specifies otherwise, any change in the provider's phone number or address that the provider did not cause (i.e., area code change, municipality renames the provider's street) must still be updated via the Form CMS-855A.

C. E-mail Addresses

Regarding the correspondence e-mail address in the Correspondence Address and Telephone Number Section of the Form CMS-855A, this e-mail address can be a generic one. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the provider.

D. Medical Record Correspondence (MRC) Address

This is the address at which MRC (such as medical record review requests) is sent to the provider. In collecting and processing this data, the contractor shall follow the same basic instructions as those concerning the correspondence address outlined in sections 10.3.1.1.2(B) and (C) above (e.g., acceptance of generic e-mail address and telephone number; cannot be billing agency address; etc.). All processing alternatives that apply to correspondence address data also apply to MRC information.

E. Other Identifying Information

Other than the tax identification number (TIN) and legal business name (LBN), the contractor may capture all information in the Correspondence Address and Telephone Number Section of the Form CMS-855A by telephone, the PCV (if applicable), e-mail, fax, or a review of the provider's web site.

10.3.1.1.3 – Section 3 (Final Adverse Legal Actions/Convictions) - Form CMS-855A

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

See section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).

10.3.1.1.4 – Section 4 (Practice Location Information) - Form CMS-855A

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. General Background

Unless CMS specifies otherwise, any change in the provider's phone number or address that the provider did not cause (i.e., area code change, municipality renames the provider's street) must still be updated via the Form CMS-855.

Any provider submitting a Form CMS-855A application must submit the 9-digit ZIP Code for each practice location listed.

(For paper applications only - If a practice location (e.g., hospital unit) has a CMS Certification Number (CCN) that is in any way different from that of the main provider, the contractor shall create a separate enrollment record in PECOS for that location. (This does not apply, however, to home health agency (HHA) branches, outpatient physical therapy/outpatient speech pathology (OPT/OSP) extension sites, and transplant centers.))

The contractor shall verify that the practice locations listed on the application actually exist and are valid addresses with the United States Postal Service (USPS). PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS Store, mailboxes, etc.), or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry.

The contractor need not verify the provider's telephone number listed on the application, though the provider must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

If the contractor cannot verify the provider's address, the contractor shall request clarifying information from the provider. If the provider states that the facility is not yet operational, the contractor may continue processing the application. However, it shall indicate in its recommendation letter that the address of the facility could not be verified. For purposes of PECOS entry, the contractor can temporarily use the date the certification statement was signed as the effective date.

(For paper applications only: In Section 4A of the Form CMS-855A, if the "type of practice location" checkbox is blank, the contractor can confirm the information via the PCV, e-mail, or fax.)

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the provider's "special payment" address (in the Practice Location Information section of the Form CMS-855A) or EFT information has changed. The provider should submit a Form CMS-855A to change this address; if the provider does not have an established enrollment record in PECOS, it must complete an entire Form CMS-855A and Form CMS-588.

If the provider is closing its business and has a termination date, the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the provider to complete the "special payment" address section of the Form CMS-855A and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so or unless an instruction in this chapter states otherwise. (See section 10.6.1.3(C)(5) of this chapter for additional information.)

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the provider has completed and signed the Form CMS-588 and shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

If an enrolled provider that currently receives paper checks submits a Form CMS-855A change request (no matter what the change involves), the provider must also submit a Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT; once a provider changes its method of payment from paper checks to EFT, it must continue using EFT. A provider cannot switch from EFT to paper checks. The contractor shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

The "special payment" address may only be one of the following:

(i) One of the provider's practice locations

(ii) A P.O. Box

(iii) The provider's billing agent. (The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.)

(iv) The chain home office address. Per Pub.100-04, chapter 1, section 30.2, a chain organization may have payments to its providers sent to the chain home office. The provider must list the chain home office's LBN on the Form CMS-588. The TIN on the Form CMS-588 should be that of the provider.

(v) Correspondence address

(vi) A lockbox. (The contractor shall request additional information if it has any reason to suspect that the arrangement, at least with respect to any special payments that might be made, may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.)

D. Out-of-State Practice Locations

If a provider is adding a practice location in another state that is within the contractor's jurisdiction -- and, for PECOS applications, to the extent PECOS permits it --- a separate, initial Form CMS-855A enrollment application is not required if all of the following conditions are met:

(i) The location is not part of a separate organization (e.g., a separate corporation, partnership);

(ii) The location does not have a separate TIN and LBN;

(iii) The state in which the new location is being added does not require the location to be surveyed;

(iv) Neither the new location nor its owner is required to sign a separate provider agreement; and

(v) The provider type in question is not required to separately enroll each of its practice locations. (For example, a federally qualified health center (FQHC) would not meet this criterion because FQHCs must separately enroll each location.)

Consider the following examples:

EXAMPLE 1 - The contractor's jurisdiction consists of States X, Y and Z. Jones Health Care Facility (JHCF), Inc. is enrolled in State X with 3 sites. It wants to add a fourth site in State Y. The new site will be under JHCF, Inc. JHCF will not be establishing a separate corporation, LBN, or TIN for the site, and - per the state and CMS policy - a separate survey and provider agreement are not necessary; moreover, CMS policy does not require this provider type to separately enroll each of its practice locations. Since all 5 conditions above are met, JHCF, Inc. can add the fourth location via a change of information request, rather than an initial application. The change request must include all information relevant to the new location (e.g., licensure, new managing employees). (For paper applications only---and to the extent required---the contractor shall create a separate PECOS enrollment record for the State Y location.)

EXAMPLE 2 - The contractor's jurisdiction consists of States X, Y and Z. JHCF, Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y but under a newly created, separate legal entity - JHCF, LP. The fourth location must be enrolled via a separate, initial Form CMS-855A.

EXAMPLE 3 - The contractor's jurisdiction consists of States X, Y and Z. Jones Health Services (JHS), Inc., is enrolled in State X with 1 location. It wants to add a second location in State Z under JHS, Inc. However, it has been determined that a separate survey and certification

of the new location are required. A separate, initial Form CMS-855A for the new location is required.

E. Additional Practice Location Information

1. Special Payments

In the "Practice Location Information/Where Do You Want Remittance Notices or Special Payments Sent" section, if neither box is checked and no address is furnished, the contractor can contact the provider by telephone, e-mail, the PCV, or fax to confirm the provider's intentions. If the provider replies that the "special payments" address is the same as the practice location, no further development is needed. If, however, the provider wants payments sent to a different address, the provider must furnish this address in the "Where Do You Want Remittance Notices or Special Payments Sent" section of the Form CMS-855A.

Note that the provider/supplier can only have one special payment address per enrollment for both PECOS and paper applications. See section 10.3(C)(2)(b) for more information.

2. Base of Operations

In the Practice Location Information/Base of Operations section, if the "Check here" box is not checked and no address is furnished, the contractor can contact the provider by telephone, e-mail, the PCV, or fax to confirm the provider's intentions. If the provider replies that the base of operations address is the same as the practice location, no further development is needed. If the provider indicates that the base of operations is at a different location, the provider must furnish this address in the Base of Operations section of the Form CMS-855A.

3. Vehicle Information

In the Practice Location Information/Vehicle Information section, if the vehicle certificates are furnished but the applicable Form CMS-855A sections are blank, the contractor can verify via telephone, the PCV, e-mail, or fax that said vehicles are the only ones the provider has.

4. Primary Practice Location (PPL) Checkboxes

The provider must identify one – but no more than one – of the practice locations it lists in Section 4(A) as its PPL. If the provider identifies multiple PPLs or no PPLs, the contractor shall develop for additional information/clarification consistent with the instructions in Chapter 10. If the provider lists multiple practice locations, identifies one of them (e.g., Location A) as its PPL, and fails to check the PPL boxes for the other listed locations (Locations B, C, and D), the contractor can assume --- absent evidence to the contrary -- that Location A is the PPL and need not require the provider to check "No" for the PPL checkboxes for Locations B, C, and D.

5. Date First Patient Seen

For each practice location listed in Section 4(A), the provider must identify the date (month, day, and year) on which the first patient was or will be seen. If the provider fails to submit this data, the contractor shall develop for it consistent with the procedures in this chapter.

6. Medical Record Storage

In Section 4(C)(2), the provider must check whether it stores its patient medical records electronically and, if it checks "Yes," identify the service used to store these records. In the latter case, an actual website need not be disclosed. Only a general reference to the type of electronic storage is required (e.g., in-house software program, online service, vendor, etc.). It lies within the contractor's discretion to determine whether the description – which, again, need only be general in nature – adequately identifies the type of electronic service; if an inadequate description is furnished, the contractor shall develop for it consistent with the procedures in this chapter. Moreover, if a website is listed, the contractor need not access it to verify that the link is indeed where the records are stored.

7. Provider-Based

If the provider checks the "Outpatient Provider-Based Department" (PBD) box in Section 4(A), it must check one of the seven succeeding checkboxes that outlines the type of PBD involved. Except if CMS directs otherwise, the contractor need not verify any of the furnished PBD data in Section 4(A), including whether the department is indeed a PBD or the type of PBD involved. In addition, even if the contractor knows the department is provider-based, the provider need not check that it is a PBD. Only if the provider checks the PBD checkbox must it also identify the type.

10.3.1.1.5 – Sections 5 and 6 (Ownership Interest and/or Managing Control Information) - Form CMS-855A

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

See section 10.6.7 et seq. of this chapter for information concerning owning and managing individuals and organizations.

Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.7 (e.g., communicating with the provider via the PCV).

10.3.1.1.6 – Section 7 (Chain Home Office Information) - Form CMS-855A

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

If the provider is part of a chain organization, it must complete the Chain Home Office Information section of the Form CMS-855A with information about the chain home office. Under 42 CFR § 421.404, a "home office" is the entity that provides centralized management and administrative services to the providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services. Other definitions relevant to chain organizations (and which are in § 421.404) include:

- Chain provider - A group of two or more providers under common ownership or control.

- Common control - Exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.

- Common ownership – Exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.

The contractor shall not delay its processing of the provider's application while awaiting the issuance of a chain home office number (i.e., a determination as to whether a set of entities qualifies as a chain organization). Such an issuance/determination is not required for a recommendation for approval.

If all of the Chain Home Office Information section is blank (including the check box in this section), no additional development is necessary. If the provider indicates that it is part of a chain but the checkboxes in the Chain Home Office Information section are blank, the contractor can verify the type of transaction involved via the PCV, e-mail, or fax.

If a chain organization listed in Section 7 also serves as the provider's billing agent, the chain must also be reported in the Billing Agency section of the Form CMS-855A.

The chain home office administrator (CHOA) must be listed as an owning and/or managing individual in Section 6 and all final adverse action data must be disclosed. (For purposes of provider enrollment, a CHOA is deemed to have managing control over the provider.) If the CHOA reported in Section 7 is listed with complete information in Section 6 (e.g., the individual's Social Security Number (SSN) is disclosed in Section 6), only the individual's first and last name need be listed in Section 7.

A chain home office must be listed as an owning and/or managing organization in Section 5 and all final adverse action data must be disclosed. (For purposes of provider enrollment, a chain home office automatically qualifies as an owning/managing organization.) If the entity is reported with complete information in Section 5, its legal business name is the only data element that must be reported in Section 7. (If blank, the contractor may develop for the cost report date, the home office's contractor, and the chain number by telephone, e-mail, the PCV, or fax.)

Note that an NPI is typically not required for a chain home office.

If blank, the following data elements can be collected by telephone, e-mail, the PCV, or fax: (i) Type of Action this Provider is Reporting; (ii) Type of Business Structure of the Chain Home Office; and (iii) the Provider's Affiliation to the Chain Home Office).

For more information on chain organizations, refer to:

- Pub. 100-04, chapter 1, sections 20.3 through 20.3.6

- 42 CFR § 421.404

- CMS change request 5720

10.3.1.1.7 – Section 8 (Billing Agency Information) - Form CMS-855A
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Billing Agency Information section of the Form CMS-855A, see section 10.6.8 of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.8.)

If the chain organization listed in Section 7 of the Form CMS-855A also serves as the provider's billing agent, the chain must be listed in Section 8 as well.

If the telephone number is blank, the contractor may verify it with the provider via telephone, the PCV, e-mail, or fax.

If all of the Billing Agency Information section is blank (including the check box), no additional development is necessary.

10.3.1.1.8 – Section 12 (Special Requirements for Home Health Agencies) - Form CMS-855A
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Special Requirements for Home Health Agencies section of the Form CMS-855A, see section 10.2.1.6(F) of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.2.1.6(F).)

If it is obvious that the entity is not enrolling as an HHA, the checkbox above this section can be left blank.

If the entity is an HHA:

(i) If the Special Requirements for Home Health Agencies/Type of Home Health Agency or Financial Documentation sections is/are blank, the contractor can verify the data with the provider via telephone, e-mail, the PCV, or fax.

(ii) If the telephone number in the Special Requirements for Home Health Agencies section is blank, the contractor can verify the data with the provider via telephone, e-mail, the PCV, or fax.

10.3.1.1.9 – Sections 13 and 14 (Contact Person and Penalties for Falsifying Information) - Form CMS-855A
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Contact Person (Section 13)

(Regarding the Contact Person section of the Form CMS-855A, see section 10.6.9 of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.9.)

If this section is completely blank, the contractor need not develop for this information and can simply contact an authorized or delegated official.

If neither box is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor may either (1) develop for this information by telephone, e-mail, the PCV, or fax, or (2) contact an authorized or delegated official.

There is no existing option on the Form CMS-855A to delete a contact person. The contractor shall therefore accept a contact person's end-date via telephone, e-mail, the PCV, fax, or mail from the individual provider, an authorized/delegated official, or a current contact person on file. The contractor shall document in PECOS who requested the termination, how the request originated (e-mail, the PCV, phone, or fax), and when the request occurred. However, the provider must still report all contact person additions via the Form CMS-855A.

B. Penalties for Falsifying Information (Section 14)

Please refer to the Penalties for Falsifying Information section of the Form CMS-855A for an explanation of penalties for deliberately furnishing false information on this application to gain or maintain Medicare enrollment.

10.3.1.1.10 – Certification Statement - Form CMS-855A

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Certification Statement – General Policies

(Unless otherwise specified, the instructions in this section 10.3.1.1.10(A) apply to: (1) signatures on the paper Form CMS-855A; and (2) electronic signatures for web applications.)

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, electronic signatures are required; the contractor may contact its PEOG BFL for questions regarding electronic signatures.

B. Paper Submissions

A signed certification statement shall accompany the paper Form CMS-855A application. If the provider submits an invalid certification statement or no certification statement at all, the contractor shall still process the application. The contractor shall solicit an appropriate certification statement as part of the development process – preferably via the PCV, e-mail or fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application); (d) missing; or (e) stamped. The contractor shall send one development request to include a list of all of the missing required data/documentation, including

the certification statement. The contractor may reject the provider's application if the provider fails to furnish the missing information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the missing information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information (including an application fee) upon review.

(ii) The contractor may return a certification statement via scanned email or fax.

(iii) Signature dates cannot be more than 120 days prior to the receipt date of the application.

(iv) For paper applications that require development, the dated signature of at least one of the provider's authorized or delegated officials must be on the certification statement that must be sent in within 30 days. Obtaining the signatures of the other authorized and delegated officials is not required.

(v) For paper changes of information (as the term "changes of information" is defined in section 10.4.4 of this chapter), if the certification statement is signed by an individual not on file with the contractor as an authorized or delegated official of the provider, the contractor may accept the certification statement. However, it shall develop for information on the person consistent with the procedures in this chapter.

(vi) The contractor need not compare the signature on the Form CMS-855A with the same authorized or delegated official's signature on file to ensure that it is the same person.

(vii) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

C. PECOS Submissions

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall (a) begin processing the application upon receipt via PECOS; (b) perform all required manual validations; and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 above and all other applicable instructions in this chapter.

(ii) If the provider submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via the PCV, e-mail, or fax. (This includes certification statements that are signed by a person unauthorized to do so under 42 CFR Part 424, subpart P.) The contractor shall send one development request to include a list of all of the data/documentation to be furnished or clarified, including, as applicable, the certification statement. The contractor may reject the provider's application if the

provider fails to furnish said data/documentation within 30 calendar days from the date of the contractor's request.

(iii) For PECOS applications that require development, at least one of the provider's authorized or delegated officials must sign any certification statement that must accompany the provider's response. Obtaining the signatures of the other authorized and delegated officials is not required.

(iv) For PECOS changes of information, if the certification statement is signed by an individual who is not on file with the contractor as an authorized or delegated official of the provider, the contractor may accept the certification statement. However, it shall develop for information on the person in question consistent with the procedures in this chapter.

(v) The contractor need not compare the signature thereon with the same authorized or delegated official's signature on file to ensure that it is the same person.

(vi) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

D. Certification Statement Development

If, as already mentioned, the provider submits an invalid certification statement (as described in subsections (B) and (C) above), the contractor shall develop for a correct certification statement and send a development letter to the provider. The provider must submit the requested certification statement as follows:

(i) Paper applications -- Via scanned email, fax, or mail. Only the actual signature page is required; the provider need not submit the additional page containing the certification terms. (This also applies to the provider's initial submission of a certification statement. Such instances require the submission of only the signature page and not the certification terms.)

(ii) Web applications – Via electronic signature.
(iii)

10.3.1.1.11 – Section 15 (Authorized Officials) - Form CMS-855A

(Rev. 11168; Issued:12-22-21; Effective:12-31-21; Implementation:01-24-22)

A. General Requirements

An authorized official must be a 5 percent direct owner, chairman of the board, etc., of the enrolling provider with the authority to bind the provider, both legally and financially, to the requirements set forth in 42 CFR § 424.510. This person must also have an ownership or control interest in the provider--- such as the general partner, chairman of the board, chief financial officer, chief executive officer, president, or someone holding a position of similar status and authority within the provider organization. One cannot use his/her status as the chief executive officer, chief financial officer, etc., of the provider's parent company, management company, or chain home office as a basis for his/her role as the provider's authorized official.

Section 424.502 specifically defines an authorized official as an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. Note that an authorized official is not restricted to the examples of the titles outlined above but can be a person of equivalent status who is an appointed official to whom the organization has granted the legal authority to act on the organization's behalf. These additional titles could include, but are not limited to, executive director, administrator, president, and vice-president. The contractor shall consider the individual's title as well as the authority granted by the organization when determining whether an individual qualifies as an authorized official. If the contractor is unsure of an authorized official's qualifications or authority, it shall contact its PEOG BFL for guidance. In addition, the contractor shall obtain PEOG BFL approval if the only role of the listed authorized official is "Contracted Managing Employee" notwithstanding his/her title or other qualifications; the PEOG BFL will confirm authority.

If the person is not listed as a "Contracted Managing Employee" in the Individual Ownership Interest and/or Managing Control Information section and the contractor has no reason to suspect that the person does not qualify as an authorized official, no further investigation is required. Should the contractor have doubts that the individual qualifies as an authorized official, it shall contact the official or the applicant's contact person to obtain more information about the official's job title and/or authority to bind. If the contractor remains unconvinced that the individual qualifies as an authorized official, it shall notify the provider that the person cannot be an authorized official. If that person is the only authorized official listed and the provider refuses to use a different authorized official, the contractor shall deny the application.

B. Number of Authorized Officials

The provider can have an unlimited number of authorized officials, so long as each meets the definition of an authorized official. However, the provider must complete the Individual Ownership and/or Managing Control section of the Form CMS-855A for each authorized official.

C. Deletion of Authorized Official

For authorized official deletions, the contractor need not obtain (1) that official's signature, or (2) documentation verifying that the person is no longer an authorized official.

D. Change in Authorized Officials

A change in authorized officials does not impact the authority of existing delegated officials to report changes and/or updates to the provider's enrollment data or to sign revalidation applications.

E. Authorized Official Not on File

If the provider submits a change request (e.g., change of address) and the authorized official signing it is not on file, the contractor shall ensure that: (1) the person meets the definition of an

authorized official; and (2) the Individual Ownership Interest and/or Managing Control Information section of the Form CMS-855 is completed for him/her. The signature of an existing authorized official is not needed to add a new authorized official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purposes of enrollment processing and reporting.

F. Effective Date

The effective date in PECOS for an authorized official should be the date of signature.

G. Social Security Number

To be an authorized official, the person must have and submit his/her SSN. He/she may not use an Individual Taxpayer Identification Number (ITIN) in lieu of an SSN in this regard.

H. Identifying the Provider

As stated earlier, an authorized official must be an authorized official of the provider, not of an owning organization, parent company, chain home office, or management company. Identifying the provider is not - for purposes of determining an authorized official's qualifications - determined solely by the provider's tax identification number (TIN). Rather, the organizational structure is the central factor. For instance, suppose that a chain drug store, Company X, wants to enroll 100 of its pharmacies with the contractor. Each pharmacy has a separate TIN and must therefore enroll separately. Yet all of the pharmacies are part of a single corporate entity – Company X. In other words, there are not 100 separate corporations in our scenario, but merely one corporation whose individual locations have different TINs. Here, an authorized official for Pharmacy #76, can be someone at X's headquarters (assuming that the definition of authorized official is otherwise met), even though this main office might be operating under a TIN that is different from that of #76. This is because headquarters and Pharmacy #76 are part of the same organization/corporation. Conversely, if #76 was a corporation that was separate and distinct from Company X, only individuals that were part of #76 could be authorized officials.

I. Signatory Requirements

1. Valid Signatures – See section 10.3.1.1.10(A) of this chapter for information on the types of acceptable signatures. If the contractor receives a digital signature that differs from those described in section 10.3.1.1.10(A), the contractor shall contact its PEOG BFL for guidance.

2. Form CMS-855A Initial Applications – For these transactions, an authorized official must sign and date the certification statement.

3. Change Requests and Revalidations - For these transactions, an authorized or delegated official may sign the certification statement. This applies to: (1) signatures on the paper Form CMS-855; (2) signatures on the certification statement for Internet-based provider enrollment; and (3) electronic signatures.

4. The authorized official's telephone number can be left blank. No further development is needed.

10.3.1.1.12 – Section 16 (Delegated Officials) - Form CMS-855A

(Rev. 11168; Issued:12-22-21; Effective:12-31-21; Implementation:01-24-22)

A. General Requirements

A delegated official is an individual to whom an authorized official listed in the Certification Statement section of the Form CMS-855A delegates the authority to report changes and updates to the provider's enrollment record or to sign revalidation applications. The delegated official's signature binds the organization both legally and financially, as if the signature were that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of an authorized official currently on file with Medicare. The delegated official must be an individual with an "ownership or control interest" in (as that term is defined in § 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of the provider.

Section 1124(a)(3) defines an individual with an ownership or control interest as:

- A five percent direct or indirect owner of the provider,
- An officer or director of the provider (if the provider is a corporation), or
- Someone with a partnership interest in the provider if the provider is a partnership

The delegated official must be a delegated official of the provider, not of an owning organization, parent company, chain home office, or management company. One cannot use his/her status as a W-2 managing employee of the provider's parent company, management company, or chain home office as a basis for his/her role as the provider's delegated official.

The provider must complete the Ownership Interest and Managing Control Information for Individuals section of the Form CMS-855A for all delegated officials.

A delegated official has no authority to sign an initial application. However, the delegated official may (i) sign a revalidation application and (ii) sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the provider's initial application.

Delegated officials may not delegate their authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the provider's Medicare data or to sign revalidation applications.

For purposes of the Delegated Officials information captured in the Delegated Official section only, the term "managing employee" means any individual (including a general manager, business manager, or administrator) who exercises operational or managerial control over the provider, or who conducts the day-to-day operations of the provider. However, this does not

include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the provider but who are not actual W-2 employees. For instance, suppose the provider hires Joe Smith as an independent contractor to run its day-to-day-operations. Under the definition of "managing employee" in the Ownership Interest and Managing Control Information for Individuals section of the Form CMS-855A, Smith would have to be listed in that section. Yet under the Delegated Officials section definition (as described above), Smith cannot be a delegated official because he is not an actual W-2 employee of the provider. Independent contractors are not considered "managing employees" under the Delegated Officials section of the Form CMS-855A.

B. W-2 Form

Unless the contractor requests it to do so, the provider need not submit a copy of the owning/managing individual's W-2 to verify an employment relationship.

C. Number of Delegated Officials

The provider can have as many delegated officials as it chooses. It also need not have any delegated officials at all. If the provider lists no delegated officials, however, the authorized official(s) remains the only individual(s) who can report changes and/or updates to the provider's enrollment data.

D. Effective Date

The effective date in PECOS for a delegated official should be the date of signature.

E. SSN

To be a delegated official, the person must have and submit his/her SSN. He/she may not use an ITIN in lieu of an SSN in this regard.

F. Deletion of a Delegated Official

For delegated official deletions, documentation verifying that the person no longer is or qualifies as a delegated official is not required. In addition, the delegated official's signature is unnecessary.

G. Delegated Official Not on File

If the provider submits a change of information (e.g., change of address) and the delegated official signing the form is not on file, the contractor shall ensure that:

(i) The person meets the definition of a delegated official,
(ii) The provider completes the Individual Ownership and/or Managing Control section of the Form CMS-855A for that person, and
(iii) An authorized official signs off on the addition of the delegated official.

(NOTE: The original change request and the addition of the new official constitute a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting)).

H. Signature on Paper Application

If the provider submits a paper Form CMS-855A change request, the contractor may accept a delegated official's signature in the Certification Statement or Delegated Official section of the Form CMS-855A.

I. Telephone Number

The delegated official's telephone number can be left blank. No further development is needed.

10.3.1.1.13 – Additional Form CMS-855A Processing Information
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Supporting Documents Section

See the Supporting Documents section of the Form CMS-855A as well as section 10.3 of this chapter for information concerning supporting documents.

B. Unsolicited Additional Information

If the provider submits additional/missing/clarifying data or documentation on its own volition (i.e., not pursuant to a contractor request), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information that a provider submits prior to the date the contractor finishes processing a previously submitted change request constitutes a separate change request rather than an update to the original change request. The contractor may process both changes simultaneously; however, the contractor shall process the first submitted change to completion before processing the second one to completion.

C. Non-Enrollment Functions

In some instances, the contractor cannot forward an application to the state until it performs certain non-enrollment functions pertaining to the application (e.g., the reimbursement unit needs to examine patient listing data). The PECOS status may be changed to "approval recommended" prior to the conclusion of the non-enrollment activity if: (1) the contractor has completed all required enrollment actions; and (2) the non-enrollment action is the only remaining unperformed activity.

D. Multiple Providers under a Single TIN

It is important for contractors to remember that multiple providers and suppliers --- even those of different types --- may have the same TIN; for instance, a CORF, an HHA, and a hospice might have a similar TIN. However, each provider must submit a separate Form CMS-855A

application. They cannot all be reported via one enrollment, though, for PECOS submissions, consolidated applications may be permitted. (See section 10.3(B)(4) for more information.)

(For paper applications only, the contractor must create a separate enrollment record for each provider under the same TIN).

E. Future Effective Dates

If the contractor cannot enter an effective date into PECOS because the provider, practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the actual effective date is established, the effective date in PECOS can be changed.

F. Provider-Based Entities

The contractor shall adhere to the following regarding the enrollment of provider-based entities:

1. Certified Provider or Certified Supplier Initially Enrolling – Suppose an HHA or other certified provider or certified supplier wishes to enroll and become provider-based to a hospital. The provider/supplier must enroll with the contractor as a separate entity. It cannot be listed as a practice location on the hospital's Form CMS-855A.

2. Certified Provider or Certified Supplier Changing its Provider-Based Status – If a certified provider or certified supplier is changing its status from provider-based to freestanding or vice versa, it need not submit any updates to its Form CMS-855A enrollment.

3. Group Practice Initially Enrolling – If a group practice is enrolling in Medicare and will become provider-based to a hospital, the group generally must enroll via the Form CMS-855B if it wants to bill for practitioner services. The group would also need to be listed or added as a practice location on the hospital's Form CMS-855A.

4. Group Practice Changing from Provider-Based to Freestanding – In this situation, the hospital should submit a Form CMS-855A change request that deletes the clinic as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.

5. Group Practice Changing from Freestanding to Provider-Based – Here, the hospital must submit a Form CMS-855A change request adding the group as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.

Unless CMS instructs otherwise, the contractor shall not delay its processing of any practice location addition application pending receipt of a provider-based attestation or CMS approval of provider-based status.

10.3.1.1.14 – Form CMS-855A Processing Alternatives

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The processing alternatives in this section 10.3.1.1.14 are in addition to, and not in lieu of, any other processing alternatives described in this chapter or another CMS directive. These processing alternatives also apply notwithstanding any instruction in this chapter to the contrary. As stated in section 10.3, however, some of the application data elements and verification procedures that have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in sections 10.3 through 10.3.1.1.10.

A. General Principle

(Subject to the exceptions listed below as well as the instructions in section 10.3, the following principle applies to all Form CMS-855A sections.)

If a data element on the provider's Form CMS-855A application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, the contractor need not obtain the missing data via an updated Form CMS-855A page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-855A, even if the data is identified elsewhere on the form or in the supporting documentation:

(i) All organizational and individual ownership and managing control information on the Form CMS-855A

(ii) Except as otherwise stated in section 10.6.6 of this chapter, any final adverse action data requested in the Final Adverse Legal Actions/Convictions section and the final adverse legal action history for any organization or individual listed in the Ownership Interest and/or Managing Control Information sections of the Form CMS-855A

(iii) All legal business names (LBNs) (e.g., provider, chain home office) (NOTE: If an application is submitted with a valid NPI and CCN combination but (1) the LBN field is blank, (2) an incomplete or inaccurate LBN is submitted, or (3) the applicant includes a DBA name in the Practice Location Information section of the Form CMS-855A and the contractor can confirm the correct LBN based on the NPI-CCN combination provided, the contractor need not develop.)

(iv) All tax identification numbers (TINs) (e.g., provider, owning organization)

(v) NPI-legacy number combinations in the Practice Location Information section of the Form CMS-855A (NOTE: The contractor may use the shared systems, PECOS, or its provider files as a resource to determine the PTAN or NPI before developing with the provider.)

(vi) Provider type

(vii) The following data in the Change of Ownership (CHOW), Acquisitions/Mergers or Consolidations sections of the Form CMS-855A:

- DBA name
- Effective dates of sale/transfer/consolidation
- Checkbox in the Identifying Information (CHOW Information) section indicating whether buyer will accept assets/liabilities
- Names of units with separate legacy numbers/NPIs
- All NPIs and legacy numbers (NOTE: The contractor may use the shared systems, PECOS, or its provider files as a resource to determine the CCN or NPI before developing with the provider).

B. Supporting Documentation Resubmission

If supporting documentation currently exists in the provider's file, the provider need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. In short, documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative (unless stated otherwise in this chapter or any CMS directive).

C. City, State, and ZIP Code

If an address in any section of the Form CMS-855A (e.g., correspondence address, practice location) lacks a city, state, or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the "zip + four" from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

D. Licenses

In situations where the provider is required to submit a copy of a particular professional or business license, certification, or registration but fails to do so, the contractor need not obtain such documentation from the provider if the contractor can verify the information independently. The contractor can do this by: (1) reviewing and printing confirmation pages from the applicable state web site; (2) requesting and receiving from the appropriate state body written confirmation of the provider's status therewith; and (3) using any other third-party verification source. In addition, if the provider submits a copy of the applicable license, certification, or registration but fails to complete the appropriate section of the form, the section need not be completed if the data in question can be verified on the license/certification itself or via any of the three mechanisms above. The contractor shall, however, note the following:

(i) The above-referenced written confirmation from a state body of the provider's status can be in the form of a letter, fax, or e-mail, but it must be in writing. Documentation of a verbal conversation between the contractor and the body in question does not qualify as appropriate confirmation.

(ii) The aforementioned licensure exception only applies to those documents that traditionally fall within the category of licenses, registrations, or certifications. It is inapplicable to materials such as adverse action documentation, bills of sale, etc. Furthermore, the exception is moot in

cases where: (a) the state does not require a particular license/certification; or (b) the license/certification has not been obtained because a state survey has not yet been performed.

E. Documentation of Missing Information Elsewhere

The contractor shall document in PECOS that the missing information covered under this section 10.3.1.1.14 was found elsewhere in the enrollment package. However, this excludes information that must be verified at the current point in time (i.e., a license without a primary source verification method).

F. Relationship to Opt-Out

The contractor shall not utilize information submitted with opt-out applications for enrollment application processing or vice-versa.

10.3.1.2 – Form CMS-855B –Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This application should be completed by supplier organizations (e.g., ambulance companies) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.

The policies in this section 10.3.1.2 et seq. apply exclusively to the Form CMS-855B (except as otherwise noted).

10.3.1.2.1 – Section 1 (Basic Information) - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. For example, suppose a supplier is changing its tax identification number via the Form CMS-855B. The supplier must submit two applications: (1) an initial Form CMS-855B as a new supplier; and (2) a Form CMS-855B voluntary termination. Both transactions cannot be reported on the same application.

With the exception of (1) the voluntary termination checkbox and (2) the effective date of termination data in the Basic Information section of the Form CMS-855B---and except as stated in section 10.6.1.3 of this chapter---any blank data/checkboxes in this section can be verified through any means chosen by the contractor (e.g., e-mail, the PCV, telephone, fax).

10.3.1.2.2 – Section 2 (Identifying Information) - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. License, Certification, and Accreditation Information

1. Background

Regarding licensure information in the Identifying Information Section of the Form CMS-855B, the extent to which the applicant must furnish licensure, certification, or accreditation data depends upon the supplier type involved. Requirements will vary by supplier type and by location; for instance, some states may require a particular supplier to be "certified" but not "licensed" (or vice versa).

The only licenses that the supplier must submit with the application are those that Medicare and/or the state requires to function as the supplier type in question. Licenses and permits not of a medical nature are not required. In some instances, licensure may not be required in a particular state at all, though the contractor in this case shall still ensure that the supplier meets all applicable state and Medicare requirements.

If the contractor knows that a particular state does not require licensure/certification and the "Not Applicable" boxes are not checked in the Identifying Information Section of the Form CMS-855B, no further development is needed.

2. Jurisdictions and Practice Locations

Except as otherwise stated in this chapter or in another CMS directive, the contractor shall verify that the supplier is licensed and/or certified to furnish services in:

(i) The state where the supplier is enrolling; and

(ii) Any other state within the contractor's jurisdiction in which the supplier (per the "Practice Location Information" section of the Form CMS-855B) will maintain a practice location

3. Permissible Independent Verification

In situations where the supplier is required to submit a copy of a particular professional or business license, certification, or registration but fails to do so, the contractor need not obtain such documentation from the supplier if the contractor can verify the information independently. The contractor can do this by: (1) reviewing and printing confirmation pages from the applicable state web site; (2) requesting and receiving from the appropriate state body written confirmation of the supplier's status therewith; and (3) using any other third-party verification source. In addition, if the supplier submits a copy of the applicable license, certification, or registration but fails to complete the appropriate section of the form, the section need not be completed if the data in question can be verified on the license/certification itself or via any of the three mechanisms above. The contractor shall, however, note the following:

(i) The above-referenced written confirmation from a state body of the supplier's status can be in the form of a letter, fax, or e-mail, but it must be in writing. Documentation of a verbal conversation between the contractor and the body in question does not qualify as appropriate confirmation.

(ii) The aforementioned licensure exception only applies to those documents that traditionally fall within the category of licenses, registrations, or certifications. It is inapplicable to materials such as adverse action documentation, bills of sale, paramedic intercept agreements, etc.

Furthermore, the exception is moot in cases where: (a) the state does not require a particular license/certification; or (b) the license/certification has not been obtained because a state survey has not yet been performed.

4. Additional Policies

a. License Reinstatement - If the applicant had a previously revoked or suspended license reinstated (and unless CMS states otherwise in this chapter or elsewhere), the applicant must submit a copy of the reinstatement notice with the application.

b. License expiration/revocation dates for non-certified suppliers - For expired licenses, the contractor shall enter into PECOS the date after the expiration as the expiration date. For revoked and suspended licenses, the contractor shall enter into PECOS the revocation date (not the day after) as the expiration date.

B. Clinical Laboratory Improvement Act (CLIA) and Drug Enforcement Agency (DEA)

CLIA and DEA certificates are not required. If the applicable CLIA and DEA certificates are not furnished or the applicable Form CMS-855B sections are blank, no further development is needed.

See section 10.6.19 et seq. of this chapter for special instructions regarding periodic license reviews.

C. Supplier Identification Information – Business Information

Unless otherwise stated in this chapter or in another CMS directive, the contractor may capture all information in the Identifying Information Section (with the exception of the TIN and LBN) by telephone, fax, e-mail, the PCV, or a review of the supplier's web site.

D. Physical Therapy/Occupational Therapy Groups

A PT/OT group must complete the questionnaire in the Identifying Information Section for PT/OT groups. In doing so:

(i) If the group indicates that it renders services in patients' homes, the contractor shall verify that the group has an established private practice where it can be contacted directly and where it maintains patients' records.

(ii) If the group answers "yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving the group exclusive use of the facilities for PT/OT services only if it has reason to question the accuracy of the group's response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

E. State Surveys

Documents that can only be obtained after state surveys or accreditation need not be included as part of the application. (This typically occurs with ASCs and portable x-ray suppliers.) The

supplier must, however, furnish those documents that can be submitted prior to the survey/accreditation.

The contractor shall include any licenses, certifications, and accreditations submitted by suppliers in the enrollment package that is forwarded to the state.

Once the contractor receives the approval recommendation notice from the state, the contractor is encouraged (but not required) to contact the state or the supplier for the applicable licensing and/or certification data and to enter it into PECOS.

F. Notarization

If the applicant submits a license that is not notarized or "certified true," the contractor shall verify the license with the appropriate state agency. (A notarized copy of an original document has a stamp that says "official seal," along with the name of the notary public, the state, the county, and the date the notary's commission expires. A certified "true copy" of an original document has a raised seal that identifies the state and county in which it originated or is stored.)

G. Correspondence Address and Telephone Number

The correspondence address in the Correspondence Address and Telephone Number Section of the Form CMS-855B must be one at which the contractor can directly contact the applicant to resolve any issues once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, chain home office, or the provider's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box. The contractor need not verify the correspondence address.

The supplier may list any telephone number it wishes as the correspondence phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence telephone number and it is required for the application submission, the contractor shall develop for this information – preferably via the PCV, e-mail, or fax. The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier. The contractor is not required to verify the telephone number.

H. E-mail Addresses

An e-mail address listed on the application can be a generic e-mail address. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier.

10.3.1.2.3 – Section 3 (Final Adverse Legal Actions/Convictions) - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

See section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 above supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).

10.3.1.2.4 – Section 4 (Practice Location Information) – Form CMS-855B

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Reporting and Verification Policies

1. ZIP Code – The supplier must submit the 9-digit ZIP Code for each practice location listed.

2. Practice Location Name - For suppliers paid via the Multi-Carrier System (MCS), the practice location name entered into PECOS shall be the legal business name. (Beginning with PECOS 2.0, however, the DBA name can be entered as the practice location name.)

3. Practice Location Verification – Except as stated otherwise in this chapter or in another CMS directive, the contractor shall verify that the practice locations listed on the application actually exist and are valid addresses with the United States Postal Service (USPS). PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS Store, mailboxes, etc.), or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry.

4. Phone Number Verification - The contractor need not verify the supplier's telephone number listed on the application, though the supplier must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

5. Special Certified Supplier Instructions (ASCs and Portable X-Ray Suppliers (PXRS)) - If the supplier's address and/or telephone number cannot be verified, the contractor shall request clarifying information from the supplier. If the supplier states that the facility and its phone number are not yet operational, the contractor may continue processing the application. However, it shall indicate in its recommendation letter that the address and telephone number of the facility could not be verified. For purposes of PECOS, the contractor can temporarily use the date the certification statement was signed as the effective date.

6. Specific Section 4 Subsection Policies

a. Practice Location Type - In Section 4A, if the "type of practice location" checkbox is blank, the contractor can confirm the information via the PCV, e-mail, or fax.

b. Section 4B - If neither box is checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the "special payments" address is indeed the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in Section 4B must be completed via the Form CMS-855B.

c. Updated Questionnaire - If the supplier (1) is adding a practice location and (2) is normally required to complete a questionnaire in the Form CMS-855B specific to its supplier type (i.e.: physical or occupational therapist groups), the entity must submit an updated questionnaire to incorporate services rendered at the new location.

d. Section 4E – If the "Check here" box in Section 4E is not checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the base of operations address is the same as the practice location, no further development is needed. If the supplier indicates that the base of operations is at a different location, the address in Section 4E must be furnished via the Form CMS-855B.

e. Section 4F - If the vehicle certificates are furnished but the applicable Form CMS-855B sections are blank, the contractor can verify via telephone, the PCV, e-mail, or fax that said vehicles are the only ones the supplier has.

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the supplier's "special payment" address (the Practice Location Information section of the Form CMS-855B) or EFT information has changed. The supplier should submit a Form CMS-855B to change this address; if the supplier does not have an established enrollment record in PECOS, it must complete an entire Form CMS-855B. (For DMEPOS suppliers, the DME MAC is responsible for obtaining, updating, and processing Form CMS-588 changes.)

If a supplier is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the supplier to complete the "special payment" address section of the Form CMS-855B and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the supplier has completed and signed the Form CMS-588 and shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

If an enrolled supplier that currently receives paper checks submits a Form CMS-855 change request – no matter what the change involves – the supplier must also submit:

- A Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.

- The contractor shall also verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

(Once a supplier changes its method of payment from paper checks to EFT, it must continue using EFT. A supplier cannot switch from EFT to paper checks.)

The "special payment" address may only be one of the following:

- One of the supplier's practice locations
- A P.O. Box
- The supplier's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.
- Correspondence address
- A lockbox. The contractor shall request additional information if it has any reason to suspect that the arrangement - at least with respect to any special payments that might be made - may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.

D. Out-of-State Practice Locations

(The policies in this section 10.3.1.2.4(D) apply unless CMS instructs otherwise in this chapter or in another directive.)

If a supplier is adding a practice location in another state that is within the contractor's jurisdiction, a separate, initial Form CMS-855B enrollment application is not required if the following 5 conditions are met:

(i) The location is not part of a separate organization (e.g., a separate corporation, partnership);

(ii) The location does not have a separate TIN and LBN;

(iii) The state in which the new location is being added does not require the location to be surveyed;

(iv) Neither the new location nor its owner is required to sign a separate certified supplier agreement; and

(v) The location is not an IDTF, ASC, or other supplier type that must individually and separately enroll each of its locations.

Consider the following scenarios:

EXAMPLE 1 - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y. The new location will be under JGP, Inc. JGP will not be establishing a separate corporation, LBN, or TIN for the fourth location. Since there is no state agency or SOG Location involvement with group practices, all five conditions are met. JGP can add the fourth location via a change of information request, rather than an initial application. The change request must include all information relevant to the new location (e.g., licensure, new managing employees). (For paper applications only---and to the extent required---the contractor shall create a separate PECOS enrollment record for the State Y location.)

EXAMPLE 2 - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y but under a newly created, separate entity - Jones Group Practice, LP. The fourth location must be enrolled via a separate, initial Form CMS-855B.

EXAMPLE 3 - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Q. Since State Q is not within the contractor's jurisdiction, a separate initial enrollment for the fourth location is necessary.

E. Unavoidable Phone Number or Address Changes - Unless CMS specifies otherwise, any change in the supplier's phone number or address that the supplier did not cause (e.g., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-855B.

10.3.1.2.5 – Sections 5 and 6 (Ownership Interest and/or Managing Control Information) - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

See section 10.6.7 et seq. of this chapter for information concerning owning and managing individuals and organizations. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.7 (e.g., communicating with the supplier via the PCV).

10.3.1.2.6 – Sections 8, 13, and 14 (Billing Agencies, Contact Persons, and Penalties for Falsifying Information) - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Except as otherwise stated, the PECOS policies in section 10.3 supersede those in sections 10.6.8 and 10.6.9 of this chapter.

A. Billing Agency Information (Section 8)

(Regarding the Billing Agency Information section of the Form CMS-855B, see section 10.6.8 of this chapter.)

If the telephone number is blank, the contractor may verify it with the supplier via telephone, the PCV, e-mail, or fax.

If all of the Billing Agency Information section is blank (including the check box), no additional development is necessary.

B. Contact Person (Section 13)

(Regarding the Contact Person section of the Form CMS-855B, see section 10.6.9 of this chapter.)

If this section is completely blank, the contractor need not develop for this information and can simply contact an authorized or delegated official.

If neither box is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor may either (1) develop for this information by telephone, the PCV, e-mail, or fax, or (2) contact an authorized or delegated official.

There is no existing option on the Form CMS-855B to delete a contact person. The contractor shall therefore accept a contact person's end-date via telephone, the PCV, e-mail, fax, or mail from the individual supplier, an authorized/delegated official, or a current contact person on file. The contractor shall document in PECOS who requested the termination, how the request originated (e-mail, phone, or fax), and when the request occurred. However, the provider must still report all contact person additions via the Form CMS-855B.

C. Penalties for Falsifying Information (Section 14)

Please refer to the Penalties for Falsifying Information section of the Form CMS-855B for an explanation of penalties for deliberately furnishing false information on this application to gain or maintain Medicare enrollment.

10.3.1.2.7 – Certification Statement - Form CMS-855B

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Unless otherwise specified in this chapter or in another CMS directive, the instructions in this section 10.3.1.2.7 apply to (1) signatures on the paper Form CMS-855B; and (2) electronic signatures for web applications.)

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, electronic signatures are required; the contractor may contact its PEOG BFL for questions regarding electronic signatures.

A. Paper Submissions

A signed certification statement shall accompany the paper Form CMS-855B application. If the supplier submits an invalid certification statement or no certification statement at all, the contractor shall still process the application. The contractor shall solicit an appropriate certification statement as part of the development process – preferably via the PCV, e-mail, or

fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application); (d) missing; or (e) stamped. The contractor shall send one development request that includes a list of all of the missing required data/documentation, including the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish the missing information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the missing information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information (including, if applicable, an application fee) upon review.

(ii) The contractor may return a certification statement via scanned email or fax.

(iii) Signature dates cannot be more than 120 days prior to the receipt date of the application.

(iv) For paper applications that require development, the dated signature of at least one of the supplier's authorized or delegated officials must be on the certification statement that must be sent in within 30 days. Obtaining the signatures of the other authorized and delegated officials is not required.

(v) For paper changes of information (as the term "changes of information" is defined in section 10.4.4 of this chapter), if the certification statement is signed by an individual not on file with the contractor as an authorized or delegated official of the supplier, the contractor may accept the certification statement. However, it shall develop for information on the person in question consistent with the procedures in this chapter.

(vi) The contractor need not compare the signature on the Form CMS-855B with the same authorized or delegated official's signature on file to ensure that it is the same person.

(vii) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

B. PECOS Submissions

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall (a) begin processing the application upon receipt via PECOS; (b) perform all required manual validations; and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 and all other applicable instructions in this chapter.

(ii) If the supplier submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via email or

fax. (This includes certification statements that are signed by a person unauthorized to do so under 42 CFR Part 424, subpart P.) The contractor shall send one development request that includes a list of all of the data/documentation to be furnished or clarified, including, as applicable, the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish said data/documentation within 30 calendar days from the date of the contractor's request.

(iii) For PECOS applications that require development, at least one of the supplier's authorized or delegated officials must sign any certification statement that must accompany the supplier's response. Obtaining the signatures of the other authorized and delegated officials is not required.

(iv) For PECOS changes of information (as the term "changes of information" is defined in section 10.4.4 of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as an authorized or delegated official of the supplier, the contractor may accept the certification statement. However, it shall develop for information on the person in question consistent with the procedures in this chapter.

(v) The contractor is not required to compare the signature thereon with the same supplier, authorized or delegated official's signature on file to ensure that it is the same person.

(vi) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

C. Certification Statement Development

If, as already mentioned, the supplier submits an invalid certification statement (as described in subsections (A) and (B) above), the contractor shall (using the procedures outlined in this chapter) develop for a correct certification statement and send a development letter to the supplier – preferably via the PCV, e-mail, or fax. The supplier must submit the requested certification statement as follows:

(i) Paper applications -- Via scanned e-mail, fax, or mail. Only the actual signature page is required; the additional page containing the certification terms need not be submitted. (This also applies to the supplier's initial submission of a certification statement; such instances require the submission of only the signature page and not the certification terms.)

(ii) Web applications – Via electronic signature.

10.3.1.2.8 – Section 15 (Authorized Officials) - Form CMS-855B

(Rev. 11168; Issued:12-22-21; Effective:12-31-21; Implementation:01-24-22)

A. General Requirements

An authorized official must be a 5 percent direct owner, chairman of the board, etc., of the enrolling supplier with the authority to bind the supplier, both legally and financially, to the requirements set forth in 42 CFR §424.510. This person must also have an ownership or control

interest in the supplier--- such as the general partner, chairman of the board, chief financial officer, chief executive officer, president, or someone holding a position of similar status and authority within the provider organization. One cannot use his/her status as the chief executive officer, chief financial officer, etc., of the supplier's parent company, management company, or chain home office as a basis for his/her role as the provider's authorized official.

Section 424.502 specifically defines an authorized official as an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. Note that an authorized official is not restricted to the examples of the titles outlined above but can be a person of equivalent status who is an appointed official to whom the organization has granted the legal authority to act on the organization's behalf. These additional titles could include, but are not limited to, executive director, administrator, president, and vice-president. The contractor shall consider the individual's title as well as the authority granted by the organization when determining whether an individual qualifies as an authorized official. If the contractor is unsure of an authorized official's qualifications or authority, it shall contact its PEOG BFL for guidance. In addition, the contractor shall obtain PEOG BFL approval if the only role of the listed authorized official is "Contracted Managing Employee" notwithstanding his/her title or other qualifications; the PEOG BFL will confirm authority.

If the person is not listed as a "Contracted Managing Employee" in the Individual Ownership Interest and/or Managing Control Information section and the contractor has no reason to suspect that the person does not qualify as an authorized official, no further investigation is required. Should the contractor have doubts that the individual qualifies as an authorized official, it shall contact the official or the applicant's contact person to obtain more information about the official's job title and/or authority to bind. If the contractor remains unconvinced that the individual qualifies as an authorized official, it shall notify the supplier that the person cannot be an authorized official. If that person is the only authorized official listed and the supplier refuses to use a different authorized official, the contractor shall deny the application.

B. Number of Authorized Officials

The supplier can have an unlimited number of authorized officials, so long as each meets the definition of an authorized official. However, the supplier must complete the Individual Ownership and/or Managing Control section of the Form CMS-855B for each authorized official.

C. Deletion of Authorized Official

For authorized official deletions, the contractor need not obtain (1) that official's signature, or (2) documentation verifying that the person is no longer an authorized official.

D. Change in Authorized Officials

A change in authorized officials does not impact the authority of existing delegated officials to report changes and/or updates to the supplier's enrollment data or to sign revalidation applications.

E. Authorized Official Not on File

If the supplier submits a change request (e.g., change of address) and the authorized official signing it is not on file, the contractor shall ensure that: (1) the person meets the definition of an authorized official; and (2) the Individual Ownership Interest and/or Managing Control Information section of the Form CMS-855B is completed for him/her. The signature of an existing authorized official is not needed to add a new authorized official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purposes of enrollment processing and reporting.

F. Effective Date

The effective date in PECOS for an authorized official should be the date of signature.

G. Social Security Number

To be an authorized official, the person must have and submit his/her SSN. He/she may not use an Individual Taxpayer Identification Number (ITIN) in lieu of an SSN in this regard.

H. Identifying the Supplier

As stated earlier, an authorized official must be an authorized official of the supplier, not of an owning organization, parent company, chain home office, or management company. Identifying the supplier is not - for purposes of determining an authorized official's qualifications - determined solely by the supplier's tax identification number (TIN). Rather, the organizational structure is the central factor. For instance, suppose that a chain drug store, Company X, wants to enroll 100 of its pharmacies with the contractor. Each pharmacy has a separate TIN and must therefore enroll separately. Yet all of the pharmacies are part of a single corporate entity – Company X. In other words, there are not 100 separate corporations in our scenario, but merely one corporation whose individual locations have different TINs. Here, an authorized official for Pharmacy #76, can be someone at X's headquarters (assuming that the definition of authorized official is otherwise met), even though this main office might be operating under a TIN that is different from that of #76. This is because headquarters and Pharmacy #76 are part of the same organization/corporation. Conversely, if #76 was a corporation that was separate and distinct from Company X, only individuals that were part of #76 could be authorized officials.

I. Signatory Requirements

1. Valid Signatures – See section 10.3.1.2.7(A) of this chapter for information on the types of acceptable signatures. If the contractor receives a digital signature that differs from those described in section 10.3.1.2.7(A), the contractor shall contact its PEOG BFL for guidance.

2. Form CMS-855B Initial Applications – For these transactions, an authorized official must sign and date the certification statement.

3. Change Requests and Revalidations - For these transactions, an authorized or delegated official may sign the certification statement. This applies to: (1) signatures on the paper Form CMS-855B; (2) signatures on the certification statement for Internet-based provider enrollment; and (3) electronic signatures.

4. The authorized official's telephone number can be left blank. No further development is needed.

10.3.1.2.9 – Section 16 (Delegated Officials) - Form CMS-855B
(Rev. 11168; Issued:12-22-21; Effective:12-31-21; Implementation:01-24-22)

A. General Requirements

A delegated official is an individual to whom an authorized official listed in the Certification Statement section of the Form CMS-855B delegates the authority to report changes and updates to the supplier's enrollment record or to sign revalidation applications. The delegated official's signature binds the organization both legally and financially, as if the signature were that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of an authorized official currently on file with Medicare. The delegated official must be an individual with an "ownership or control interest" in (as that term is defined in § 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of the supplier.

Section 1124(a)(3) defines an individual with an ownership or control interest as:

- A five percent direct or indirect owner of the supplier,

- An officer or director of the supplier (if the supplier is a corporation), or

- Someone with a partnership interest in the supplier if the supplier is a partnership

The delegated official must be a delegated official of the supplier, not of an owning organization, parent company, chain home office, or management company. One cannot use his/her status as a W-2 managing employee of the supplier's parent company, management company, or chain home office as a basis for his/her role as the supplier's delegated official.

The supplier must complete the Ownership Interest and Managing Control Information for Individuals section of the Form CMS-855B for all delegated officials.

A delegated official has no authority to sign an initial application. However, the delegated official may (i) sign a revalidation application and (ii) sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the supplier's initial application.

Delegated officials may not delegate their authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the supplier's Medicare data or to sign revalidation applications.

For purposes of the Delegated Officials information captured in the Delegated Official section only, the term "managing employee" means any individual (including a general manager, business manager, or administrator) who exercises operational or managerial control over the provider, or who conducts the day-to-day operations of the supplier. However, this does not include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the supplier but who are not actual W-2 employees. For instance, suppose the provider hires Joe Smith as an independent contractor to run its day-to-day-operations. Under the definition of "managing employee" in the Ownership Interest and Managing Control Information for Individuals section of the Form CMS-855B, Smith would have to be listed in that section. Yet under the Delegated Officials section definition (as described above), Smith cannot be a delegated official because he is not an actual W-2 employee of the provider. Independent contractors are not considered "managing employees" under the Delegated Officials section of the Form CMS-855B.

B. W-2 Form

Unless the contractor requests it to do so, the supplier need not submit a copy of the owning/managing individual's W-2 to verify an employment relationship.

C. Number of Delegated Officials

The supplier can have as many delegated officials as it chooses. It also need not have any delegated officials at all. If the supplier lists no delegated officials, however, the authorized official(s) remains the only individual(s) who can report changes and/or updates to the supplier's enrollment data.

D. Effective Date

The effective date in PECOS for a delegated official should be the date of signature.

E. SSN

To be a delegated official, the person must have and submit his/her SSN. He/she may not use an ITIN in lieu of an SSN in this regard.

F. Deletion of a Delegated Official

For delegated official deletions, documentation verifying that the person no longer is or qualifies as a delegated official is not required. In addition, the delegated official's signature is unnecessary.

G. Delegated Official Not on File

If the supplier submits a change of information (e.g., change of address) and the delegated official signing the form is not on file, the contractor shall ensure that:

(i) The person meets the definition of a delegated official,
(ii) The supplier completes the Individual Ownership and/or Managing Control section of the Form CMS-855B for that person, and
(iii) An authorized official signs off on the addition of the delegated official.

(NOTE: The original change request and the addition of the new official constitute a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting)).

H. Signature on Paper Application

If the provider submits a paper Form CMS-855B change request, the contractor may accept a delegated official's signature in the Certification Statement or Delegated Official section of the Form CMS-855B.

I. Telephone Number

The delegated official's telephone number can be left blank. No further development is needed.

10.3.1.2.10 – Additional Form CMS-855B Processing Information
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The processing alternatives in section 10.3.1.2.10(E) are in addition to, and not in lieu of, any other processing alternatives described in this chapter or another CMS directive. These processing alternatives also apply notwithstanding any instruction in this chapter to the contrary. As stated in section 10.3, however, some of the application data elements and verification procedures that have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in section 10.3 and section 10.3.1.2 through 10.3.1.2.9.

A. Supporting Documents (Section 17)

See the Supporting Documents Section of the Form CMS-855B as well as section 10.3 for information concerning supporting documents.

B. Attachment 1 for Ambulance Service Suppliers

In section D of Attachment 1 of the Form CMS-855B, the "Land," "Air," and "Marine" boxes need not be checked (or developed) if the type of vehicle involved is clear. In addition, the contractor need not develop for the written statement signed by the President, Chief Executive Officer, or Chief Operating Officer of the airport from where the aircraft is hangared that furnishes the name and address of the facility.

See section 10.2.2.10 of this chapter for more detailed processing instructions on Attachment 1.

C. Attachment 2 for Independent Diagnostic Testing Facilities

See section 10.2.2.4 of this chapter for more detailed processing instructions on Attachment 2.

D. Attachment 3 for Opioid Treatment Programs

See section 10.2.7 of this chapter for more detailed processing instructions on Attachment 3.

E. Provider-Based Entities

The contractor shall adhere to the following regarding the enrollment of provider-based entities:

- **Group Practice Initially Enrolling –** If a group practice is enrolling in Medicare and will become provider-based to a hospital, the group generally must enroll via the Form CMS-855B if it wants to bill for practitioner services. The group would also need to be listed or added as a practice location on the hospital's Form CMS-855A.
- **Group Practice Changing from Provider-Based to Freestanding** – In this situation, the hospital should submit a Form CMS-855A change request that deletes the clinic as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.
- **Group Practice Changing from Freestanding to Provider-Based** – Here, the hospital must submit a Form CMS-855A change request adding the group as a practice location. The group may also need to change the type of clinic it is enrolled as; this may require a new Form CMS-855B.

Unless CMS instructs otherwise, the contractor shall not delay the processing of any practice location addition applications pending receipt of provider-based attestations or CMS approval of provider-based status.

F. Additional Processing Information and Alternatives

1. Unsolicited Additional Information

If the supplier submits additional/missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information that a supplier submits prior to the date the contractor finishes processing a previously submitted change request constitutes a separate change request rather than an update to the original change request. The contractor may process both changes simultaneously; however, the contractor shall process the first submitted change to completion before processing the second one to completion.

2. Information Disclosed Elsewhere

If a data element on the supplier's Form CMS-855B application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with

the application, the contractor need not obtain the missing data via an updated Form CMS-855B page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-855B, even if the data is identified elsewhere on the form or in the supporting documentation:

- All ownership and managing control information in the Organizational or Individual Ownership and/or Managing Control sections of the Form CMS-855B

- Except as otherwise stated in section 10.6.6 of this chapter, any final adverse action data requested in the Final Adverse Legal Actions/Convictions Section and the Organizational and Individual Ownership and/or Managing Control/Final Adverse Legal Action History sections of the Form CMS-855B

- All legal business names (LBN) or legal names (NOTE: If an application is submitted with a valid NPI-PTAN combination but (1) the LBN field is blank, (2) an incomplete or inaccurate LBN is submitted, or (3) the applicant includes a DBA name in the Practice Location Information section of the Form CMS-855B -- and the contractor is able to confirm the correct LBN based on the NPI-PTAN combination provided, the contractor need not develop.)

- All tax identification numbers (TIN)

- NPI-legacy number combinations in the Practice Location Information section of the Form CMS-855B (NOTE: The contractor may use the shared systems, PECOS, or its provider files as a resource to determine the PTAN or NPI before developing with the supplier.)

- Supplier type in the Identifying Information section of the Form CMS-855B

3. Supporting Documentation Resubmission

If the supporting documentation currently exists in the supplier's file, the supplier need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative, unless stated otherwise in this chapter or another CMS directive. Also, per section 10.6.19(H) of this chapter, the contractor shall document in PECOS that the missing information was found elsewhere in the enrollment package. (This excludes information that must be verified at the current point in time (i.e., a license without a primary source verification method.) In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

4. City, State, and ZIP Code

If an address (e.g., correspondence address, practice location) lacks a city, state or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

5. Inapplicable Questions

The supplier need not check “no” for questions that obviously do not apply to its supplier type.

6. Authorized/Delegated Official Telephone Number

The telephone numbers in these sections can be left blank. No further development is needed.

10.3.1.3 – Form CMS-855I – Medicare Enrollment Application for Physicians and Non-Physician Practitioners

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

This application should be completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries and, as applicable, wish to reassign their benefits under § 424.80. (This includes a physician or practitioner who (1) is the sole owner of a professional corporation, professional association, or limited liability company and (2) will bill Medicare through this business entity.)

10.3.1.3.1 - Section 1 (Basic Information) – Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Purpose and Verification

In this section, the supplier indicates the reason for submittal of the application. (This includes establishing, terminating, or changing reassignments.) Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. For example, suppose a supplier is voluntarily terminating an enrollment as one supplier type and enrolling as a different supplier type; both transactions cannot be reported on the same application.

Excluding (1) the voluntary termination checkbox and (2) the effective date of termination---and except as stated in section 10.6.1.3 of this chapter---any blank data/checkboxes in the Basic Information section can be verified through any means (e.g., the PCV, e-mail, telephone, fax).

B. Voluntary Termination Reminder

When a practitioner submits a Form CMS-855I application to either (1) add a practice location in a new state or (2) relocate to a new state entirely, the contractor that received the application shall determine whether the practitioner still has an active PECOS enrollment record in the “other” state(s). If PECOS indeed indicates that the individual has an active practice location in the other state(s), the contractor should remind the practitioner that if he/she no longer intends to practice in that state, he/she must submit a Form CMS-855I voluntary termination application to the contractor for that jurisdiction. The reminder should be furnished in the approval letter that the receiving contractor sends to the practitioner or, if more appropriate, via the PCV, e-mail, or other form of written correspondence.

C. Break in Medical Practice

If the contractor receives a Form CMS-855I from a practitioner who was once enrolled in Medicare but has not been enrolled with any Medicare contractor for the previous 2 years, the contractor shall verify with the state (a) where the practitioner last worked and (b) whether the practitioner was convicted of a felony or had his/her license suspended or revoked. If such an adverse action was imposed, the contractor shall take action consistent with the instructions in this chapter.

10.3.1.3.2 - Section 2 (Personal Identifying Information) – Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Licensure Information

1. General Instructions

(The extent to which the applicant must complete the licensure information depends upon the supplier type involved. Requirements will vary by supplier type and by location; for instance, some states may require a particular supplier type to be "certified" but not "licensed," or vice versa. (The license and certification "Not Applicable" checkboxes are for instances where a state does not require licensure).)

The only licenses that must be submitted with the application are those required by Medicare or the state to function as the supplier type in question. Licenses and permits that are not of a medical nature are not required. In addition, and as mentioned above, instances can occur where the supplier need not be licensed at all in a particular state; the contractor shall still ensure, however, that the supplier meets all applicable state and Medicare requirements.

The contractor shall verify that the supplier is licensed and/or certified to furnish services in:

- The state in which the supplier is enrolling.

- Any other state within the contractor's jurisdiction in which the supplier (per the "Practice Location Information" section of the Form CMS-855I) will maintain a practice location.

The contractor shall also ensure that the individual answers "Yes" or "No" to the Section 2(B)(1) question regarding compact licenses if individual indicates that he/she is licensed. (See subsection (A)(6) below for more information on compact licenses.)

2. Notarization

If the applicant submits a license that is not notarized or "certified true," the contractor shall verify the license with the appropriate state agency. (A notarized copy of an original document has a stamp that states "official seal," along with the name of the notary public, the state, the county, and the expiration date of the notary's commission. A certified "true copy" of an original document has a raised seal that identifies the state and county in which it originated or is stored.)

3. Temporary Licenses

If the supplier submits a temporary license, the contractor shall note the expiration date in PECOS. Should the supplier fail to submit the permanent license after the temporary license expiration date, the contractor shall initiate revocation procedures. (A temporary permit – one in which the applicant is not yet fully licensed and must complete a specified number of hours of practice to obtain the license – is not acceptable.)

4. Revoked/Suspended Licenses

If the applicant had a previously revoked or suspended license reinstated, the applicant must submit a copy of the reinstatement notice with the application.

5. License Expiration/Revocation Dates for Non-Certified Suppliers

For expired licenses, the contractor shall enter in PECOS the day after the expiration as the expiration date. For revoked and suspended licenses, the contractor shall enter in PECOS the revocation date (not the day after) as the expiration date. (See section 10.6.19(T) of this chapter for special instructions related to periodic license reviews.)

6. Interstate License Compacts

A new trend in medicine has arisen involving interstate license compacts. While physician compacts streamline the licensure process for physicians who want to practice in multiple states, a separate license from each state in which the physician intends to practice is still issued (if all requirements are met). CMS will continue to rely on the license issued by the state medical board to help confirm compliance with federal requirements.

In a similar vein, certain non-physician practitioner (NPP) compacts allow the NPP to work in a compact member state (other than their home state) without going through the normal process for licensure in the remote state. NPPs working under the authorization of such a compact must meet both the licensure requirements outlined in the primary state of residence and those established by the compact laws adopted by the legislatures of the interstate compact states.

At present, there are interstate compacts involving physicians, physical therapists, occupational therapists, speech language pathologists, and psychologists (though none for nurse practitioners). More are possible.

Licenses obtained through an interstate license compact for the above supplier types shall be treated as valid, full licenses for the purposes of meeting federal requirements. The contractor shall thus accept Form CMS-855I applications from applicants reporting a license obtained via an interstate license compact. In addition, the contractor shall attempt to verify the interstate license obtained through the compact using the state licensing board website(s) or compact website (if one exists); if neither technique can confirm the interstate license, the contractor shall request documentation from the supplier that validates said data.

B. Correspondence Address, Medical Record Correspondence Address, and Telephone Number

1. Correspondence Address

The correspondence address must be one where the contractor can directly contact the applicant to resolve any issues once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

The contractor need not verify the correspondence address.

2. Medical Records Correspondence Address

The medical records correspondence address must be one where the contractor can directly contact the applicant regarding medical records once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

Note that: (1) the contractor need not verify the medical records correspondence address; and (2) the medical records correspondence address does not apply to individuals reassigning all benefits.

3. Telephone Number

The supplier may list any telephone number he/she wishes as the correspondence or medical record correspondence phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence or medical record telephone number and it is required for the application submission, the contractor shall develop for this information – preferably via the PCV, e-mail, or fax. The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier. The contractor need not verify the telephone number.

C. E-mail Addresses

An e-mail address listed on the application can be a generic e-mail address. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier.

D. Specialties

A physician must indicate his/her supplier specialty via a checkmark, an "X," or other symbol; if the physician has more than one specialty, he/she must indicate these specialties, showing "P" for primary and "S" for secondary. (Non-physician practitioners must indicate their supplier type.)

The contractor shall verify that any supplier identifying a secondary specialty on the Form CMS-855I application has the appropriate medical license. The contractor shall validate the license using the state's medical license website. If an active license is not found, the contractor shall

develop via telephone, fax, email, or mail to confirm the supplier's intent and to obtain a copy of the license, if applicable.

The contractor shall deny the application if the individual fails to meet the requirements of his/her physician specialty (primary and/or secondary) or supplier type.

Notwithstanding the foregoing instructions in this subsection (D), if a Form CMS-855I enrollment application is submitted to report a primary or secondary specialty change, the contractor shall not contact the physician, practitioner, or contact person directly to confirm either the change itself or the individual's intent to change his/her specialty.

E. Education

1. Non-Physician Practitioners - The contractor shall verify all required educational information for non-physician practitioners. While the non-physician practitioner must meet all federal and state requirements, he/she need not provide documentation of courses or degrees taken to satisfy these requirements unless the contractor requests it. To the maximum extent possible, the contractor shall use means other than the practitioner's submission of documentation---such as a state or school web site---to validate the person's educational qualifications.

2. Physicians - A physician need not submit a copy of his/her degree unless the contractor requests it. To the maximum extent possible, the contractor shall use means other than the physician's submission of documentation---such as a state or school web site--to validate the person's educational status.

F. Relocation to a New State: License Reviews

When a practitioner submits a Form CMS-855I application to either (1) add a practice location in a new state or (2) relocate to a new state entirely, the contractor that received the application shall review state licensing board information for the "prior" state to determine:

- Whether the practitioner had his/her medical license revoked, suspended, or inactive (due to retirement, death, or voluntary surrender of license), or otherwise lost his/her license, and

- If the practitioner has indeed lost his or her medical license, whether he/she reported this information via the Form CMS-855I within the timeframe specified in 42 CFR § 424.520.

If the practitioner is currently enrolled and did not report the adverse action to Medicare in a timely manner, the contractor shall---unless another directive in this chapter instructs otherwise, such as section 10.6.6----revoke the practitioner's Medicare enrollment and establish the appropriate reenrollment bar length. If the practitioner is submitting an initial enrollment application (e.g., is moving to a new state and contractor jurisdiction) and did not report the adverse action in Section 3 of the CMS-855I, the contractor shall--- unless another directive in this chapter instructs otherwise---- deny the enrollment application.

10.3.1.3.3 – Section 3 (Final Adverse Legal Actions/Convictions) - Form CMS-855I

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

See section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).

10.3.1.3.4 – Section 4 (Business Information) - Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Practice Location Verification

The contractor shall verify that the practice locations listed on the application exist and are valid addresses with the United States Postal Service (USPS). PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS Store, mailboxes, etc.), or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry. To reiterate: the practice location address in the Practice Location Information section must be a valid address with USPS; addresses entered in PECOS are verified via computer software to determine if they are valid and deliverable.

Each practice location is to be verified. However, the contractor shall not call the practice locations (or the contact person listed on the application) to validate them. The verification means described in the previous paragraph (and, if applicable to the provider/supplier type, a site visit) shall instead be used. Only if development is needed to confirm the location (e.g., USPS cannot validate the location) may the contractor telephone the location or contact person.

Any supplier submitting a Form CMS-855I application must submit the 9-digit ZIP Code for each practice location listed.

If the “Business Structure Information” checkboxes in Section 4A are blank, the contractor can confirm the information via the PCV, e-mail, or fax.

A practitioner who only renders services in patients' homes (i.e., house calls) must supply his/her home address in the Practice Location Information section. In addition, if a practitioner renders services in a retirement or assisted living community, the Practice Location Information section must include the name and address of that community. In either case, the contractor shall verify that the address is a physical address. Post office boxes and drop boxes are not acceptable.

If the physician or non-physician practitioner uses his/her home address as his/her practice location and exclusively performs services in patients’ homes, nursing homes, etc., no site visit is necessary.

If an individual practitioner (1) is adding a practice location and (2) is normally required to complete a questionnaire in the Personal Identifying Information section of the Form CMS-855I

specific to its supplier type (i.e., physical therapists), the person must submit an updated questionnaire to incorporate services rendered at the new location.

For suppliers paid via the Multi-Carrier System (MCS)--and except as otherwise stated in section 10.3--the practice location name entered in PECOS shall be the legal business name.

B. Telephone Number Verification

The contractor need not verify the supplier's telephone number listed on the application, though the supplier must report one. If the supplier does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

C. Unintended Changes

Unless CMS specifies otherwise, any change in the supplier's phone number or address that the supplier did not cause (i.e., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-855I.

D. Remittance Notices/Special Payments Mailing Address section

The "special payment" address may only be one of the following:

- One of the supplier's practice locations
- A P.O. Box
- A Lockbox. (The contractor shall request additional information if it has any reason to suspect that the arrangement---at least with respect to any special payments that might be made---may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.)
- The supplier's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.
- Correspondence address

If neither box in this section is checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the "special payments" address is the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in the Remittance Notices/Special Payments Mailing Address section must be completed via the Form CMS-855I.

E. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the supplier's "special payment" address (Business Information of the Form CMS-855I) or EFT information has changed. The supplier should submit a Form CMS-855I to change this address; if the supplier does not have an established enrollment record in PECOS, it must complete an entire Form CMS-855I and Form CMS-588. The Durable Medical Equipment MAC is responsible for obtaining, updating, and processing Form CMS-588 changes.

In situations where a supplier is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the supplier to complete the "special payment" address section of the Form CMS-855I and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

F. EFT

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the supplier has completed and signed the Form CMS-588 and shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

If an enrolled supplier that currently receives paper checks submits a Form CMS-855I change request – no matter what the change involves – the supplier must also submit:

- A Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.

- The contractor shall also verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

(Once a supplier changes its method of payment from paper checks to EFT, it must continue using EFT. A supplier cannot switch from EFT to paper checks.)

G. Solely-Owned Organizations

1. Paper Applications

All pertinent data for solely-owned organizations can be furnished via the Form CMS-855I alone. The contractor, however, shall require the supplier to submit a Form CMS-855B and CMS-855I if, during the verification process, it discovers that the supplier is not a solely-owned organization. (**NOTE**: A solely-owned supplier type that normally completes the Form CMS-855B to enroll in Medicare must still do so. For example, a solely-owned LLC that is an ambulance company must complete the Form CMS-855B even though the Practice Location Information/Sole Proprietor/Sole Proprietorship section makes mention of solely-owned LLCs.

Use of the Practice Location Information section of the Form CMS-855I is limited to suppliers that perform physician or practitioner services.)

(Sole proprietorships need not complete the Business Information portions of Section 4 of the Form CMS-855I. Per definition, a sole proprietorship is not a corporation, professional association, etc. Do not confuse a sole proprietor with a physician whose business is that of a corporation, LLC, etc., of which he/she is the sole owner.)

In the Business Information section, the supplier may list a type of business organization other than a professional corporation, a professional association, or a limited liability company (e.g., closely-held corporation). This is acceptable so long as that business type is recognized by the state in which the supplier is located.

The contractor shall verify all data furnished in the Business Information section (e.g., legal business name, TIN, adverse legal actions). If the Business Information section is left blank, the contractor may assume it does not pertain to the applicant.

A solely-owned physician or practitioner organization that utilizes the Business Information section to enroll in Medicare can generally submit change of information requests to Medicare via the Form CMS-855I. However, if the change involves data not captured on the Form CMS-855I, the change must be made on the applicable CMS form (e.g., Form CMS-855B).

H. Individual Reassignment/Affiliation Information

If the applicant indicates that he/she intends to render all or part of his/her services in a private practice, clinic/group, or any organization to which he/she would reassign benefits, the contractor shall ensure that the applicant (or the group or organization, as applicable) has completed Section 4(F)(1)/(2) of the Form CMS-855I for each party to which the applicant is reassigning benefits. The contractor shall also verify that each individual, clinic/group practice, or organization to which benefits are being reassigned is enrolled in Medicare. If it is not, the contractor shall enroll the individual, clinic/group practice, or organization prior to approving the reassignment.

See section 10.3.1.4 of this chapter for detailed instructions regarding the processing of reassignments.

I. Sole Proprietor Use of EIN

The practitioner may obtain a separate EIN if he/she wants to receive reassigned benefits as a sole proprietor.

J. NPI Information for Groups

If a reassignee is already established in PECOS (i.e., status of "approved" unless the Form CMS-855I is submitted for the purpose of revalidation), the reassignor need not submit the reassignee's NPI in Section 4(F) of the Form CMS-855I.

K. Out-of-State Practice Locations

Except as stated otherwise in section 10.3 or in another CMS directive, if a supplier is adding a practice location in another state, a separate, initial Form CMS-855I enrollment application is required for that location even if:

- The location is part of the same organization (e.g., a solely-owned corporation),
- The location has the same tax identification number (TIN) and legal business name (LBN), and
- The location is in the same contractor jurisdiction.

To illustrate, suppose the contractor's jurisdiction consists of States X, Y, and Z. Dr. Jones, a sole proprietor, is enrolled in State X with 2 locations. He wants to add a third location in State Y under his social security number and his sole proprietorship's employer identification number. A separate, initial Form CMS-855I application is required for the State Y location.

10.3.1.3.5 - Sections 6, 8, 12, 13, and 14 - Form CMS-855I

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Except as otherwise stated, the PECOS policies in section 10.3 supersede those in sections 10.6.7 et seq., 10.6.8, and 10.6.9 (e.g., communicating with the provider via the PCV.)

Section 6 - See section 10.6.7 et seq. of this chapter for information concerning managing individuals and organizations.

Section 8 - See section 10.6.8 of this chapter for information concerning billing agencies. (Note that if the telephone number in this section is blank, the number can be verified with the supplier via telephone, the PCV, e-mail, or fax. If the entire section is blank (including the check box), no additional development is needed.)

Section 12 – See the Supporting Documents section of the Form CMS-855I for information concerning supporting documents.

Section 13 - Contact Persons

- If this section is completely blank, the contractor need not develop for this information and can simply contact the physician/practitioner.
- If the "Contact the individual listed in Section 2A" checkbox in Section 13 is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor can either: (1) develop for this information via telephone, the PCV, e-mail, or fax; or (2) contact the physician/practitioner.

See section 10.6.9 of this chapter for more information concerning the Contact Persons section of the Form CMS-855I.

Section 14 - Penalties for Falsifying Information

See the Penalties for Falsifying Information section of the Form CMS-855I for an explanation of penalties for deliberately furnishing false information in this application to gain or maintain Medicare enrollment.

10.3.1.3.6 - Section 15 (Certification Statement) - Form CMS-855I
(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Applicability and Format

Unless otherwise specified, the instructions in this section 10.3.1.3.6 apply to (1) signatures on the paper Form CMS-855I and (2) electronic signatures.

For paper applications, valid signatures include handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options established via software, such as Adobe). For web applications, electronic signatures are required; the contractor can contact its PEOG BFL for questions regarding electronic signatures.

B. Signatories

The enrolling or enrolled physician or non-physician practitioner is the only person who can sign the Form CMS-855I. (This applies to initial enrollments, changes of information, reactivations, revalidations, etc.). This includes solely-owned entities listed in the Business Information section of Section 4 of the Form CMS-855I. A physician or non-physician practitioner may not delegate the authority to sign the Form CMS-855I on his/her behalf to any other person. (In the case of death, however, an executor of the estate may sign on behalf of the deceased supplier, though this only applies to change of information applications.)

C. Paper Submissions

A signed certification statement must accompany the paper Form CMS-855I application. If the supplier submits an invalid certification statement or fails to submit a certification statement at all, the contractor shall still proceed with processing the application. An appropriate certification statement shall be solicited as part of the development process – preferably via the PCV, e-mail, or fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application; (d) signed by someone other than the physician or non-physician practitioner (except as noted in section 10.3.1.3.6(B)); (e) missing; or (f) stamped. The contractor shall send one development request to include a list of all of the missing required data/documentation, including the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish the missing information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested it.

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information.

(ii) The certification statement may be returned via scanned email or fax.

(iii) Signature dates cannot be more than 120 days prior to the receipt date of the application.

(iv) The contractor need not compare the supplier's signature with one already on file for that person to ensure it is the same individual.

(v) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

D. PECOS Submissions

If the supplier submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via the PCV, e-mail or fax. (This includes certification statements that are: signed by someone other than the physician or non-physician practitioner (except as noted in section 10.3.1.3.6(B)). The contractor shall send one development request to include a list of all of the data/documentation to be furnished or clarified, including, as applicable, the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish said data/documentation within 30 calendar days from the date the contractor requested the missing information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall (a) begin processing the application upon receipt via PECOS, (b) perform all required manual validations, and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 above and all other applicable instructions in this chapter.

(ii) The contractor need not compare the supplier's signature with one already on file for that person to ensure it is the same individual.

(iii) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

E. Certification Statement Development

The supplier must submit a newly signed certification statement as part of a development request as follows:

(i) Paper applications: Via scanned e-mail, fax, or mail. (Only the actual signature page is required; the additional page containing the certification terms need not be submitted. This also applies to the supplier's initial submission of a certification statement; such instances require the submission of only the signature page and not the certification terms.)

(ii) Web applications – Via electronic signature.

F. Privacy Statement

All information collected on the Form CMS-855I shall be entered into PECOS. The Privacy Act permits CMS to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." CMS will only release PECOS information that can be associated with an individual as provided for under Section III "Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. CMS will only collect the minimum personal data necessary to achieve the purpose of PECOS. To view the routine uses in their entirety, go to: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0532-PECOS.pdf.

10.3.1.3.7 - Additional Processing Information and Alternatives – Form CMS-855I

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Processing a Form CMS-855I Ownership Change of Information Application

When a sole owner practitioner has sold his/her group to another individual practitioner and the EIN remains unchanged, the contractor shall process the transaction as a change of information via the Form CMS-855I to change the group's owner. In doing so, the contractor shall:

(i) Verify that the EIN is solely owned by the new owner.

(ii) Make no change to the PTAN or effective date.

(iii) If applicable, require the prior sole owner individual to submit a voluntary termination application to terminate their individual enrollment/reassignment.

B. Unsolicited Additional Information

If the supplier submits missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information that a supplier submits prior to the date the contractor finishes processing a previously submitted change request shall be processed as a separate change request rather than an update to the original change request. The contractor may process both changes simultaneously, but the change that was submitted first shall be processed to completion prior to the second one being processed to completion.

C. Processing Alternatives

As stated in section 10.3, some of the application data elements and verification procedures that have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in section 10.3 and sections 10.3.1.3 through 10.3.1.3.6.

1. Information Disclosed Elsewhere

If a data element on the supplier's Form CMS-855I application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, the contractor need not obtain the missing data via an updated Form CMS-855I page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-855I, even if the data is identified elsewhere on the form or in the supporting documentation:

a. Except as otherwise stated in section 10.6.6 of this chapter, any final adverse action data requested in sections 3, 4A, and 6B of the Form CMS-855I

b Legal business names (LBN) or legal names (Note: If an application is submitted with a valid NPI-PTAN combination but (1) the LBN field is blank, (2) an incomplete or inaccurate LBN is submitted, or (3) the applicant includes a DBA name in the Business Information section of the Form CMS-855I --- and the contractor can confirm the correct LBN based on the NPI-PTAN combination provided, the contractor need not develop. (This also applies to the Employer's Name for PAs in the Personal Identifying Information (PA Information) section of the Form CMS-855I).)

c. Tax identification numbers (TIN)

d. NPI-legacy number combinations in the Business Information section of the Form CMS-855I. (The contractor may use the shared systems, PECOS, or its provider files as a resource to determine the PTAN or NPI before developing with the supplier.)

e. Practitioner type in the Personal Identifying Information section of the Form CMS-855I

If the supporting documentation currently exists in the supplier's file, the supplier need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Unless stated otherwise in this chapter or another CMS directive, documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative. Also, the contractor shall document in PECOS that the missing information was found elsewhere in the enrollment package. (This excludes information that must be verified at the current point in time (i.e., a license without a primary source verification method).) In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

2. Licenses

If the supplier is required to submit a copy of a particular professional or business license, certification, registration, or degree but fails to do so, the contractor need not obtain such documentation from the supplier if the contractor can verify the information independently. This can be done by: (1) reviewing and printing confirming pages from the applicable state, professional, or school web site; (2) requesting and receiving from the appropriate state, professional, or educational body written confirmation of the supplier's status therewith; or (3) utilizing another third-party verification source. Similarly, if the supplier submits a copy of the applicable license, certification, registration, or degree but fails to complete the applicable section of the form, the section need not be completed if the data in question can be verified on the license/certification itself or via any of the three mechanisms described above.

(The above-referenced written confirmation of the supplier's status can be in the form of a letter, fax, or e-mail, but it must be in writing. Documentation of a verbal conversation between the contractor and the body in question does not qualify as appropriate confirmation.)

This exception only applies to documents that traditionally fall within the category of licenses, registrations, certifications, or degrees. It is inapplicable to items such as adverse action documentation, etc. Furthermore, the exception is moot in cases where the state does not require a particular license/certification.

3. Drug Enforcement Agency Certificates (DEA)

DEA certificates are not required. If the applicable DEA certificate is not furnished or the applicable Form CMS-855I section is blank, no further development is needed.

4. City, State, and ZIP Code

If an address (e.g., correspondence address, practice location) lacks a city, state, or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

5. Inapplicable Questions

The supplier need not check "no" for questions that obviously do not apply to its supplier type. For instance, a nurse practitioner need not complete the Personal Identifying Information (Resident Information) section of the Form CMS-855I.

6. Additional Alternatives

(i) If blank, the "Type of Other Name" and "Gender" can be captured orally.

(ii) If the contractor is aware that a particular state does not require licensure/certification and the "Not Applicable" boxes are not checked in the Personal Identifying Information section, no further development is needed.

(iii) Personal Identifying Information (Physician Specialty) section - If the supplier uses a checkmark, an "X," or other symbol to identify his/her primary and secondary specialties (as opposed to a "P" or "S"), no additional development is needed.

(iv) When processing a non-physician practitioner's (NPP) application, the contractor need not automatically request a copy of the NPP's degree or diploma (if it is not submitted) if his/her education can be verified through other authorized means. Requesting a copy of the degree or diploma should only be done if educational information cannot otherwise be verified.

(v) Medical or Professional School and Year of Graduation – If the Form CMS-855I lacks the medical or professional school and/or the year of graduation but the information is disclosed in the supporting documentation submitted with the application or it already exists in PECOS, no further development is needed.

10.3.1.4 - Reassignment of Medicare Benefits Via the Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Background

Consistent with 42 CFR § 424.80(b)(1) and (b)(2) and Pub. 100-04, Chapter 1, sections 30.2.1(D) and (E) and 30.2.6 and 30.2.7, Medicare may pay: (1) a physician or other provider's or supplier's employer if the provider or supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services; or (2) an entity (i.e., a person, group, or facility) that is enrolled in the Medicare program for services furnished by a physician or other provider or supplier under a contractual arrangement with that entity. This means that Part A and Part B entities other than physician/practitioner group practices can receive reassigned benefits, assuming the requirements for a reassignment exception are otherwise met.

Reassignments of benefits are now facilitated via the Form CMS-855I. The Form CMS-855R has been discontinued.

B. General Reassignor Policies

An individual who renders Medicare Part B services and seeks to reassign his/her benefits to an eligible entity should complete Sections 4(F)(1) and (2) of the Form CMS-855I for each party eligible to receive reassigned benefits; the individual must be enrolled in Medicare as a physician/practitioner prior to reassigning his/her benefits. The applicable sections of the Form CMS-855I (e.g., Section 1(A) (Reason for Submittal); Section 1(B) (Reassignment of Benefits checkbox); Sections 4(F)(1) and (2); Section 15; etc.) must also be completed for any individual who is adding, terminating, changing an existing reassignment. (Note that Section 4(F)(3) is optional.)

The individual can report multiple new, changed, or terminated reassignments to parties with the same or different employer identification numbers (EINs) on a single Form CMS-855I by submitting separate Section 4(F)s and Section 15(C)s with the appropriate reassignee signatures. (For instance, if a physician is reassigning to Groups A, B, and C, an authorized/delegated official of A, B, and C, respectively, must sign a separate Section 15(C).) The contractor shall

issue one approval letter using the applicable model letter in sections 10.7.6(D) and 10.7.6(M) of chapter 10.

For reassignment terminations, the effective date of termination as indicated on the Form CMS-855I is the day after the effective date of termination. Payment will no longer be made to the reassignee the day after the termination effective date. To illustrate, suppose a physician submits a Form CMS-855I to terminate a reassignment to a group. She lists June 30, 2025, as the termination date. The termination effective date listed in PECOS and any correspondence to the supplier should be July 1, 2025.

There could be rare situations where an unenrolled individual seeks to reassign his/her benefits and submits only Section 4(F) of the Form CMS-855I. The contractor in this situation shall develop for an initial enrollment application from the individual.

The contractor need not verify whether the reassigning individual is a W-2 employee or a 1099 contractor.

Regarding reassignment and revoked or deceased physicians, see section 10.6.17(G)(1) of this chapter.

C. Policies Concerning Reassignees

1. Site of Service

Per Pub. 100-04, chapter 1, section 30.2.7, a reassignment of benefits to any eligible party is permitted regardless of where the service was rendered or whether the party owns or leases that location. As such, the contractor need not verify the reassignee's ownership or leasing arrangement with respect to the reassignment.

2. Organization/Group Receiving the Reassigned Benefits

The most common reassignment situation is a physician/practitioner who reassigns his/her benefits to a physician/practitioner group. Here, the reassignee's authorized or delegated official must sign Section 15(C) of the reassignor's Form CMS-855I.

3. Individual Receiving Reassigned Benefits

An individual can receive reassigned benefits. This can occur, for instance, when a physician/practitioner reassigns his/her benefits to a physician/practitioner who is either (1) a sole proprietor or (2) the sole owner of an entity listed in the Business Information section of the Form CMS-855I. Here, the only required forms are separate Form CMS-855Is from the reassignor and the reassignee. (No Form CMS-855B or Form CMS-855A is involved.) The reassignee must sign Section 15(C) of the reassignor's Form CMS-855I. (Note that Section 15(C) applies to all reassignees, regardless of whether they are organizations or individuals. In the former case, the organization's authorized/delegated official must sign Section 15(C); with the latter, the individual reassignee must sign.)

The contractor shall follow the instructions in Pub. 100-04, Chapter 1, sections 30.2 – 30.2.16 to ensure that the reassignee is indeed eligible to receive reassigned benefits.

4. Additional Information

If the reassignee is not enrolled in Medicare, said party must complete, as applicable, an initial Form CMS-855B, Form CMS-855A, or Form CMS-855I.

Benefits are reassigned to a provider or supplier, not to the provider/supplier's practice location(s). As such, the reassignor need not update his/her reassignment data on the Form CMS-855I each time the reassignee adds a practice location.

When a group practice adds a new practice location, each physician/practitioner who reassigns to the group and wants to bill from this new location must have a new PTAN issued to him/her if the group is issued a new PTAN. (The group will only be issued a new PTAN if the new location is in a separate fee locality.)

D. Additional Signature Policies

1. Who Must Sign

For initial/new reassignments, both the reassignor and reassignee (or an authorized/delegated official of the latter) must sign, respectively, Section 15(B) and (C) of the reassignor's Form CMS-855I. If either required signature is missing, the contractor shall develop for it.

For changes in reassignment data or for reassignment terminations (and as similar situations were handled with the Form CMS-855R), only the reassignor or reassignee must submit the termination or applicable changed information in Section 4(F) and sign Section 15(B) or (C) (as applicable).

2. Official On/Not on File

An authorized/delegated official who signs Section 15(C) of the Form CMS-855I must be currently on file with the contractor as such. If this is a new enrollment --- with a joint submission of the Form(s) CMS-855A or CMS 855B and Form CMS-855I --- the person must be listed on the Form CMS-855A or Form CMS-855B as an authorized/delegated official.

There may be situations where a Form CMS-855I is submitted and the reassignee is already enrolled in Medicare via the Form CMS-855B. However, the authorized/delegated official is not on file. In this case, the contractor shall develop for a Form(s) CMS-855A or CMS-855B change request that adds the new authorized/delegated official.

3. Development Needed

If the contractor must develop for information in Section 4(F)(1) or (2), the following apply:

(i) Initial reassignments (as part of an initial Form CMS-855I or a Form CMS-855I change of information that adds a new reassignment): Both the reassignor and reassignee (or, for entities,

an authorized/delegated official thereof) must sign any certification statement that must accompany the reassignor's response.

(ii) All other transactions – Only the reassignor or reassignee need sign any required certification statement.

4. Other Signature Policies

The contractor shall follow all other applicable signature policies (e.g., form of signature) outlined in section 10.3.1.3.6 of this chapter.

5. Processing Alternatives

As applicable, the contractor may apply the processing alternatives identified in section 10.3.1.3.7 to the Section 4(F) data.

E. Inter-Jurisdictional Reassignments

If a reassignor is reassigning their benefits to a reassignee located in another contractor jurisdiction (a permissible practice), the principles in this section 10.3.1.4(E) apply unless another CMS directive states otherwise.

1. The reassignor must be properly licensed or otherwise authorized to perform services in the state in which he/she has his/her practice location. The practice location can be an office or even the individual's home (for example, a physician interprets test results in his home for an independent diagnostic testing facility).

2. The reassignor need not – pursuant to the reassignment - enroll in the reassignee's contractor jurisdiction nor be licensed/authorized to practice in the reassignee's state. If the reassignor will be performing services within the reassignee's state, the reassignor must enroll with the contractor for (and be licensed/authorized to practice in) that state.

3. The reassignee must enroll in the contractor jurisdictions in which (1) it has its own practice location(s), and (2) the reassignor has his or her practice location(s). In Case (2), the reassignee:

(i) Shall identify the reassignor's practice location as a practice location on its Form CMS-855B or Form CMS-855I.

(ii) Shall select the practice location type as "Other health care facility" and specify "Telemedicine location" in the Practice Location Information of its Form CMS-855.

(iii) Need not be licensed/authorized to perform services in the reassignor's state.

To illustrate, suppose Dr. Smith is in Contractor Jurisdiction X and is reassigning his benefits to Jones Medical Group in Contractor Jurisdiction Y. Jones must enroll with X and with Y. Jones need not be licensed/authorized to perform services in Dr. Smith's state. However, in the

Practice Location Information section of the Form CMS- 855B it submits to X, Jones must list Dr. Smith's location as its practice location.

F. Reassignment to CAHs

Reassignment to a Part A provider or supplier might occur when: (1) a physician or practitioner reassigns benefits to a hospital, skilled nursing facility, or critical access hospital billing under Method II (CAH II); or (2) a nurse practitioner reassigns to a CAH II.

If the entity receiving the reassigned benefits is not a CAH II, it must enroll with the contractor via a Form CMS-855B, and the physician/practitioner reassigning benefits must complete and submit a Form CMS-855I.

If the entity receiving the reassigned benefits is a CAH II, the entity need not complete a separate Form CMS-855B to receive reassigned benefits. The physician/practitioner can reassign benefits directly to the CAH II's Part A enrollment. The distinction between CAHs billing Method I vs. Method II only applies to outpatient services. It does not apply to inpatient services.

Under Method I:

- The CAH bills for facility services
- The physicians/practitioners bill separately for their professional services

Under Method II:

- The CAH bills for facility services
- If a physician/practitioner has reassigned his/her benefits to the CAH, the CAH bills for that particular physician's/practitioner's professional service
- If a CAH has elected Method II, the physician/practitioner need not reassign his/her benefits to the CAH. For those physicians/practitioners who do not reassign their benefits to the CAH, the CAH only bills for facility services and the physicians/practitioners separately bill for their professional services (akin to Method I).

Although physicians and non-physician practitioners are not required to reassign their benefits to a CAH that bills Method II, doing so allows them to participate in the Electronic Health Records (EHR) Incentive Program for Eligible Professionals (EPs).

In this scenario, the Form CMS-855I shall be submitted to the Part B MAC and the Form CMS-855A submitted to the Part A MAC. The Part B MAC is responsible for reassigning the individual to the Part A entity.

The reassignment to the Part A entity shall only occur if the Form CMS-855A for the CAH II has been finalized. This can be determined by viewing PECOS to identify if an approved enrollment exists for the CAH II. If one does not, the Part B MAC shall return the Form CMS-855I to the

provider on the ground that it is inapplicable to the transaction in question (i.e., the Form CMS-855A has not been finalized). If an enrollment record exists but is pending state/SOG review, the Part B MAC shall contact the Part A MAC to determine if state/SOG Location (as applicable) approval has been received but not yet updated in PECOS prior to returning the applications.

G. Reassignments Related to Revoked or Deactivated Reassignee

The contractor shall end-date in PECOS all reassignment associations and the associated Provider Transaction Access Numbers (PTANs) when revoking or deactivating an individual or organization (reassignee) that is receiving reassigned benefits from an individual practitioner. The end-date shall be the same as the effective date of the revocation or deactivation; this will ensure the appropriate end-date in the Multi-Carrier System (MCS) and prevent improper use of those PTANs. However, the contractor shall not deactivate the individual practitioner's (reassignor's) enrollment record even if (1) the reassigned PTAN is the only PTAN on the individual's enrollment record and/or (2) no other active locations exist (private practice locations or reassignments); the contractor shall allow the practitioner's/reassignor's enrollment record to remain in an approved status.

When sending a deactivation, revocation, or voluntary withdrawal letter to the deactivated or revoked non-certified Part B supplier, said letter shall include the following language: "Please notify all physician assistants and/or group members who reassign benefits to your organization that, in accordance with 42 CFR §424.540(a)(2), their Medicare enrollment status may be deactivated if they fail to update their enrollment record within 90 calendar days."

H. Group and Reassignment Reactivation

If a group practice submits a reactivation application after being deactivated for non-response to a revalidation request, the contractor shall reactivate the group's reassignments when the group's reactivation application has been approved; Form CMS-855I applications for the reassignments are not required. The effective dates assigned to the reassigned providers shall align with the group's effective date per existing reactivation instructions. (This section 10.3.1.4(H) only applies to deactivations based on a non-response to a revalidation request.)

I. Additional Information

The contractor:

- Shall follow this chapter's existing instructions (and all other applicable CMS guidance) for validating information furnished by a physician/practitioner on the Form CMS-855I, including any reassignment data in Sections 4(F)(1) and (2).

- Shall follow the instructions in section 10.6.2 of this chapter regarding the application of effective dates.

10.3.1.5 – Form CMS-855O – Medicare Enrollment Application for Eligible Ordering and Certifying Physicians, and other Eligible Professionals

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This form is used by physicians and other eligible professionals who wish to enroll in Medicare solely for the purpose of ordering and certifying the services/items described in 42 CFR § 424.507(a) and (b). These physicians and other eligible professionals do not and will not send claims to a contractor for the services they furnish. In addition, suppliers who have opted out of Medicare are not permitted to enroll via the Form CMS-855O for purposes of ordering or certifying.

The physician/other eligible professional need not submit a Form CMS-460, a Form CMS-588, or an application fee with his or her Form CMS-855O.

10.3.1.5.1 – Sections 1 through 7 of the Form CMS-855O

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Basic Information (Section 1)

In this section, the ordering or certifying individual indicates the reason for the application submittal. Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the ordering or certifying individual may only check one reason for submittal.

With the exception of the voluntary termination checkbox---and except as stated in section 10.6.1.3 of this chapter---any blank data/checkboxes in the Basic Information section can be verified via any means (e.g., e-mail, telephone, fax).

B. Identifying Information (Section 2)

1. License/Certification/Registration Information

The extent to which the ordering or certifying individual must complete the licensure, certification, or accreditation information depends upon the individual's supplier type. Requirements will vary by supplier type and by location; for instance, some states may require a particular supplier type to be "certified" but not "licensed," or vice versa. In general, individuals will have licensure information to submit. However, a "License Not Applicable" check box is furnished for cases where a state does not require licensure or, for unlicensed residents, if the application submission includes either:

(a) A residency contract signed and dated by both an official of the institution and the resident physician; or
(b) A letter on institution letterhead signed and dated by an official of the institution that (i) confirms the applicant's status as a resident physician and (ii) contains, at a minimum, the applicant's name.

The only licenses that must be submitted with the application are those required by Medicare or the state to function as the ordering or certifying supplier type in question. Licenses and permits not of a medical nature are not required. In addition, cases might arise where the individual need

not be licensed in a particular state at all; however, the contractor shall still ensure that the supplier meets all applicable state and Medicare requirements.

If the supplier is required to submit a copy of a particular professional or business license, certification, registration, or degree but fails to do so, the contractor need not obtain such documentation from the supplier if the contractor can verify the information independently. This can be done by: (1) reviewing and printing confirming pages from the applicable state, professional, or school web site; (2) requesting and receiving from the appropriate state, professional, or educational body written confirmation of the supplier's status therewith; or (3) utilizing another third-party verification source. Likewise, if the supplier submits a copy of the applicable license, certification, registration, or degree but fails to complete the applicable section of the form, the section need not be completed if the data in question can be verified on the license/certification itself or via any of the three mechanisms above.

2. Correspondence Address and Telephone Number

The correspondence address must be one at which the contractor can directly contact the applicant to resolve any issues once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, chain home office, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address. The contractor need not verify the correspondence address.

The applicant may list any telephone number he/she wishes as the correspondence phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence telephone number and the latter is required for the application submission, the contractor shall develop for this information – preferably via the PCV, e-mail, or fax. The contractor shall accept a particular phone number if it has no reason to suspect it does not belong to or is not somehow associated with the supplier. The contractor need not verify the telephone number.

3. E-mail Addresses

An e-mail address listed on the application can be a generic one. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect it does not belong to or is not somehow associated with the supplier.

4. Drug Enforcement Agency (DEA)

DEA certificates need not be submitted if the applicable DEA information was furnished on the Form CMS-855. Likewise, if the aforementioned certificates are furnished but the applicable Form CMS-855 sections are blank, no further development is needed.

C. Final Adverse Legal Actions/Convictions (Section 3)

See section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).

D. Medical Specialty Information (Section 4)

The contractor shall validate that any supplier identifying a primary specialty on the Form CMS-855O has the appropriate medical license. The contractor shall validate the license using the state's medical license website. If an active license is not found, the contractor shall develop via telephone, fax, the PCV, e-mail, or mail to confirm the supplier's intent and to obtain a copy of the license, if applicable.

E. Important Address Information (Section 5)

The address information furnished in the Important Address Information section of the Form CMS-855O helps the contractor contact the supplier directly, if necessary.

F. Contact Person Information (Section 6)

(See section 10.6.9 of this chapter for more information on contact persons. Except as otherwise stated, the PECOS policies in section 10.3 above supersede those in section 10.6.9.)

If Section 6 is completely blank, the contractor need not develop for this information and can simply contact the physician or practitioner.

There is no existing option on the Form CMS-855O form to delete a contact person. The contractor shall therefore accept end-dates of a contact person via phone, the PCV, e-mail, fax, or mail from the individual himself/herself or a current contact person on file. The contractor shall document in PECOS who requested the termination, how it was requested (email, phone or fax), and when it was requested. The addition of contact persons must still be reported via the Form CMS-855O.

G. Penalties for Falsifying Information (Section 7)

See the Penalties for Falsifying Information section of the Form CMS-855O for the penalties that apply to suppliers for deliberately furnishing false information on this application to gain or maintain Medicare enrollment.

10.3.1.5.2 – Section 8 (Certification Statement) - Form CMS-855O

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. General Policies

The enrolling or enrolled physician or other eligible professional is the only person who can sign the Form CMS-855O. This person cannot delegate the authority to sign the Form CMS-855O on his/her behalf to any other individual. This applies to initial enrollments, changes of information, reactivations, voluntary withdrawals, etc. (Note: In the case of death, an executor of the estate may sign on behalf of the deceased supplier. This situation would only apply to change of information applications.)

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, electronic signatures are required; the contractor may contact its PEOG BFL for questions regarding electronic signatures.

B. Paper Applications

A signed certification statement shall accompany the paper Form CMS-855O application. If the supplier submits an invalid certification statement or fails to submit any certification statement at all, the contractor shall still proceed with processing the application. An appropriate certification statement shall be solicited as part of the development process – preferably via the PCV, e-mail, or fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application); (d) signed by someone other than the physician or practitioner (except as otherwise noted in this section 10.3.1.5.2); (e) missing; or (f) stamped. The contractor shall send one development request to include a list of all of the missing required data/documentation, including the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish the missing information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the missing information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information.

(ii) The certification statement may be returned via scanned email or fax.

(iii) Signature dates cannot be more than 120 days prior to the receipt date of the application.

(iv) For paper applications that require development, the supplier's dated signature must be on the certification statement that is to be submitted within 30 days.

(v) For paper changes of information applications---and except as stated in section 10.3.1.5.2(A)--the contractor shall only accept a certification statement signed by the individual physician or practitioner.

(vi) The contractor need not compare the Form CMS-855O signature with the same person's signature on file to ensure it is the same individual.

(vii) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

C. PECOS Submissions

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall (a) begin processing the application upon receipt via PECOS; (b) perform all required manual validations; and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 and all other applicable instructions in this chapter.

(ii) If the supplier submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via the PCV, e-mail, or fax. (This includes certification statements that are signed by someone other than the physician or practitioner who signed the form (except as otherwise noted in this section 10.3.1.5.2(A)). The contractor shall send one development request to include a list of all of data/documentation to be furnished or clarified, including, as applicable, the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish said data/documentation within 30 calendar days from the date of the contractor's request.

(iii) For PECOS applications that require development, the supplier's dated signature must be on the certification statement to be sent in within 30 days.

(iv) For PECOS change of information applications, the contractor shall only accept a certification statement signed by the individual physician or practitioner.

(v) The contractor need not compare the Form CMS-855O signature with the same person's signature on file to ensure it is the same individual.

(vi) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

D. Certification Statement Development

Newly signed certification statements furnished per a development request must be submitted as follows:

(i) Paper applications -- Via scanned email, fax, or mail. Only the actual signature page is required; the provider need not submit the additional page containing the certification terms. (This also applies to the provider's initial submission of a certification statement. Such instances require the submission of only the signature page and not the certification terms.)

(ii) Web applications – Via electronic signature.

E. Privacy Statement

The Privacy Act permits CMS to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The CMS will only release PECOS information that can be associated with an individual as provided for under Section III "Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. CMS will only collect the minimum personal data necessary to achieve the purpose of PECOS. To view the routine uses in

their entirety go to: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0532-PECOS.pdf.

10.3.1.5.3 – Form CMS-855O Initial Applications and Change Requests

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The contractor shall follow all applicable instructions in section 10.3 when processing Form CMS-855O initial applications and change requests.

A. Processing Initial Form CMS-855O Submissions

1. Returns

Section 10.4.1.4.2 of this chapter (which reflects 42 CFR § 424.526) outlines the reasons for which the contractor may immediately return a Form CMS-855O. If the contractor determines that one or more of these reasons applies, it may return the form in accordance with the instructions outlined in that section.

2. Verification

Unless stated otherwise in this chapter or in another CMS directive, the contractor shall ensure that all information on the Form CMS-855O is verified. This includes, but is not limited to:

a. Verification of the individual's name, date of birth, social security number, and NPI.

b. Verification that the individual meets the requirements for his/her supplier type.

c. Verification that the individual is of a supplier type that can legally order or certify.

d. Reviewing the Medicare Exclusion Database (MED) and System for Award Management (SAM) to ensure that the individual is not excluded or debarred. (See section 10.6.6 of this chapter for additional adverse action verifications that may be required.)

If, at any time during the verification process, the contractor needs additional or clarifying information from the physician/eligible professional, it shall follow existing CMS instructions for obtaining said data (e.g., sending a development letter). The information must be furnished to the contractor within 30 calendar days of the contractor's request.

3. Disposition

Upon completion of its review of the form, the contractor shall approve, deny, or reject it.

a. Denial

Grounds for denial are as follows:

i. The supplier is not of a type that is eligible to use the Form CMS-855O.

ii. The supplier is not of a type that is eligible to order or certify items or services for Medicare beneficiaries.

iii. The supplier does not meet the licensure, certification, or educational requirements for his or her supplier type.

iv. The supplier is excluded per the MED and/or debarred per the SAM.

If the contractor believes that another ground for denial exists for a particular submission, it should contact its PEOG BFL for guidance.

b. Rejection

The Form CMS-855O may be rejected if the supplier fails to furnish all required information on the form within 30 calendar days of the contractor's request to do so. (This includes situations in which information was submitted but could not be verified.) The basis for rejection shall be 42 CFR § 424.525(a). (See section 4.1.4.3(A)(1) for more information on rejection bases.)

c. Denial or Rejection – PECOS and Letters

When denying or rejecting an initial Form CMS-855O, the contractor shall: (1) switch the PECOS record to a "denied" or "rejected" status (as applicable); and (2) send a letter to the supplier notifying him/her of the denial or rejection and the reason(s) for it. The letter shall follow the applicable letter formats described in section 10.7, et seq. Denial letters shall be sent via certified mail. Rejection letters shall be sent by mail, the PCV, or e-mail. (NOTE: A denial triggers appeal rights. A rejection does not.)

d. Approval

If the Form CMS-855O is approved, the contractor shall: (1) switch the PECOS record to an "approved" status, and (2) send a letter (via mail, the PCV, or e-mail) to the supplier notifying him/her of the approval. The letter shall follow the applicable format outlined in section 10.7.3 of this chapter.

4. Miscellaneous Policies

The contractor shall observe the following:

a. The supplier shall be treated as a non-participating supplier (or "non-par").

b. If the supplier is employed by the DVA, the DOD, or the IHS, he/she – for purposes of the Form CMS-855O - need only be licensed or certified in one state. Said state need not be the one in which the DVA or DOD office is located.

c. Nothing in this section 10.3.1.5.3(A) affects any existing CMS instructions regarding the processing of opt-out affidavits.

d. Suppliers cannot submit an abbreviated version of the Form CMS-855I in lieu of the Form CMS-855O.

e. Per 42 CFR § 424.522(b), the effective date of a Form CMS-855O enrollment shall be the date on which the contractor received the application if all other requirements are met.

f. If the supplier's Form CMS-855O has been approved and he/she later wants to obtain Medicare billing privileges, he or she must voluntarily withdraw his/her Form CMS-855O enrollment prior to receiving Medicare billing privileges. (The supplier must complete the Form CMS-855I in order to receive Medicare billing privileges.)

B. Processing Form CMS-855O Change of Information Requests

1. Receipt

Section 10.4.1.4.2 of this chapter outlines the reasons for which the contractor may immediately return a Form CMS-855O. If the contractor determines that one or more of these reasons applies, it may return the change request via the instructions outlined in that section.

Suppliers who are enrolled in Medicare via the Form CMS-855I may not report changes to their enrollment information via the Form CMS-855O. They must use the Form CMS-855I. Likewise, suppliers whose Form CMS-855O submissions have been approved must use the Form CMS-855O to report information changes; they cannot use the Form CMS-855I for this purpose.

2. Verification

Unless stated otherwise in this chapter or in another CMS directive, the contractor shall verify the new information that the supplier furnished on the Form CMS-855O. (This includes checking the supplier against the MED and the SAM.) If, at any time during the verification process, the contractor needs additional or clarifying information, it shall follow existing CMS instructions for obtaining said data (e.g., sending a developmental letter). The information must be furnished to the contractor within 30 calendar days of the contractor's request.

C. Disposition

Upon completion of its review of the change request, the contractor shall approve, deny, or reject the submission. The principal ground for denial will be that the new information was furnished but could not be verified. If the contractor believes this is the case or if another ground for denial exists with respect to a particular submission, it should contact its PEOG BFL for guidance.

The change request may be rejected if the supplier failed to furnish all required information on the form within 30 calendar days of the contractor's request to do so. The basis for rejection shall be 42 CFR § 424.525(a). (See section 4.1.4.3(A)(1) for more information on rejection bases.)

When denying or rejecting the change request, the contractor shall: (1) switch the PECOS record to a "denied" or "rejected" status (as applicable); and (2) send a letter (via mail, the PCV, or e-mail) to the supplier notifying him/her of the denial or rejection and the reason(s) for it.

If the change request is approved, the contractor shall (1) switch the PECOS record to an "approved" status and (2) send a letter (via mail, the PCV, or e-mail) to the supplier notifying him/her of the approval.

D. Relocation

Since the Form CMS-855O is a national enrollment, suppliers who relocate to another state need not disenroll in the current state and reenroll in the new state. The contractor that maintains the Form CMS-855O enrollment in PECOS is responsible for processing the change request, even if the supplier is relocating to a state outside of their jurisdiction. If any new licenses and/or certifications are obtained as a result of the supplier's relocation, the contractor shall ensure that the updated information is captured in the supplier's enrollment record.

This policy applies to any physician, non-physician practitioner, or resident who is enrolled via the Form CMS-855O.

10.3.1.5.4 – Form CMS-855O Processing Alternatives and Miscellaneous Policies

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Processing Alternatives

The alternatives in this section 10.3.1.5.4(A) are applicable to all sections of the Form CMS-855O, unless otherwise specified. As stated in section 10.3, however, some of the application data elements and verification procedures that have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in sections 10.3 through 10.3.1.5.3.

1. General Alternatives

(i) If blank, "Type of Other Name" and "Gender" can be captured orally.

(ii) If the contractor knows that a particular state does not require licensure/certification and the "Not Applicable" boxes are not checked in the Personal Identifying Information (License/ Certification/Registration Information) section, no further development is needed.

(iii) When processing a non-physician practitioner's (NPP) application, the contractor need not request a copy of the NPP's degree or diploma (if it is not submitted) if his/her education can be verified through other authorized means. Requesting a copy of the degree or diploma should only be done if educational information cannot otherwise be verified.

2. Information Disclosed Elsewhere

If a data element on the Form CMS-855O application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the

application, the contractor need not obtain the missing data via an updated Form CMS-855O page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-855O, even if the data is identified elsewhere on the form or in the supporting documentation:

(i) Except as otherwise stated in section 10.6.6 of this chapter, any final adverse action data requested in the Final Adverse Legal Actions section

(ii) Legal names

(iii) Tax identification number (TIN)

(iv) NPI-legacy number combinations in the Identifying Information section (if applicable) (Note: The contractor may use the shared systems, PECOS, or its provider files as a resource to determine the PTAN or NPI before developing with the supplier.)

(v) Data in the Basic Information section

If the supporting documentation currently exists in the supplier's file, the supplier need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative unless stated otherwise in this chapter or in another CMS directive. Also, the contractor shall document in PECOS that the missing information was found elsewhere in the enrollment package. (However, this excludes information that must be verified at the current point in time (i.e., a license without a primary source verification method)). In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

3. City, State, and ZIP Code

If a particular address lacks a city or state, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or Delivery Point Validation in PECOS.

4. Sectional Processing Alternatives

The processing alternatives in this section 10.3.1.5.4 are in addition to, and not in lieu of, all other processing alternatives in section 10.3.1.5, et seq.

B. Unsolicited Additional Information

If the supplier submits additional/missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information that a supplier submits prior to the date the contractor finishes processing a previously submitted change request constitutes a separate change request rather than an update to the original change

request. The contractor may process both changes simultaneously; however, the change that was submitted first shall be processed to completion prior to the second one being processed to completion.

C. Conversion from Form CMS-855O to Form CMS-855I – PECOS Requirements

Internet-based PECOS permits an individual supplier to convert his/her current Form CMS-855O application to a Form CMS-855I enrollment and vice versa. Such suppliers shall follow the current process for creating a new application. When PECOS detects existing approved enrollments, the supplier will be prompted to select from a list of those enrollments that will be used to pre-populate the information for the new application. The supplier must confirm that he/she wants to withdraw the existing enrollments before the new application may be submitted.

The enrollments to be withdrawn are displayed in a new section of the ADR in PECOS Administrative Interface (AI). The contractor shall review this information and take the appropriate action to voluntarily withdraw the enrollments listed. The contractor shall begin processing the Form CMS-855I enrollment but leave it in "In Review" status while withdrawing the other enrollments. (For paper applications, a logging and tracking (L&T) submittal reason of Voluntary Termination shall be used to withdraw the Form CMS-855O enrollment.) The effective date of the withdrawn enrollments shall be one day prior to the effective date of the Form CMS-855I enrollment. If the Form CMS-855O enrollment requiring withdrawal is outside of the contractor's jurisdiction, the contractor shall notify the other contractor via the PCV or email using the "Associate Profile Contact List," stating that the enrollment needs to be voluntarily withdrawn. The second contractor shall take action based on the email and retain the email as documentation.

If the supplier submits a paper Form CMS-855I and a current Form CMS-855O enrollment exists within the contractor jurisdiction, the contractor shall voluntarily withdraw the Form CMS-855O enrollment. If the current Form CMS-855O enrollment is outside of the contractor's jurisdiction, the contractor shall notify the other contractor via the PCV or e-mail (using the "Associate Profile Contact List") that the enrollment needs to be voluntary withdrawn. The second contractor shall take action based on the email and retain the email as documentation.

If the supplier submits a paper Form CMS-855O to voluntarily withdraw his/her enrollment as well as a paper Form CMS-855I to begin billing Medicare, the contractor shall not contact the supplier to confirm the submissions unless the contractor has reason to believe that what was submitted was not the supplier's intention. If it is determined that the supplier submitted applications to convert his/her existing Form CMS-855O enrollment into a Form CMS-855I enrollment in error (either via paper or PECOS), the contractor shall return the application (thus returning the enrollment record back to its previous state) because it is not needed and/or is inapplicable to the situation.

G. Form CMS-855O Processing Guide

Go to https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending to view the CMS-855O Processing Guide, which constitutes a general Form CMS-855O processing

guide for suppliers and contractors. The procedures described in the Guide, which include processing alternatives and processing instructions for the Form CMS-855O, take precedence over all other instructions in this chapter concerning the processing of Form CMS-855O applications.

10.3.1.5.5 – Form CMS-855O Revocations

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

If the contractor determines that grounds exist for revoking the supplier's Form CMS-855O enrollment, it shall:

(i) Switch the supplier's PECOS record to a "revoked" status

(ii) End-date the PECOS record

(iii) Send a letter via certified mail to the supplier stating that his/her Form CMS-855O enrollment has been revoked. The letter shall follow the format outlined in section 10.7.8 of this chapter.

Grounds for revoking the supplier's Form CMS-855O enrollment are as follows:

(i) The supplier is no longer of a type that is eligible to order or certify

(ii) The supplier no longer meets the licensure, certification, or educational requirements for his or her supplier type

(iii) The supplier is excluded per the MED and/or debarred per the SAM

For purposes of the Form CMS-855O only, the term "revocation" effectively means that:

(i) The supplier may no longer order or certify Medicare services based on his/her having completed the Form CMS-855O process.

(ii) If the supplier wishes to submit another Form CMS-855O, he/she must do so as an initial applicant.

There are appeal rights associated with the revocation of a supplier's Form CMS-855O enrollment.

10.3.1.6 – Form CMS-855S – Medicare Enrollment Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This application should be completed by DMEPOS suppliers. .

(Note that the Form CMS-855S section numbers in PECOS may not correspond precisely to those on the paper Form CMS-855S.)

10.3.1.6.1 – Sections 1 through 13 – Form CMS-855S

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Basic Information (Section 1)

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. Additionally, the supplier will identify its business and business location in this section.

B. Identifying Information (Section 2)

1. Locations and Addresses - Except for locations used only as warehouse and/or repair facilities, the supplier must submit a completed Form CMS-855S application for each physical location. Each address must be a street address as recorded by the USPS, and P.O. boxes will not be accepted.

2. Hours – The supplier must list their posted hours of operation as displayed at the aforementioned business location. Unless otherwise stated in this chapter or in another CMS directive, the supplier shall have a minimum of 30 hours of operation per week.

3. Unavoidable Phone Number or Address Changes – Unless CMS specifies otherwise, any change in the supplier's phone number or address that the supplier did not cause (e.g., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-855S.

See section 10.2.5 of this chapter for information on accreditation requirements.

C. Final Adverse Legal Actions (Section 3)

See section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the supplier via the PCV).

D. Important Address Information (Section 4)

See the Important Address Information section of the Form CMS-855S for more background on this matter.

E. Ownership Interest and/or Managing Control Information (Organizations) (Section 5)

See section 10.6.7 et seq. of this chapter for information concerning owning and managing organizations.

F. Ownership Interest and/or Managing Control Information (Individuals) (Section 6)

See section 10.6.7 et seq. of this chapter for information concerning owning and managing individuals.

G. Comprehensive Liability Insurance Information and Surety Bond Information (Section 7)

See section 10.2.5 of this chapter for information regarding comprehensive liability insurance and surety bond information.

H. Billing Agency Information (Section 8)

(See section 10.6.8 of this chapter for more information on billing agencies. Except as otherwise stated, the PECOS policies in section 10.3 above supersede those in section 10.6.8.)

If the telephone number in the Billing Agency Information section is blank, the number can be verified with the supplier by telephone, the PCV, e-mail, or fax. If the entire section is blank (including the check box), no additional development is necessary.

I. Supporting Documents (Section 12)

See the Supporting Documents section of the Form CMS-855S for information concerning supporting documents.

J. Contact Person Information (Section 13)

If this section is completely blank, the contractor need not develop for this information and can simply contact an authorized or delegated official.

If neither box is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor can either: (1) develop for this information by telephone, the PCV, e-mail, or fax; or (2) contact an authorized or delegated official.

There is no existing option on the Form CMS-855S to delete a contact person. The contractor shall therefore accept end-dates of a contact person via telephone, the PCV, e-mail, fax, or mail from the individual supplier, the authorized or delegated official, or a current contact person on file. The contractor shall document in PECOS who requested the termination, how it was requested (email, phone or fax), and when it was requested. The addition of contact persons must still be reported via the appropriate Form CMS-855S.

See section 10.6.9 of this chapter for more information on contact persons. Except as otherwise stated, the PECOS policies in section 10.3 above supersede those in section 10.6.9.

K. Penalties for Falsifying Information (Section 14)

See the Penalties for Falsifying Information section of the Form CMS-855S for an explanation of penalties that apply to suppliers for deliberately furnishing false information in this application to gain or maintain enrollment in the Medicare program.

10.3.1.6.2 – Authorized and Delegated Officials – Form CMS-855S

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. General Requirement

For Form CMS-855S initial applications, the certification statement must be signed and dated by an authorized official of the supplier. (See section 10.1.1 for a definition of "authorized official" and section 10.3.1.1.11 for detailed information on authorized officials.). For Form CMS-855S applications to change, update, and/or revalidate the supplier's Medicare enrollment data, the certification statement may be signed and dated by an authorized or delegated official of the supplier.

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, electronic signatures are required; the contractor may contact its PEOG BFL for questions regarding electronic signatures.

B. Qualifications

1. Authorized Officials

See section 10.3.1.1.11 for information regarding the requirements to be an authorized official.

2. Delegated Officials

A delegated official is an individual to whom an authorized official delegates the authority to report changes and updates to the supplier's enrollment record or to sign revalidation applications. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of the authorized official currently on file with Medicare.

The delegated official must be an individual with an "ownership or control interest" in (as that term is defined in §1124(a)(3) of the Social Security Act) or be a W-2 managing employee of the supplier. Section 1124(a)(3) defines an individual with an ownership or control interest as:

(i) A five percent direct or indirect owner of the supplier,

(ii) An officer or director of the supplier (if the supplier is a corporation), or

(iii) Someone with a partnership interest in the supplier if the supplier is a partnership

The delegated official must be a delegated official of the supplier, not of an owning organization, parent company, chain home office, or management company. One cannot use his/her status as a W-2 managing employee of the supplier's parent company, management company, or chain home office as a basis for his/her role as the supplier's delegated official.

Section 6 (Ownership Interest and/or Managing Control Information) of the Form CMS-855S must be completed for all delegated officials.

A delegated official has no authority to sign an initial application. However, as explained above, a delegated official may (i) sign a revalidation application or change request and (ii) sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the supplier's initial application.

Delegated officials may not delegate their authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the supplier's Medicare data or to sign revalidation applications.

For purposes of the Delegated Officials information captured in the Individual Ownership Interest and/or Managing Control Information section only, the term "managing employee" means any individual--including a general manager, business manager, or administrator--who exercises operational or managerial control over the supplier, or who conducts the day-to-day operations of the supplier. However, this does not include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the supplier but who are not actual W-2 employees. For instance, suppose the supplier hires Joe Smith as an independent contractor to run its day-to-day-operations. Under the definition of "managing employee" in the Individual Ownership and/or Managing Control section of the Form CMS-855S, Smith would have to be listed in that section. Yet Smith cannot be a delegated official because he is not an actual W-2 employee of the supplier. Independent contractors are not considered "managing employees" for purposes of qualifying as a delegated official.

2. W-2 Form - Unless the contractor requests it to do so, the supplier need not submit a copy of the owning/managing individual's W-2 to verify an employment relationship.

3. Number of Delegated Officials - The supplier can have as many delegated officials as it chooses. Conversely, the supplier need not have any delegated officials. Should no delegated officials be listed, however, the authorized official(s) remains the only individual(s) who can report changes and/or updates to the supplier's enrollment data.

4. Effective Date - The delegated official's effective date in PECOS should be the effective date listed in the Delegated Officials section or the receipt date of the Form CMS-855S application.

5. Social Security Number - To be a delegated official, the person must have and must submit his/her social security number (SSN). An Individual Taxpayer Identification Number (ITIN) cannot be used in lieu of an SSN in this regard.

6. Deletion of a Delegated Official - If a delegated official is being deleted, documentation verifying that the person no longer is or qualifies as a delegated official is not required. Also, the signature of the deleted official is not needed.

7. Delegated Official Not on File - If the supplier submits a change of information (e.g., change of address) and the delegated official signing the form is not on file, the contractor shall ensure that: (1) the person meets the definition of a delegated official; (2) Section 6 of the Form CMS-855S is completed for that person; and (3) an authorized official signs off on the addition of the delegated official. (NOTE: The original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purposes of enrollment processing and reporting.)

8. Signature on Paper Application

If the supplier submits a paper Form CMS-855S change request, the contractor may accept the signature of a delegated official in the Assignment of Delegated Officials or Authorized Official Certification Statement and Signature sections of the Form CMS-855S.

In addition, the Delegated Official's telephone number can be left blank. No further development is needed.

C. Privacy Statement

The Privacy Act permits CMS to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The CMS will only release PECOS information that can be associated with an individual as provided for under Section III "Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. CMS will only collect the minimum personal data necessary to achieve the purpose of PECOS. To view the routine uses in their entirety go to: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0532-PECOS.pdf.

10.3.1.6.3 – Additional Processing Information and Alternatives for Form CMS-855S

(Rev. 11839; Issued: 02-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Unsolicited Additional Information

If the supplier submits missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information that a supplier submits prior to the date the contractor finishes processing a previously submitted change request is no longer considered to be an update to that change request. Rather, it is considered to be and shall be processed as a separate change request. The contractor may process both changes simultaneously, but the change that was submitted first shall be processed to completion prior to the second one being processed to completion.

B. Information Disclosed Elsewhere

If a data element on the supplier's Form CMS-855S application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, the contractor need not obtain the missing data via an updated Form CMS-855S page and a newly-signed certification statement. No further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-855S, even if the data is identified elsewhere on the form or in the supporting documentation:

(i) Except as otherwise stated in section 10.6.6 of this chapter, any final adverse action data requested in the Final Adverse Legal Actions section and in the Final Adverse Legal Action History of the Organizational and Individual Ownership and/or Managing Control sections of the Form CMS-855S

(ii) Tax identification numbers (TIN)

(iii) Supplier type in the Products/Accreditation Information section of the Form CMS-855S

If the supporting documentation currently exists in the supplier's file, the supplier is not required to submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative, unless stated otherwise in this chapter or another CMS directive. Also, , the contractor shall document in PECOS that the missing information was found elsewhere in the enrollment package. (This excludes information that must be verified at the current point in time (i.e., a license without a primary source verification method).) In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

10.3.2 – CMS-20134 – Enrollment Form: Information and Processing

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The Form CMS-20134 application (Medicare Enrollment Application for Medicare Diabetes Prevention Program (MDPP) Suppliers) should be completed by organizations furnishing MDPP services to Medicare beneficiaries. In-Person MDPP suppliers participating in the Center for Medicare and Medicaid Innovation's expanded model, which exclusively furnishes MDPP to beneficiaries in in-person settings with limited exceptions for virtual makeup sessions, may begin enrolling in Medicare on January 1, 2018.

This section 10.3.2 et seq. contains instructions for processing the various sections of the Form CMS-20134 and addresses important related MDPP policies. When processing Form CMS-20134 applications submitted via PECOS, the contractor shall also follow the applicable PECOS instructions in section 10.3 of this chapter. In the event a policy or operational practice in section 10.3.2 et seq. is contrary to that in section 10.3 (e.g., communication mechanisms, validation, documentation submission), the latter takes precedence.

10.3.2.1 – CMS-20134 (Section 1 - Basic Information)
(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

(See section 10.2.6 of this chapter for more information on Medicare Diabetes Prevention Programs.)

A. Reason for Submittal

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. For example, suppose a supplier is changing its tax identification number (TIN). The supplier must submit two applications: (1) an initial Form CMS-20134 as a new supplier; and (2) a Form CMS-20134 voluntary termination. Both transactions cannot be reported on the same application.

Excluding (1) the voluntary termination checkbox and (2) the effective date of termination data in the Basic Information section of the Form CMS-20134, any blank data/checkboxes in the Basic Information section can be verified through any means the contractor chooses (e.g., e-mail, telephone, the PCV, fax).

B. Centers for Disease Control (CDC) Diabetes Prevention Recognition Program (DPRP)

To be eligible to enroll as an MDPP supplier, an entity must have either:

- MDPP preliminary recognition or
- DPRP full recognition

Note that MDPP preliminary recognition includes both interim preliminary recognition as designated by CMS as well as preliminary DPRP recognition as designated by the CDC.

Organizations with preliminary or full CDC DPRP recognition must submit to CMS a copy of its recognition letter provided by CDC. To verify the applicant's eligibility, the contractor shall:

- Verify that a letter has been submitted for each organizational code provided in Sections 2 and 4 of the Form CMS-20134
- Verify that (1) any letters provided have appropriate letterhead from CDC and (2) each reflects that the organization has met either preliminary or full recognition with an expiration date that has not passed.
- Verify that the organization code or codes provided in Sections 2 and 4 of the Form CMS-20134 matches both the organization code on the letter(s) and the organization code on CDC's online registry, which is updated just-in-time and can be found at https://dprp.cdc.gov/cms/download.
- Verify that the CDC's online registry or any list provided by CMS indicates that the entity associated with that organization code is associated with either an in-person or in-person with a distance learning component delivery mode and that a delivery

mode of in-person or in-person with a distance learning component is noted in the letter's letterhead.
- Verify that CDC's online registry indicates that the entity associated with that organization code has met either preliminary or full recognition.
- Verify that the name associated with the organization code on CDC's online registry is consistent with what is listed on the letter, as well as what is provided in Sections 2 or 4 of the Form CMS-20134

Certificates or letters of the above recognitions are the only eligibility documents required by Medicare to function as the supplier type in question. Any other licenses, certificates, and permits that (1) are not of a medical nature or (2) are of a medical nature but unrelated to MDPP are not required.

C. Recognition Status

In situations where an MDPP supplier is required to submit a copy of its CDC recognition but fails to do so, the contractor need not obtain such documentation from the supplier if the contractor can verify the information independently. This may be done by: (1) reviewing and printing (or electronically saving in PECOS) confirming pages from the Centers for Disease Control and Prevention Web site; (2) requesting and receiving from the CDC written confirmation of the supplier's status therewith; or (3) utilizing another third-party verification source. Similarly, if the supplier submits a copy of the applicable recognition but fails to complete the applicable section of the form, the section need not be completed if the data in question can be verified on the recognition itself or via any of the three mechanisms described above in this paragraph. The contractor shall not develop for a correction to the form if the recognition information can be verified as described above.

The above-referenced written confirmation of the supplier's status can be in the form of a letter, fax, or email, but it must be in writing. Documentation of a verbal conversation between the contractor and the body in question does not qualify as appropriate confirmation.

10.3.2.2 – CMS-20134 (Section 2 - Identifying Information)
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Correspondence Address and Telephone Number

Regarding the Correspondence Address section of the Form CMS-20134, the correspondence address must be one where the contractor can directly contact the applicant to resolve any issues once the supplier is enrolled in Medicare. Although the contractor need not verify the correspondence address, the latter cannot be the address of a billing agency, management services organization, chain home office, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

Concerning the telephone number in the Correspondence Address section of the Form CMS-20134, the supplier may list any telephone number it wishes as the correspondence

phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence telephone number and the latter is required for the application submission, the contractor shall develop for this information using the procedures outlined in this chapter (e.g., the PCV for PECOS applications). The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier. The contractor is not required to verify the telephone number.

B. E-mail Addresses

An e-mail address listed on the application can be a generic e-mail address. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier.

Regarding unavoidable phone number or address changes (and unless CMS specifies otherwise), any change in the supplier's phone number or address that the supplier did not cause (e.g., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-20134.

C. Supplier Identification Information

Regarding Supplier Identification Information – Business Information, the contractor may capture all information in the Identifying Information (Business Information) section (with the exception of the TIN and legal business name (LBN) by telephone, fax, the PCV, e-mail, or a review of the supplier's Web site.

10.3.2.3 – CMS-20134 (Section 3 - Final Adverse Legal Actions/Convictions)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Refer to section 10.6.6 of this chapter for information regarding final adverse actions. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).

10.3.2.4 – CMS-20134 (Section 4 - MDPP Location Information)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Background

The MDPP location address must be a valid address with the United States Postal Service (USPS). Addresses entered into PECOS are verified via computer software to determine if they are valid and deliverable. The contractor shall verify that each practice location listed on the application actually exists and is a valid address with the USPS. PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS

Store, mailboxes, etc.) or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry.

The contractor shall verify that the reported telephone number is operational and connects to the practice location/business listed on the application. However, the contractor need not contact every location for applicants that are enrolling multiple locations; the contractor can verify each location's telephone number with the applicable contact person listed on the application and note the verification accordingly in PECOS. (The telephone number must be one where patients and/or customers can reach the applicant to ask questions or register complaints.) The contractor may also match the applicant's telephone number with known, in-service telephone numbers - via, for instance, the Yellow Pages or the Internet - to correlate telephone numbers with addresses. If the provider uses his/her/its cell phone for their business, the contractor shall verify that this is a telephone connected directly to the business. If the contractor cannot verify the telephone number, it shall request clarifying information; the inability to confirm a telephone number may indicate that an onsite visit is necessary. In some instances, a 1-800 number or out-of-state number may be acceptable if the 's MDPP location is in another state but his/her/its practice locations are within the contractor's jurisdiction.

In addition:

- Any supplier submitting a Form CMS-20134 application must submit the 9-digit ZIP Code for each practice location listed.

- In the MDPP Location Information section of the Form CMS-20134, the checkboxes identifying the type of MDPP location must be completed to indicate if the location is the MDPP supplier's administrative location or the community setting. If the type of location is apparent to the contractor, the MDPP supplier need not complete the administrative location type. The contractor can confirm the information via telephone, e-mail, the PCV, or fax.

- Each administrative location shall be verified. However, the contractor need not separately contact each location on the application. Such verification can be done via the contact person listed on the application; the contact person's verification shall be documented in PECOS.

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in CMS Publication (Pub.) 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or electronic funds transfer (EFT) payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the supplier's "special payment" address (Practice Location section of the Form CMS-20134) or EFT information has changed. The supplier should submit a Form CMS-20134 or Form CMS-588 request to change this address; if the supplier does not have an established enrollment record in PECOS, it must complete an entire Form CMS-20134

and Form CMS-588. The Durable Medical Equipment MAC is responsible for obtaining, updating, and processing Form CMS-588 changes.

In situations where the supplier is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the supplier to complete the "special payment" address section of the Form CMS-20134 and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the supplier has completed and signed the Form CMS-588 and shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

In the MDPP Location Information/Remittance Notice and Special Payments Address section of the Form CMS-20134, if neither box is checked and no address is provided, the contractor can contact the supplier by telephone, e-mail, the PCV, or fax to confirm the supplier's intentions. If the "special payments" address is indeed the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in Section 4B of the Form CMS-20134 must be completed.

If an enrolled supplier that currently receives paper checks submits a Form CMS-20134 change request – no matter what the change involves – the following apply:

- The supplier must submit a Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.

- The contractor shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

- Once a supplier changes its method of payment from paper checks to EFT, it must continue using EFT. A supplier cannot switch from EFT to paper checks.)

The "special payment" address may only be one of the following:

    - One of the supplier's practice locations

    - A P.O. box

    - The supplier's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least

with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.

- The chain home office address. Per Pub.100-04, chapter 1, section 30.2, a chain organization may have payments to its providers sent to the chain home office. The LBN of the chain home office must be listed on the Form CMS-588. The TIN on the Form CMS-588 should be that of the supplier.

- Correspondence address

- A lock box

D. Additional MDPP Supplier Location Information

The MDPP set of services is unique in that it is delivered in group settings and can be delivered by non-traditional health care providers who meet certain eligibility criteria. Given this aspect of MDPP suppliers, MDPP services are often delivered within community locations to increase access. Thus, the locations associated with MDPP suppliers differ slightly than traditional practice locations of other health care providers and suppliers.

1. Administrative Locations

MDPP suppliers must have at least one administrative location and report all administrative locations on their Form CMS-20134 or PECOS equivalent. As noted in section 10.1.1 of this chapter, an administrative location is the physical location: (1) associated with the supplier's operations; (2) from where coaches are dispatched or based; and (3) where MDPP services may or may not be furnished. If an entity enrolls as an MDPP supplier but does not furnish MDPP services at its administrative location, it should deliver and disclose any and all community settings where it furnishes MDPP services.

An administrative location:

- Cannot be a private residence

- Must have signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building. Such signage may include, for example, the MDPP supplier's LBN or doing business as (DBA) name, as well as hours of operation.

- Must be open for business and have employees, staff, or volunteers present during operational hours

All administrative locations related to the MDPP supplier must be disclosed. However, given that MDPP suppliers may be non-traditional health care providers engaged in non-health care related activities, not all organizations run by the entity may constitute an administrative location. For example, if an advocacy organization operates two sites and

only one of them offers MDPP services, only the site offering MDPP would be considered an administrative location. Should a coach be based or dispatched from their non-administrative location site to offer MDPP services in community settings, this location would become an administrative location. (See section 10.2.6 of this chapter for information regarding the frequency with which MDPP suppliers must report this change.)

As MDPP suppliers fall within the high-risk level of categorical screening under 42 CFR § 424.518, their administrative locations are subject to site visits. See sections 10.6.20(A) and (B) of this chapter for additional information concerning site visits.

2. Community Settings

When determining whether a location is considered an administrative location or a community setting, MDPP suppliers must consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually provides other services benefiting the community. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services; that is, a community setting is a location where the supplier furnishes MDPP services outside of its administrative locations in a meeting location that is open to the public but not primarily associated with the supplier.

An MDPP supplier must update its enrollment application with locations where services are furnished in community settings. While these settings are not subject to site visits, they serve as a form of recordkeeping and accountability for the MDPP supplier.

3. Out-of-State Practice Locations

If a supplier is adding a practice location in another state that is within the contractor's jurisdiction, a separate, initial Form CMS-20134 enrollment application is not required if both of the following conditions are met:

- The location is not part of a separate organization (e.g., a separate corporation, partnership)

- The location does not have a separate TIN and LBN

Consider the following examples:

Example 1 - The contractor's jurisdiction consists of States X, Y and Z. Jones MDPP Center (JMC), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y. The new location will be under JMC, Inc. JMC will not be establishing a separate corporation, LBN, or TIN for the fourth location. Both of the above conditions are therefore met. JMC can add the fourth location via a change of information request rather than an initial application. The change request must include all information relevant to the new location (e.g., licensure, new managing employees).

Example 2 - The contractor's jurisdiction consists of States X, Y and Z. Jones MDPP Practice (JMP), Inc., is enrolled in State X with three locations. It wants to add a fourth location in State Y but under a newly created, separate entity - Jones MDPP Practice, LP. The fourth location must be enrolled via a separate, initial Form CMS-20134.

Example 3 - The contractor's jurisdiction consists of States X, Y and Z. Jones MDPP Practice (JMP), Inc., is enrolled in State X with three locations. It wants to add a fourth location in State Q. Since State Q is not within the contractor's jurisdiction, a separate initial enrollment for the fourth location is necessary.

10.3.2.5 – CMS-20134 (Sections 5 & 6 - Owning and Managing Organizations and Individuals)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Sections 5 and 6 of the Form CMS-20134 collect data regarding the MDPP supplier's organizational and individual owners and managing parties. For detailed information regarding the completion of these sections and the validation of the data thereon, see section 10.6.7 of this chapter.

Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.7 et seq. (e.g., communicating with the provider via the PCV).

10.3.2.6 – Reserved for Future Use

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

10.3.2.7 – CMS-20134 (Section 7 – Coach Roster)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Background Information

Only organizations, and not individuals, are eligible to enroll as an MDPP supplier. However, MDPP services are furnished to Medicare beneficiaries by MDPP coaches in group settings. Though these individuals furnish MDPP services on behalf of MDPP suppliers, only the MDPP supplier itself enrolls in Medicare. To enable CMS to better ensure the integrity of the program and the safety of the beneficiaries it serves, MDPP suppliers must report identifying information on coaches in the Coach Roster section of the Form CMS-20134. If a coach is being added or changed, the updated information must be reported via a Form CMS-20134 change request

B. Coach Eligibility and Screening

As indicated in section 10.2.6 of this chapter and as outlined in the MDPP supplier standards, MDPP suppliers cannot include on their roster (or allow MDPP services to be furnished by) an ineligible coach. Accordingly, an MDPP coach must not:

- Currently have Medicare billing privileges revoked and be currently subject to a reenrollment bar

- Currently have its Medicaid billing privileges terminated for-cause or be excluded by a state Medicaid agency

- Currently be excluded from any other federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

- Currently be debarred, suspended, or otherwise excluded from participating in any other federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

- Have, in the previous 10 years, one of the following state or federal felony convictions:

  - Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

  - Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

  - Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

  - Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

Upon enrollment or any changes to the Coach Roster section of the Form CMS-20134 that results in a new coach being added, the contractor shall verify that the coach is not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG) or through the System for Award Management (SAM) (formerly, the General Services Administration Excluded Parties List System) and, to the extent possible, whether or not an individual coach meets the above eligibility criteria. Should the contractor determine that an ineligibility criterion has been met pursuant to that screening but is either unsure of the matter or unclear as to what action should next be taken, the contractor may contact its Provider Enrollment & Oversight Group (PEOG) Business Function Lead (BFL) for guidance.

C. Coach Eligibility Start and End-Dates

MDPP coaches may have a high turnover rate. To document which coaches are active with a supplier at a given time, each coach will have an eligibility start and, if applicable, an eligibility end-date.

For each change to the Coach Roster section of the Form CMS-20134, the MDPP supplier must indicate the date of such change. (If the date of change for an individual coach is completely blank, the contractor must develop for this information.) Per 42 CFR § 424.205(d), an MDPP supplier must report all changes to its coach roster within 30 days of the change.

If the contractor determines the coach to be ineligible, the coach's eligibility start and end-date shall be documented as the same date; this effectively means that the coach was never eligible. Two other means by which a coach may get an eligibility end-date are as follows:

- When the MDPP supplier removes that coach from its roster. Here, the eligibility end-date would be the date the MDPP supplier indicated when it updated the Coach Roster section to remove the coach.
- When the MDPP supplier with which he or she is associated is revoked or does not revalidate its enrollment. Here, the coach's eligibility end-date is the same as the date the MDPP supplier's billing privileges were no longer effective.

An MDPP supplier may only be paid for services furnished by eligible coaches within their eligibility start and end-dates.

D. Consequences for Coach Ineligibility

If the contractor or CMS determines that an MDPP supplier has an ineligible coach on its roster, the MDPP coach would be non-compliant with the MDPP supplier standards. The supplier would thus have its enrollment denied or revoked, as appropriate under §§ 424.530(a)(1) or 424.535(a)(1). Consistent with existing procedures, MDPP suppliers may submit a corrective action plan (CAP) removing this coach from its roster within 30 days of receiving notice of its enrollment denial or revocation, and, if compliant and as applicable, could obtain or maintain Medicare enrollment. (See section 10.6.18 of this chapter for more information on CAPs.) In this CAP situation, the supplier need not submit any documentation beyond updating the Coach Roster section of the Form CMS-20134 to remove the ineligible coach.

E. Special Revocation for Knowingly Using an Ineligible Coach

While MDPP supplier standards indicate that an MDPP supplier may not include an ineligible coach on its roster or allow him/her to furnish MDPP services on its behalf to Medicare beneficiaries, the MDPP supplier is not prohibited from continuing to employ or otherwise permit the coach to volunteer for other services unrelated to MDPP. Should CMS identify that an MDPP supplier is knowingly allowing an ineligible coach to continue furnishing MDPP services, the MDPP supplier would be revoked under § 424.205(h)(5) and any other revocation authority. In this context, "knowingly" means that the MDPP supplier meets all of the following five conditions; specifically, the supplier:

- Received an enrollment denial or revocation notice for failing to meet the MDPP standard in § 424.205(d)(3);
- Was provided notice by CMS or the contractor of the coach's ineligibility, and the applicable reason(s);
- Submitted a CAP to remove the coach;
- Became compliant once again and obtained or maintained its enrollment; but
- Continued to allow the ineligible coach who was removed from the Coach Roster section of the Form CMS-20134 to provide MDPP services in violation of the CAP.

See section 10.4(M)(4)(d) of this chapter for more information.

10.3.2.8 – CMS-20134 (Section 8 – Billing Agency Information)
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Billing Agency Information section of the Form CMS-20134, refer to section 10.6.8 of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.8.)

Note that if the telephone number in Section 8 is blank, the number can be verified with the supplier by telephone, the PCV, e-mail, or fax. If the section is blank (including the check box), no additional development is necessary.

10.3.2.9 – CMS-20134 (Section 13 – Contact Person)
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Contact Person section of the Form CMS-20134, see sections 10.3 and 10.6.9 of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.9.)

If Section 13 is completely blank, the contractor need not develop for this information and can simply contact an authorized or delegated official. If neither box in Section 13 is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor can either: (1) develop for this information by telephone, the PCV, e-mail, or fax; or (2) contact an authorized or delegated official.

There is no current option on the Form CMS-20134 to delete a contact person. Therefore, the contractor shall accept the end-date of a contact person via telephone, email, the PCV, fax, or mail from the individual supplier, the authorized or delegated official, or a current contact person on file. The contractor shall document in PECOS who requested the termination, how it was requested (email, phone or fax), and when it was requested. The addition of contact persons must still be reported via the Form CMS-20134.

(See section 10.6.9 of this chapter for more information regarding the Contact Person section of the Form CMS-20134.)

10.3.2.10 – CMS-20134 (Section 14 – Penalties for Falsifying Information)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

See the Penalties for Falsifying Information section of the Form CMS-20134 for an explanation of penalties that apply to MDPP suppliers for deliberately furnishing false information on the Form CMS-20134 to obtain or maintain Medicare enrollment.

10.3.2.11 – CMS-20134 (Section 15 – Certification Statement and Authorized Officials)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Unless indicated otherwise below or in another CMS directive, the instructions in this section apply to (1) signatures on the paper Form CMS-20134, and (2) signatures for PECOS applications.)

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options in software, such as Adobe) are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

A. Paper Submissions

A signed certification statement shall accompany the paper Form CMS-20134. If the supplier submits an invalid certification statement or no certification statement at all, the contractor shall still continue processing the application. An appropriate certification statement shall be solicited as part of the development process – preferably via the PCV, email, or fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) was signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application; (d) missing altogether; or (e) stamped. The contractor shall send one development request that lists all of the missing/deficient required data/documentation, including the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish the missing information and/or correct the deficient data on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

- The contractor shall begin processing the application upon receipt and shall develop for missing/deficient certification statements and all other missing/deficient information, including the application fee, upon review.

- As applicable, the certification statement may be returned via scanned email or fax.

- As mentioned previously, signature dates cannot be prior to 120 days of the receipt date of the application.

- For paper applications that require development, it is only necessary that the dated signature of at least one of the supplier's authorized or delegated officials be on the certification statement that must be sent in within 30 days; the signatures of the other authorized and delegated officials need not be obtained.

- For paper change of information applications (as the term "changes of information" is defined in section 10.4 et al. of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as being an authorized or delegated official of the supplier, the contractor may accept the certification statement but shall develop for information on this person.

- The contractor need not compare the signature on the Form CMS-20134 with the same authorized or delegated official's signature on file to ensure that it is the same person.

- The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

B. PECOS Submissions

Unless stated otherwise in this chapter or in another CMS directive:

(i) The contractor shall (a) begin processing the application upon receipt via PECOS; (b) perform all required manual validations; and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 and all other applicable instructions in this chapter.

(ii) If the supplier submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via the PCV, email, or fax. (This includes certification statements that are signed by a person unauthorized to do so under 42 CFR Part 424, subpart P.) The contractor shall send one development request that includes a list of all of the data/documentation to be furnished or clarified, including, as applicable, a correct certification statement. The contractor may reject the supplier's application if the supplier fails to furnish said data/documentation within 30 calendar days from the date of the contractor's request.

(iii) For PECOS applications that require development, at least one of the supplier's authorized or delegated officials has to sign any certification statement that must accompany the supplier's response. Obtaining the signatures of the other authorized and delegated officials is not required.

(iv) For PECOS changes of information (as the term "changes of information" is defined in section 10.4.4 of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as an authorized or delegated official of the supplier, the contractor may accept the certification statement. However, it shall develop for information on the person in question consistent with the procedures in this chapter.

(v) The contractor is not required to compare the signature thereon with the same supplier's, authorized official's, or delegated official's signature on file to ensure that it is the same person.

(vi) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

C. Certification Statement Development

If, as already mentioned, the supplier submits an invalid certification statement (as described in subsections (A) and (B)), the contractor shall develop for a correct certification statement and send a development letter to the supplier. The provider must submit the requested certification statement as follows:

(i) Paper applications -- Via scanned email, fax, or mail. Only the actual signature page is required; the provider need not submit the additional page containing the certification terms. (This also applies to the provider's initial submission of a certification statement. Such instances require the submission of only the signature page and not the certification terms.)

(ii) PECOS applications – Via electronic or uploaded signature.

D. Authorized Officials

Except as stated otherwise, the instructions in this section 10.3.2.11(D) apply to: (1) signatures on the paper Form CMS-20134; and (2) electronic or uploaded signatures for PECOS applications.)

1. Requirements

As defined in 42 CFR § 424.502, an authorized official is an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. The person must have the authority to legally and financially bind the supplier to) the requirements set forth in 42 CFR § 424.510 (and other applicable Medicare regulations) and to act on behalf of the organization.

An authorized official is not restricted to the examples of the titles outlined above; however, the person must hold a position of similar status and authority within the provider or supplier organization. Additional titles could include, but are not limited to, executive director, administrator, president, and vice-president. The contractor shall consider the individual's title and the authority granted by the organization when determining whether an individual qualifies as an authorized organization. If the contractor is unsure of the person's qualifications or authority, it shall contact its PEOG BFL for further clarification. The contractor shall obtain PEOG BFL approval if the only role of the listed authorized official is "Contracted Managing Employee."

If an authorized official is listed as a "Contracted Managing Employee" in the Individual Ownership and/or Managing Control section of the Form CMS-20134 and does not qualify as an authorized official under some other category in this section, he/she cannot be an authorized official. The contractor shall notify the supplier accordingly. If the person is not listed as a "Contracted Managing Employee" in the Individual Ownership and/or Managing Control section and the contractor has no reason to suspect that the person does not qualify as an authorized official, no further investigation is required. Should the contractor have doubts that the individual qualifies as an authorized official, it shall contact the official or the applicant's contact person to obtain more information about the official's job title and/or authority to bind. If the contractor remains unconvinced that the individual qualifies as an authorized official, it shall notify the supplier that the person cannot be an authorized official. If that person is the only authorized official listed and the supplier refuses to use a different authorized official, the contractor shall deny the application.

For purposes of determining an authorized official's qualifications, identifying the supplier is not determined solely by the supplier's TIN. Rather, the organizational structure is the central factor. For instance, suppose a chain drug store, Company X, wants to enroll 100 of its pharmacies with the contractor. Each pharmacy has a separate TIN and must therefore enroll separately. Yet all of the pharmacies are part of a single corporate entity – Company X. In other words, there are not 100 separate corporations in our scenario but merely one corporation whose individual locations have different TINs. Here, an authorized official for Pharmacy #76 can be someone at X's headquarters (assuming the definition of authorized official is otherwise met), even though this main office might be operating under a TIN that is different from that of #76. This is because headquarters and Pharmacy #76 are part of the same organization/corporation.

2. Required Signature

For Form CMS-20134 initial applications, the certification statement must be signed and dated by an authorized official of the supplier. (See sections 10.1.1 and 10.3.2.11(D) of this chapter for a definition of "authorized official.") The supplier can have an unlimited number of authorized officials so long as each meets the definition of an authorized official. The Individual Ownership and/or Managing Control section of the Form CMS-20134 must be completed for each authorized official.

(For revalidation and changes of information, either the authorized or delegated official must sign the application. (See sections 10.1.1 and 10.3.2.12 of this chapter for a definition of "delegated official.").

3. Changes and Deletions in Authorized Officials

A change in authorized officials does not impact the authority of existing delegated officials to report changes and/or updates to the supplier's enrollment data or to sign revalidation applications.

If an authorized official is being deleted, the contractor need not obtain (1) that official's signature or (2) documentation verifying that the person is no longer an authorized official.

4. Authorized Official Not on File

If the supplier submits a change of information (e.g., change of address) and the authorized official signing the form is not on file, the contractor shall ensure that: (1) the person meets the definition of an authorized official; and (2) the Individual Ownership and/or Managing Control section of the Form CMS-20134 is completed for that person. The signature of an existing authorized official is not needed to add a new authorized official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting.

5. Effective Date

The effective date in PECOS for the Certification Statement section of the Form CMS-20134 should be the date of signature.

6. Social Security Number

To be an authorized official, the person must have and must submit his/her social security number (SSN). An Individual Taxpayer Identification Number (ITIN) cannot be used in lieu of an SSN in this regard.

7. Telephone Number

The authorized official's telephone number can be left blank. No further development is needed.

10.3.2.12 – CMS-20134 (Section 16 – Delegated Officials)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Background

A delegated official is an individual to whom an authorized official listed in the Certification Statement section of the Form CMS-20134 delegates the authority to report changes and updates to the supplier's enrollment record or to sign revalidation applications. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to enrollment information is that of the authorized official currently on file with Medicare. A delegated official has no authority to sign an initial application. However, the delegated official may (i) sign a revalidation application and (ii) sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the supplier's initial application.

The delegated official must be an individual with an "ownership or control interest" in (as that term is defined in § 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the supplier.

Section 1124(a)(3) defines an individual with an ownership or control interest as:

- A five percent direct or indirect owner of the provider,
- An officer or director of the provider (if the provider is a corporation), or
- Someone with a partnership interest in the provider (if the provider is a partnership)

For purposes of information captured in the Delegated Official section only, the term "managing employee" means any individual (including a general manager, business manager, or administrator) who exercises operational or managerial control over the supplier, or who conducts the day-to-day operations of the supplier. However, this does not include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the supplier but who are not actual W-2 employees. For instance, suppose the supplier hires Joe Smith as an independent contractor to run its day-to-day-operations. Under the definition of "managing employee" in the Individual Ownership and/or Managing Control section of the Form CMS-20134, Smith would have to be listed in that section. Yet under the Delegated Official section definition (as described above), Smith cannot be a delegated official because he is not an actual W-2 employee of the supplier. Independent contractors are not considered "managing employees" under the Delegated Official section of the Form CMS-20134.

The Ownership Interest and Managing Control Information in the Individual Ownership and/or Managing Control section of Form CMS-20134 must be completed for all delegated officials.

B. Specific Delegated Official Policies

1. Further Delegation – A delegated official may not delegate his/her authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the supplier's Medicare data or to sign revalidation applications.

2. W-2 Form - Unless the contractor requests it to do so, the supplier need not submit a copy of the owning/managing individual's W-2 to verify an employment relationship.

3. Number of Delegated Officials - The supplier can have as many delegated officials as it chooses. Conversely, the supplier need not have any delegated officials. Should no delegated officials be listed, however, the authorized official(s) remains the only individual(s) who can report changes and/or updates to the supplier's enrollment data.

4. Effective Date - The effective date in PECOS for the Delegated Official section of the Form CMS-20134 should be the date of signature.

5. Social Security Number - To be a delegated official, the person must have and must submit his/her SSN. An ITIN cannot be used in lieu of an SSN in this regard.

6. Deletion of Delegated Official - If a delegated official is being deleted, documentation verifying that the person no longer is or qualifies as a delegated official is not required. Also, the signature of the deleted official is not needed.

7. Delegated Official Not on File - If the supplier submits a change of information (e.g., change of address) and the delegated official signing the form is not on file, the contractor shall ensure that (1) the person meets the definition of a delegated official, (2) the Individual Ownership and/or Managing Control section of the Form CMS-20134 is completed for that person, and (3) an authorized official signs off on the addition of the delegated official. (NOTE: The original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting.)

8. Signature on Paper Application - If the supplier submits a paper Form CMS-20134 change request, the contractor may accept the signature of a delegated official in the Certification Statement or Delegated Official sections of the Form CMS-20134.

9. Telephone Number - In addition, the delegated official's telephone number can be left blank. No further development is needed.

10.3.2.13 – CMS-20134 (Section 17 – Supporting Documents)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(In addition to the instructions in this section 10.3.2.13, refer to: (1) the Supporting Documents section of the Form CMS-20134 for information concerning supporting documents; and (2) section 10.3 of this chapter for instructions regarding the submission of documentation with PECOS applications.)

As already stated in this section 10.3.2.1, MDPP suppliers must have MDPP preliminary recognition or full recognition, as determined by CMS. See section 10.3.2.1 for more information on required documentation.

10.3.2.14 – Additional Form CMS-20134 Processing Information and Alternatives

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The processing alternatives in section 10.3.2.14 are in addition to, and not in lieu of, any other processing alternatives described in this chapter or another CMS directive. These processing alternatives also apply notwithstanding any instruction in this chapter to the contrary. As stated in section 10.3, however, some of the application data elements and verification procedures that

have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in section 10.3.

A. Unsolicited Additional Information

If the supplier submits missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information a supplier submits prior to the date the contractor finishes processing a previously submitted change request is no longer considered to be an update to that change request. Rather, it is considered to be and shall be processed as a separate change request. The contractor may process both changes simultaneously, but the change that was submitted first shall be processed to completion prior to the second one being processed to completion.

B. Information Disclosed Elsewhere

If a data element on the supplier's Form CMS-20134 application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, the contractor need not obtain the missing data via an updated Form CMS-20134 page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-20134, even if the data is identified elsewhere on the form or in the supporting documentation:

- Any final adverse action data requested in the Final Adverse Legal Actions/Convictions section (Section 3) and Organizational and Individual Ownership and/or Managing Control Final Adverse Legal Action History sections (Sections 5B and 6B) of the Form CMS-20134

- The applicant's legal business name (LBN) or legal name (Note: If an application is submitted with a valid National Provider Identifier (NPI) and Provider Transaction Access Number (PTAN) combination but (1) the LBN field is blank, (2) an incomplete or inaccurate LBN is submitted, or (3) the applicant includes a DBA name in the MDPP Location Information section of the Form CMS-20134, the contractor need not develop if it can confirm the correct LBN based on the NPI and PTAN combination provided.

- Tax Identification Number

(The contractor may use the shared systems, PECOS, or its supplier files as a resource to determine the PTAN or NPI before developing with the supplier.)

If required supporting documentation currently exists in the supplier's file, the supplier need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a

previously submitted enrollment application, or documentation currently uploaded in PECOS, qualifies as a processing alternative unless stated otherwise in this chapter or any CMS directive. Also, per section 10.6.19(H) of this chapter, the contractor shall document in PECOS that the missing information was found elsewhere in the enrollment package. However:

- This excludes information that must be verified at the current point in time (e.g., a license without a primary source verification method)
- The contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa

C. City, State, and ZIP Code

If an address (e.g., correspondence address, practice location) lacks a city, state or zip + four, the contractor can verify the missing data in any manner it chooses. (Note that the contractor can obtain the zip + four from either the USPS or the Delivery Point Validation in PECOS.)

10.3.3 – Other Enrollment Forms: Information and Processing

(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

The forms or form types described in this section 10.3.3 et seq. are routinely submitted with an enrollment application.

For purposes of sections 10.3.3.1 and 10.3.3.2, all references to the Form CMS-855 include the Form CMS-20134, unless otherwise stated.

10.3.3.1 – Form CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

An EFT agreement (Form CMS-588) authorizes CMS to deposit Medicare payments directly into a provider/supplier's bank account.

A. Processing the Form CMS-588 – Specific Situations

When a Form CMS-588 is received, the contractor shall review the form and develop for any deficiencies or missing information prior to approval. All EFT data shall be entered into PECOS.

1. Unsolicited Information

If the provider/supplier submits missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall form review.

2. Missing or Incorrect Provider Transaction Access Number (PTAN) or CMS Certification Number (CCN) on the Form CMS-588

If the PTAN and/or CCN is missing or incorrect but the contractor can ascertain the correct number (1) via the supporting documents submitted, (2) elsewhere on the form, or (3) via PECOS, the shared systems, or the provider files, the contractor need not pursue development. (Note that social security numbers and employer identification numbers do not fall within this exception.)

3. Missing or Incorrect Social Security Number (SSN) or Employer Identification Number (EIN) Checkbox on the Form CMS-588

If the Form CMS-588 is received and the checkbox for the SSN or EIN is either not checked or is incorrectly checked, the contractor may proceed without further development if the contractor can ascertain the correct option via the supporting documents submitted or elsewhere on the form.

4. Name on Account

As stated on the Form CMS-588, the account to which EFT payments are made must exclusively bear the name of the physician or individual practitioner, or the legal business name (LBN) of the person or entity enrolled with Medicare. Accordingly, the contractor shall accept accounts that (1) solely list the LBN or (2) list the LBN and the Doing Business As name (so long as the LBN is listed first).

B. Form CMS-588 Information Specific to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

For Form CMS-855S enrollments, CMS only requires the Form CMS-588 with initial enrollment applications.

C. Form CMS-588 Signature Requirements

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

D. Verification

Providers and suppliers may submit a Form CMS-588 via paper or through PECOS. In either case, the contractor shall ensure that:

(i) All EFT arrangements comply with CMS Pub. 100-04, chapter 1, section 30.2.5.

(ii) The information submitted on the Form CMS-588 is complete and accurate. (Except as otherwise stated in this chapter or another CMS directive, the contractor shall develop for any missing information.)

(iii) The provider/supplier submitted (1) a voided check or (2) a letter from the bank verifying the account information.

(iv) The routing number and account number matches what was provided on the Form CMS-588.

(v) The signature is valid.

(vi) The contractor shall forgo development if the "Part I: Reason for Submission (Individual vs. Group)" section is left blank or an incorrect option is selected but the contractor can make the correct determination based on the provider/supplier's existing file or additional information submitted with the application.

E. Miscellaneous EFT Policies

1. Banking Institutions

All payments must be made to a banking institution. EFT payments to non-banking institutions (e.g., brokerage houses, mutual fund families) are not permitted.

If the provider/supplier's bank of choice does not or will not participate in the provider/supplier's proposed EFT arrangement, the provider/supplier must select another financial institution.

2. Sent to the Wrong Unit

If a provider/supplier submits an EFT change request to the contractor but not to the latter's enrollment unit, the recipient unit shall forward it to the enrollment staff, which shall then process the change. The enrollment unit is responsible for processing EFT changes. As such, while it may send the original EFT form back to the recipient unit, the enrollment unit shall keep a copy of the EFT form and append it to the provider/supplier's Form CMS-855 in the file.

3. Bankruptcies and Garnishments

If the contractor receives a copy of a court order to send payments to a party other than the provider/supplier, it shall contact the applicable SOG Location's Office of General Counsel.

4. Closure of Bank Account

If a provider/supplier has closed its bank/EFT account but will remain enrolled in Medicare, the contractor shall place the provider/supplier on payment withhold until a Form CMS-588 (and Form CMS-855, if applicable) is submitted and approved by the contractor. If such an agreement is not submitted within 90 days after the contractor learned that the account was

closed, the contractor shall commence deactivation procedures in accordance with the instructions in this chapter. The basis for deactivation would be § 424.540(a)(2) due to the provider/supplier's failure to submit updated EFT information within 90 days of the change.

5. Reassignments

If a physician or non-physician practitioner is reassigning all of his/her benefits to another supplier and the latter is not currently on EFT, neither the practitioner nor the reassignee needs to submit a Form CMS-588. This is because (1) the practitioner is not receiving payment directly, and (2) accepting a reassignment does not qualify as a change of information request. If, however, the group later submits a change of information request and is not on EFT, it must submit a Form CMS-588.

6. Final Payments

If a non-certified supplier (e.g., physician; ambulance supplier) voluntarily withdraws from Medicare and needs to obtain its final payments, the contractor shall send such payments to the supplier's EFT account of record. If the account is defunct, the contractor can send payments to the supplier's "special payments" address or, if none is on file, to any of the supplier's practice locations on record. If neither the EFT account nor the aforementioned addresses are available, the supplier shall submit a Form CMS-855 or Form CMS-588 request identifying where it wants payments to be sent.

7. Chain Organizations

Per CMS Pub. 100-04, chapter 1, section 30.2, a chain organization may have payments to its providers be sent to the chain home office. However, and except as otherwise permitted for PECOS applications under PECOS 2.0, any mass EFT changes (involving large numbers of chain providers) must be submitted and processed in the same fashion as any other change in EFT data. For instance, if a chain has 100 providers and each wants to change its EFT account to that of the chain home office, 100 separate Form CMS-588s must be submitted (again, unless PECOS 2.0 permits a consolidated submission for PECOS applications). If any of the chain providers have never completed a Form CMS-855 before, they must do so at that time.

8. Consolidation of EFT Accounts

The contractor shall follow the instructions in section 10.6.23 of this chapter regarding the consolidation of a provider's or supplier's EFT accounts. These instructions take precedence over any contrary guidance in this chapter.

9. Address on EFT Form

Notwithstanding any guidance to the contrary in this chapter or on the Form CMS-588, the account holder's street address (including city, state, and zip) on the EFT form can be the provider's or supplier's:

- *Practice location address (if the provider or supplier has multiple practice locations, any location address may be used);*
- *Correspondence address;*
- *Special payment address; or*
- *Chain home office (CHO) address (though only for providers reporting a CHO on the Form CMS-855A).*

10.3.3.2 – Form CMS-460 – Medicare Participating Physician or Supplier Agreement

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

This agreement establishes that the Medicare provider/supplier accepts assignment of the Medicare Part B payment for all services (1) for which the participant is eligible to accept assignment under the Medicare law and regulations and (2) which are furnished while the agreement is in effect. (This only applies to suppliers that complete the Forms CMS-855B, CMS-855S, and CMS-855I.) The contractor shall follow the instructions in CMS Pub. 100-04, chapter 1, sections 30 through 30.3.12.3 when handling issues related to par agreements and assignment. Queries concerning the interpretation of such instructions shall be referred to the responsible CMS component.

Individual physicians and non-physician practitioners who only reassign benefits to a clinic/group practice inherit the par status established by the clinic/group practice; accordingly, these physicians and non-physician practitioners need not submit the Form CMS-460. However, if the individual physician/practitioner maintains a private practice separate from the reassignment, he/she may designate his/her own par status. See the instructions in CMS Pub. 100-04, chapter 1, section 30 for applying the correct par status to clinic/group practices, organizations and individuals in private practice.

A. PECOS Information

All suppliers must choose to be either par or non-par when enrolling and must maintain the same par status across all lines of business. The contractor shall search PECOS to determine if an enrollment already exists with the enrolling provider/supplier's legal business information (i.e.: legal business name, federal tax identification number).

No par status change shall be made by the contractor without confirmation from the provider/supplier first. In the event that a provider/supplier submits a par agreement and they are currently enrolled as non-par, the contractor must confirm with the provider/supplier that the change in the par status is valid for all lines of business. Likewise, if a provider/supplier does not submit a par agreement, and they are enrolled as par or non-par, the contractor shall confirm that the provider/supplier is not changing their current par status across all lines of business. *Note also that an already-enrolled supplier is not required to submit a new CMS-460 if they are enrolling in another state or contractor jurisdiction. However, in accordance with Pub. 100-4, chapter 1, section 30.3.12.H., a copy of the already-enrolled supplier's CMS-460 must be provided to the new contractor.*

B. Valid signatures

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options created in software, such as Adobe) are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

10.4 – Medicare Enrollment: Contractor Processing Duties and Related Policies

(Rev. 11020; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

10.4.1 – General Processing Functions

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This section 10.4.1 et seq. outlines the general methods that contractors shall follow when processing enrollment applications. (More specific processing activities can be found elsewhere in this chapter (e.g., sections 10.3.1 et seq., 10.6.6, etc.)). Should an inconsistency or gap exist between the general procedures outlined in section 10.4.1 et seq. and those of greater specificity in other sections of this chapter, the latter shall take precedence unless otherwise noted; this includes the instructions in section 10.3 concerning PECOS applications.

The CMS stresses that nothing in this section 10.4.1 et seq. (except as stated to the contrary) supplants more detailed instructions in this chapter (or another CMS directive) pertaining to, for instance: (1) processing alternatives; (2) referrals to the state agency; (3) processing policies specific to certain CMS applications (e.g., CMS-855, CMS-20134) and certain sections thereof.

All references to "provider" include "supplier" unless stated otherwise.

10.4.1.1 – Overview of the Process

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Typical Steps

In general, the application review and verification process is as follows:

1. Contractor receives application

2. Contractor reviews application and verifies data thereon. (For PECOS applications, some of this data will have been verified when the provider enters its enrollment information into PECOS.)

3. If (i) required data/documentation is missing, (ii) data cannot be verified, and/or (iii) there are data discrepancies, contractor requests missing/clarifying information from the provider.

4. If applicable, contractor (i) verifies any newly furnished data or (ii) seeks additional data/clarification from provider

5. Certain situations may require referral to the state agency (the state) and, after receiving information from the state, referral to CMS PEOG before a final determination is rendered.

6. Final determination

Section 10.4.1 et seq. is structured so as to generally follow the preceding six steps.

B. Non-Form CMS-855 and CMS- 20134 Documentation

There are situations where the contractor processes non-Form CMS-855 and CMS- 20134 forms and other documentation relating to provider enrollment. Such activities include, but are not limited to:

- EFT agreements (Form CMS-588) submitted alone
- "Do Not Forward" issues
- Par agreements (Form CMS-460)
- Returned remittance notices
- Informational letters received from other contractors
- Diabetes self-management notices
- Verification of new billing services
- Paramedic intercept contracts
- 1099 issues that need to be resolved
- Opt-out affidavits
- Surety bond updates and cancellations

The contractor shall:

(i) Follow the instructions in section 10.3 regarding the uploading into PECOS of documentation received outside of an application submission; and

(ii) Note in PECOS the date of the document submission with a description of the document. (The specific language lies within the contractor's discretion.)

10.4.1.2 – Receipt of Application

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Acknowledgment of Receipt of Application

The contractor may, but is not required to, send out acknowledgment letters or e-mails in cases where PECOS did not automatically do so.

B. Pre-Screening of Application

The contractor is no longer required to pre-screen provider enrollment applications.

C. Reassignment Packages

(For PECOS applications, note that some of the following instructions regarding development may not apply and the contractor can thus disregard them. This is because PECOS will require the applicable missing forms at the time the provider is completing the application.)

In situations where an entity wants to simultaneously (i) enroll a group practice, (ii) enroll the individual practitioners therein, and (iii) reassign benefits accordingly, the instructions below apply. (With the elimination of the Form CMS-855R, the prior instructions in this section 4.1.2(C) may differ from those below.) As early in the process as possible, the contractor shall examine the incoming forms to see if a reassignment may be involved; also, the contractor is encouraged (though not required) to have the same analyst handle all applications in the package. For instance, suppose a brand-new group wants to enroll but submits only the Form CMS-855B without including the Form CMS-855Is (and the reassignment information thereon) for its group members (i.e., the Form CMS-855B arrives alone without the other forms). The contractor shall develop for the other forms if they are not submitted upon receipt and processing of the Form CMS-855B.

10.4.1.3 – Review of Applications10_4_1_4s10_4_1_3_5

(Rev. 11020; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Unless stated otherwise in this chapter or in another CMS directive, the instructions in this section 10.4.1.3 et seq. apply to:

- The Form CMS-855A, Form CMS-855B, Form CMS-855I, Form CMS-855R, Form CMS-855O, Form CMS-20134, and opt-out affidavits.

- All Form CMS-855, CMS-20134, and opt-out affidavit transaction types identified in this chapter (e.g., changes of information, reassignments).

10.4.1.3.1 – Initial Steps of Review of Application

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Opening Review – Basic Activities

Except as stated otherwise in this chapter (see sections 10.3, 10.3.1 et seq., and 10.4.1 for more details) or when a processing alternative applies, the contractor shall undertake the following:

1. Confirmation of Completion - Ensure that the provider has completed all required data elements on the Form CMS-855, Form CMS-20134, or opt-out affidavit (including all effective dates) and that all supporting documentation has been furnished. The contractor shall also ensure that the provider has completed the application in accordance with the instructions (1) in this chapter and in all other CMS directives and (2) on the Form CMS-855 or Form CMS-20134. (The instructions on the Form CMS-855 or Form CMS-20134 shall be read and applied in addition to, and not in lieu of, the instructions in this chapter and all other applicable CMS directives.)

2. Verification - Verify and validate all information the provider furnished on the Form CMS-855, Form CMS-20134, or opt-out affidavit (assuming a data source is available). (For PECOS applications, note that PECOS will automatically verify certain information. See section 10.3 of this chapter for more information.)

3. State Agency - Coordinate with the state and/or SOG Location as needed.

4. Exclusion/Debarment – Follow the instructions in section 10.6.6 of this chapter with respect to reviewing the MED and SAM.

B. Paper Applications

1. General Background Information

The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information (including the application fee) upon review. This includes but is not limited to:

- Ensuring that all required data elements on the application have been completed and that all required supporting documentation has been submitted

- Ensuring that the provider submitted a valid and dated certification statement signed by an appropriate individual (e.g., the enrolling physician for Form CMS-855I applications)

- Validating all data on and submitted with the application (assuming that a data source is available)

- As applicable, and consistent with section 10.3 of this chapter, entering into PECOS all information contained on the application.

Except as otherwise prescribed in section 10.3 of this chapter, the contractor may begin the verification process at any time.

2. Photocopying Pages

The contractor may accept photocopied pages in any Form CMS-855 or Form CMS-20134 it receives so long as the application contains a valid signature. For example, suppose a corporation wants to enroll five medical clinics it owns. The Section 5 data on the Form CMS-855B is exactly the same for all five clinics. The contractor may accept photocopied Section 5 pages for these providers. However, valid signatures must be furnished in Section 15 of each application.

3. White-Out & Highlighting

The contractor shall not write on or highlight any part of the original Form CMS-855 or Form CMS-20134 application or any supplementary pages the applicant submits (e.g., copy of license). Provider usage of white-out is acceptable, although the contractor should contact the applicant to resolve any ambiguities. In addition, the contractor must determine whether the amount of white-out used on a particular application is within reason. For instance, if an entire application page is whited-out, the contractor should request that the page be resubmitted.

C. PECOS Applications

The contractor shall begin processing the application upon receipt and shall develop for additional/clarifying/missing data consistent with the instructions in section 10.3 and other pertinent sections of this chapter.

10.4.1.3.2 – Data Verification

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Means of Verification

Except as stated otherwise in this chapter or in another CMS directive, the contractor shall verify and validate – via the most cost-effective methods available, including via PECOS (as described and directed in section 10.3) - all information furnished by the provider on or with its application, assuming a data source is available. The general purpose of the verification process is to ensure that all of the data furnished on the Form CMS-855 or Form CMS-20134 is accurate.

Examples of verification techniques include, but are not limited to: (i) site visits; (ii) third-party data validation sources; (iii) state professional licensure and certification websites (e.g., medical board sites); (iv) federal licensure and certification websites (if applicable); (v) state business web sites (e.g., to validate “doing business as” name); and (vi) Yellow Pages (e.g., to verify certain phone numbers).

The list of verification techniques identified in this section 10.4.1.3.2 is not exhaustive. Except as prescribed otherwise in section 10.3, if the contractor is aware of another means of validation that is as cost-effective and accurate as those listed, it may use it. However, all SSNs and NPIs listed on the application shall be verified through PECOS. The contractor shall not request an SSN card or driver’s license to verify an individual’s identity or SSN.

B. Overall Verification Principles

Unless stated otherwise in this chapter or in another CMS directive, the following apply:

1. A data element is considered "verified" when, after attempting at least one means of validation, the contractor is confident that the data is accurate. (The contractor shall use its best judgment when making this assessment.)

2. The contractor need only make one verification attempt (i.e., need only use one validation technique) before either: (i) concluding that the furnished data is accurate; or (ii) requesting clarifying information if the data element cannot be verified (though the contractor is encouraged to make a second attempt using a different validation means prior to requesting clarification).

C. Concurrent Reviews

(For PECOS application submissions, note that PECOS's automatic verifications of applications from related entities shall take precedence – e.g., in terms of length of time between application submissions, depth of the relationship between the associated parties – over the instructions in this section 10.4.1.3.2(C).)

If the contractor receives multiple Form CMS-855 or Form CMS-20134s for related entities, it can perform concurrent reviews of similar data. For instance, suppose a chain home office submits initial Form CMS-855As for four of its chain providers. The ownership information (Sections 5 and 6) and chain home office data (Section 7) is the same for all four providers. The contractor need only verify the ownership and home office data once; it need not do so four times – once for each provider. However, the contractor shall document in each provider's PECOS record that a single verification check was made for all four applications.

For purposes of this requirement: (1) there must be an organizational, employment, or other business relationship between the entities; and (2) the applications must have been submitted within a few weeks of each other. As an illustration, assume that Group Practice A submits an initial Form CMS-855B on January 1. Group Practice B submits one on October 1. Section 6 indicates that Joe Smith is a co-owner of both practices, though both entities have many other owners that are not similar. In this case, the contractor must verify Mr. Smith's data in both January and October. It cannot use the January verification and apply it to Group B's application because: (1) the applications were submitted nine months apart; and (2) there is no evidence that the entities are related.

D. Contacting another Contractor

During the verification process, the contractor may need to contact another Medicare contractor for information regarding the provider. The latter contractor shall respond to the former contractor's request within three business days absent extenuating circumstances.

E. Proof of Life Documentation

When an enrollment record is updated to reflect an erroneous date or report of death, the contractor shall request documentation that supports "proof of life" (e.g., Retirement, Survivors, and Disability Insurance document issued by SSA). If the provider cannot obtain such

documentation, the contractor shall submit a request to its PEOG BFL containing the provider's name, date of birth, and SSN so that CMS can confirm proof of life with SSA.

10.4.1.3.3 – Requesting Missing/Clarifying Data/Documentation (Development)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This section 10.4.1.3.3 addresses the contractor's solicitation of missing/clarifying information/documentation and/or a valid certification statement. The policies herein apply except as otherwise stated in this chapter (e.g., section 10.3) or another CMS directive.

A. Only One Request Needed

The contractor need only make one request. Of course, the contractor should respond to any of the provider's telephone calls, e-mails, etc., resulting from the request. Yet the contractor need not – on its own volition – make an additional request unless the contractor uncovers missing data (or data that must be clarified) that it failed to detect prior to sending the original development letter.

To the extent possible, the contractor should avoid contacting the provider for missing/clarifying data/documentation until it has attempted to validate all of the data on the application. This will obviate the need to contact the provider each time the contractor discovers an issue.

B. Commencement of Timeframe

The provider has 30 calendar days to furnish the information or documentation the contractor requested. This 30-day clock commences on the day on which the contractor sends the development request (e.g., via the PCV).

C. Telephonic Requests

Unless otherwise stated in this chapter or in another CMS directive, telephonic requests for missing/clarifying data/documentation are generally not permitted for paper or PECOS applications; it is important that requests for information or clarification be formalized in writing. However, in cases where CMS permits telephonic requests for such data, the contractor shall adhere to the following:

1. A telephonic request is made when the contractor: (1) speaks with an appropriate provider official, or (2) leaves a message either with an appropriate official's staff (e.g., his/her executive assistant) or with an appropriate official's voice mail service. In situation (2), the contractor shall leave the name and telephone number of an appropriate individual at the contractor site who the official can contact; otherwise, the contact does not qualify as a legitimate request for clarification.

2. When leaving a message, the contractor shall also state that the requested data/clarification must be furnished within 30 days.

3. Telephone requests shall be made on weekdays between 9 am and 5 pm of the provider's time zone.

4. The 30-day clock begins on the day (1) of the telephone conversation with the appropriate official, or (2) the message is left.

5. All telephone activity that falls within this subsection (C) shall be documented in PECOS consistent with the instructions in section 10.6.19(H) of this chapter.

D. Inability to Contact Provider

If the contractor cannot, for the reasons listed in (i) through (iii) below, communicate with the provider to request information/documentation, it shall attempt one alternative means of communication:

(i) The mailed letter is returned because the provider is not at that address;

(ii) The contractor cannot e-mail (e.g., via the PCV) the letter to the provider because of issues with the recipient's e-mail system; or

(iii) The provider's fax number is repeatedly busy

If an alternative communication, too, cannot be completed for one of the above reasons, the contractor need not make another attempt to obtain the data and may reject the application once the applicable 30-day period expires. However, it is strongly advised that the contractor make a third attempt to contact the provider prior to taking this step, especially if it appears the provider is acting in good faith. (The contractor shall document in PECOS each attempt to contact the provider.)

(With respect to e-mail (including via the PCV), an alternative communication includes sending an e-mail to another listed contact person, delegated official, or authorized official.)

E. Development Reasons and Elements of Letter

1. Paper Applications

a. Reasons to Develop

Development is necessary if the provider or supplier: (i) submits an application with at least one missing required data element; (ii) fails to submit at least one required document; (iii) submits an invalid certification statement; (iv) writes "N/A" (or a variation thereof) in response to a question that requires a "yes" or "no" answer; or (v) submits the full application via fax or e-mail unless the contractor has provided for an exception based on extenuating circumstances or the submission via this means is otherwise authorized by CMS. (If the contractor instructs the provider to submit the application via fax or e-mail, the contractor shall inform its PEOG BFL.)

Development is also required if the contractor determines that clarification is needed regarding certain information (e.g., particular data cannot be verified or there are data inconsistencies).

b. Elements of a Development Letter

If any of the development reasons in section 10.4.1.3.3(E)(1)(a) above apply, the contractor shall send a development letter to the provider – preferably via the PCV, e-mail or fax - that contains, at a minimum, the applicable elements in (i) through (vi) below. (See section 10.7 et seq. of this chapter for these model letters.)

i. A list of all of the missing required data/documentation, an explanation of the certification statement's deficiencies, and/or the issues/information to be clarified.

ii. A request that the provider submit the missing data/documentation, clarification, and/or revised certification statement within 30 calendar days.

iii. Unless the only data that is missing is documentation, a request that the provider submit an appropriately signed and dated certification statement. (This certification statement will cover both the submission of any missing data as well as any deficiencies associated with the original certification statement.) The provider may submit the certification statement via scanned e-mail, fax or mail.

(A new certification statement is not required if the only missing material is documentation or if the requested clarification does not require any changes to the provider's Form CMS-855 or CMS-20134 application.)

iv. If missing data is involved, the contractor shall direct the provider to the CMS Web site at which the CMS-855 or CMS-20134 forms can be found.

v. A fax number and mailing address to which the missing/clarifying data/documentation/correct certification statement can be sent to the contractor. An e-mail address may be included if applicable.

vi. The name and phone number of a contact person at the contractor site. An e-mail address may be included if applicable.

2. PECOS Applications

a. Reasons to Develop

Development is necessary if the provider or supplier: (i) submits an application with at least one required data element that needs clarification; or (ii) fails to submit at least one required document.

b. Elements of a Development Request

When developing for more information, the contractor shall send a request to the provider via the PCV containing:

(i) A list of all missing documentation or information to be clarified;

(ii) A request that the provider submit the data/materials in question within 30 calendar days; and

(iii) The name and phone number (an e-mail address is optional) of a contact person at the contractor site.

The contractor shall not attempt to contact the provider for the missing/clarified information or documentation prior to sending the PCV request referenced above, though the contractor is free to make a follow-up contact with the provider after sending the PCV request.

10.4.1.3.4 - Receiving Missing/Clarifying Data/Documentation (Response to Development)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Note that references to missing information will generally only apply to paper applications.)

A. Requirement to Furnish All Missing/Clarifying Material

The provider must furnish all missing/clarifying data/documentation the contractor requested within the 30-day timeframe. Whether the provider furnished all information is a decision resting solely with the contractor. Should the provider furnish some (but not all) of the requested data/clarification within the specified time period, the contractor need not contact the provider again to request the remaining information. For instance, suppose the contractor requested clarification regarding data the provider furnished in Sections 3, 4, and 5 of the Form CMS-855A. The provider only clarified the Section 3 data. The contractor may reject the application without attempting another contact.

B. Format of Furnishing Missing/Clarifying Data

1. Paper Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider shall: (1) provide the missing/clarification information (excluding documentation) on the applicable Form CMS-855 or CMS-20134 page(s) and (2) submit the material via mail, fax, the PCV, or scanned e-mail. A newly signed and dated certification statement must accompany the Form CMS-855 or CMS-20134 page(s) containing any missing data – unless the only missing information is supporting documentation, in which case no new certification statement is needed. The provider may submit the certification statement via scanned e-mail, fax, the PCV, or mail (paper submissions) along with any missing information.

2. PECOS Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider must furnish the clarifying data/documentation and/or missing/clarifying documentation via PECOS. (See section 10.3 for more information.)

C. Format of Clarifying Data

(For both paper and PECOS applications, the provider must submit any missing/clarifying data or documentation and any required new certification statement within 30 days of the original request for clarification (rather than 30 days from the date of any follow-up request to provide the data.))

1. Paper Applications

In cases where clarifying (as opposed to missing) information is requested, the contractor may accept the clarification by e-mail, fax, the PCV, or letter. If the provider furnishes the clarification via telephone, the contractor shall – unless another CMS directive states otherwise - request that the provider furnish said clarification in writing (preferably via e-mail).

If the furnished clarification requires the provider to change or alter data that must be reported on the paper Form CMS-855 or CMS-20134, the contractor shall instruct the provider (via a follow-up e-mail or fax) to (1) submit the revised data on the applicable paper CMS-855 or CMS-20134 or PECOS application and (2) furnish a new certification statement. The provider must submit the certification statement via scanned PCV, e-mail, fax, or mail.

2. PECOS Applications

The provider must furnish any clarifying information or missing documentation via the PCV if no updates to its PECOS application are needed (e.g., no documentation need be uploaded, no changes to its Section 4 enrollment data are required). If application updates and/or documentation are required, the contractor shall instruct the provider (via the PCV) to (1) submit the clarified information via PECOS and (2) furnish a new certification statement in PECOS. (Paper certification statements are not permitted.)

Consider the following illustrations:

EXAMPLE 1: The contractor notifies the provider via an e-mailed letter on March 1 of a discrepancy regarding its ownership information on the paper Form CMS-855A. The provider e-mails the contractor on March 3 and explains the discrepancy. Based on this e-mail, the contractor determines that the provider must correct its ownership data in Section 5 of its Form CMS-855A. The contractor sends a follow-up e-mail to the provider on March 7 instructing the provider to do so. The provider must submit the revised data on the Form CMS-855 or CMS-20134 (with a new certification statement) by March 31 (not April 6, or 30 days from the date of the follow-up e-mail).

EXAMPLE 2: The contractor notifies the provider via a PCV-transmitted letter on March 1 of a discrepancy regarding certain ownership information on its PECOS Form CMS-855A. The provider telephones the contractor on March 6 and explains the discrepancy to the contractor's satisfaction. Although the discrepancy does not require the provider to make any revisions to its Form CMS-855A, the contractor shall request that the provider furnish its explanation in writing via the PCV no later than 30 days from its March 1 e-mail (or March 31), not 30 days from the date of its March 6 request for the written explanation.

EXAMPLE 3: The contractor notifies the provider via a PCV-transmitted letter on March 1 of a discrepancy regarding certain ownership information on its PECOS Form CMS-855A. Determining (based on the contractor's notification) that the ownership information it provided was incorrect, it submits a revised Section 5 of its Form CMS-855A to the contractor with a new certification statement via PECOS but without any accompanying explanation of the change. The contractor receives the revised Section 5 on March 12. If the contractor determines that the discrepancy has been resolved via the revised submission, it need not contact the provider for a written explanation. (This is because the clarification was furnished in writing via the Form CMS-855 or CMS-20134 itself.) If, however, the contractor would like a written explanation or otherwise needs clarification about the submission, it may request that the provider submit a written explanation via the PCV no later than March 31.

D. Maintenance of Received Material

Paper Applications – The contractor shall maintain all missing/clarifying information or documentation received (including new certification statements) in PECOS via the uploading process described in section 10.3.

PECOS Applications – The contractor shall maintain in PECOS all clarifying information/documentation and/or missing documentation.

10.4.1.3.5 – Provider/Supplier Fails to Submit Requested Data/Documentation
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

If, in the contractor's view, the provider failed to submit all of the requested data/documentation and/or a valid certification statement if required (e.g., as a correction to the original certification statement, as part of a request for missing data, etc.), the contractor may:

- Reject the application if the 30-day period has elapsed,

- Wait until the 30-day period has elapsed and then reject the application, or

- Extend the 30-day period no more than an additional 30 days if (1) it appears that the provider is making a good-faith effort to comply with the development letter and/or (2) the provider furnished most of the requested data. For instance, suppose the contractor requested 5 pieces of clarifying information. The provider timely submitted 4 of them and furnished a signed certification statement. Since the provider appears to be acting in good faith, the contractor is encouraged to continue working with the provider.

If the provider fails to fully respond to a second request, the contractor may either: (1) reject the application if the original 30-day period has elapsed, (2) wait until the 30-day period has elapsed and then reject the application, or (3) make a third request using the procedures described above.

10.4.1.4 – Application Disposition
(Rev. 11020; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

10.4.1.4.1 – Approvals
(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(This section 10.4.1.4.1 does not apply in situations where another CMS instruction contains alternative direction.)

A. Non-Certified Suppliers and Individual Practitioners

(This section 10.4.1.4.1(A) does not apply to ambulatory surgical centers, portable x-ray suppliers, DMEPOS suppliers, MDPP suppliers, or providers and suppliers that complete the Form CMS-855A.)

If the contractor approves a supplier's enrollment, it shall notify the supplier via letter of the approval. The letter shall follow the content and format of the applicable model letter in section 10.7 et seq. of this chapter.

The contractor shall send the approval letter via e-mail, mail, or fax for paper applications (and the PCV for PECOS applications) within 5 business days of approving the enrollment application in PECOS. (This timeframe should allow for the updating the enrollment information in the shared systems (MCS, FISS or VMS)). For all applications other than the Form CMS-855S, the contractor shall send the letter to the supplier's contact person if one is listed; otherwise, the contractor may send the letter to the supplier at the supplier's correspondence address or special payment address.

B. Certified Providers and Certified Suppliers

(This section 10.4.1.4.1(B) only applies to: (1) initial Form CMS-855A applications or CHOW, acquisition/merger, or consolidation applications submitted by the new owner; and (2) initial ambulatory surgical center and portable x-ray supplier applications. Note also that this subsection (B) contains only general instructions regarding certified provider/supplier approvals. Instructions in other chapter 10 sections (e.g., sections 10.2.1 et seq., 10.2.2 et seq., section 10.3, 10.6.1 et seq.) may contain more specific direction, such as with the processing of FQHC applications. Except as stated otherwise, these more specific instructions take precedence over those in this section 10.4.1.4.1(B)). To illustrate, processes for "transitioned" provider initial enrollment (e.g., hospitals, HHAs) are described in provider-specific sections of section 10.2.1, et seq.) and take precedence over those in this section 10.4.1.4.1(B).

If the contractor decides to recommend approval of the provider or supplier's application, the contractor shall send a recommendation letter to the applicable state agency, with a copy to the SOG Location. The recommendation letter shall follow the guidance and format of the applicable template letter in section 10.7 et seq. of this chapter. The contractor may also include an explanation of any special circumstances, findings, or other information that the state should know about. The letter can be sent to the state/SOG Location via mail, fax, or e-mail.

Also, the contractor:

(i) Shall send either a photocopy (not the original), faxed version, or e-mail version of the final completed Form CMS-855 to the state agency, along with all updated Form CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. (which can also be sent via mail, fax, or e-mail). If the Form CMS-855, associated documentation, and recommendation letter are mailed, they should be included in the same package.

(ii) Shall not send a copy of the Form CMS-855 to the SOG Location unless the latter specifically requests it or if the transaction in question is one for which state involvement is unnecessary.

(iii) Notify the applicant that the contractor has completed its initial review of the application. The notification can be furnished via e-mail, the PCV, or via the letter identified in Section 10.7.5 of this chapter (which may be sent to the applicant's contact person). The contractor may, but is not required to, send a copy of its recommendation letter to the provider as a means of satisfying this requirement. However, the contractor should not send a copy to the provider if the recommendation letter contains sensitive information.

C. DMEPOS Suppliers

As stated in 42 CFR § 424.57(b), a DMEPOS supplier must, among other things, meet the following conditions to be eligible to receive payment for a Medicare-covered item: (i) the supplier has submitted a complete Form CMS-855S (including all supporting documentation) to the applicable contractor); and (ii) the item was furnished on or after the date the contractor issued to the supplier a DMEPOS supplier number conveying Medicare billing privileges.

D. Medicare Diabetes Prevention Program (MDPP) Suppliers

As stated in 42 CFR § 424.205(d), an MDPP supplier must, among other things, not have an ineligible coach on its roster. Though the MDPP supplier's effective date for billing privileges is the date a successful Form CMS-20134 application was submitted, the contractor must notify MDPP suppliers of their application approval because some MDPP suppliers may not begin furnishing services until receiving such information.

If the contractor approves an MDPP supplier's enrollment, it shall notify the supplier via letter of the approval. The letter shall follow the content and format of the applicable model letter in section 10.7 et seq. of this chapter.

Absent a CMS instruction or directive to the contrary, the contractor shall send the approval letter within 5 business days of approving the enrollment application in PECOS. The letter shall be sent to the supplier's contact person if one is listed; otherwise, the contractor may send the letter to the supplier's correspondence address or special payment address.

For claims submitted by MDPP suppliers prior to the date of enrollment, the contractor shall follow the instructions in Pub. 100-04, chapter 1, section 70, with respect to the claim filing limit. Payments cannot be made for services furnished prior to the date the applicant submitted an application or CAP that resulted in successful enrollment.

E. Additional Copies of Approval Letters

With the exception of Form CMS-855S applications, if any contact person listed on a provider/supplier's enrollment record requests a copy of the provider/supplier's Medicare approval letter, the contractor shall send it to the contact person via e-mail, the PCV, fax, or mail. (This excludes certification letters from the state or SOG Location, for the contractor does not generate these approvals. Also, see section 10.3 of this chapter for information regarding those contact persons for PECOS applications/enrollments who can and cannot receive documents or information pertaining to a specific application.)

For Form CMS-855S application approval letters, suppliers may contact their applicable NPE East or NPE West contractor for a copy thereof.

10.4.1.4.2 - Returns

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Reasons/Grounds for Return

(See 42 CFR § 424.526 for regulatory provisions regarding application returns.)

Notwithstanding any other directive to the contrary in this chapter or another CMS directive, the contractor (including the NSC) may immediately return the enrollment application to the provider only in the instances described below and which are outlined in § 424.526(a)(1) through (13). Except as otherwise indicated in the specific return reason, this policy applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations, etc.) (Note that some of these return reasons may no longer apply or will be rendered moot with the advent of PECOS 2.0):

(1) The provider/supplier sent its paper Form CMS-855, Form CMS-588, or Form CMS-20134 to the incorrect contractor for processing (e.g., the application was sent to Contractor X instead of Contractor Y).

(2) The contractor received the application more than 60 days prior to the effective date listed on the application. (This does not apply to (i) initial Form CMS-855A applications and (ii) ambulatory surgical centers and portable x-ray suppliers submitting an initial Form CMS-855B application.)

(3) The seller or buyer in a CHOW submitted its Form CMS-855A or Form CMS-855B application more than 90 days prior to the anticipated date of the sale.

(4) The contractor received an initial application more than 180 days prior to the effective date listed on an application from an ambulatory surgical center, a portable x-ray supplier, or a provider/supplier submitting a Form CMS-855A application.

(5) The contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider/supplier submitted an initial application prior to the expiration of their existing reenrollment bar or reapplication bar.

(7) The application is not needed for (or is inapplicable to) the transaction in question. Examples include, but are not limited to, the following:

- A rebuttal decision has been issued (therefore, the submitted Form CMS-855, Form CMS-588, or Form CMS-20134 is not needed). (See section 10.4.8.1(A) of this chapter for more information.)

- The application is to be returned per section 10.6.1.1.3.1.1 of this chapter.

(8) The provider/supplier submitted a revalidation application more than 7 months prior to their revalidation due date.

(9) The MDPP supplier submitted an application with a coach start date more than 30 days in the future.

(10) A provider/supplier requests that their application be withdrawn prior to or during processing.

(11) A provider/supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider/supplier submits a paper Form CMS-855 or Form CMS-20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider/supplier submits a Form CMS-855A or Form CMS-855B initial application followed by a Form CMS-855A or Form CMS-855B change of ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS-855A or Form CMS-855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS-855A or Form CMS-855B application.

(The difference between a "rejected" application and a "returned" application is that the former is typically based on the provider's failure to respond to the contractor's request for missing or clarifying information. A "returned" application is effectively considered a non-submission.)

Note that the contractor need not request additional information in any of these scenarios. For instance, if the application is not necessary for the particular transaction, the contractor can return the application immediately; if the provider already submitted an application fee, the contractor shall follow existing instructions regarding the return of the fee.

B. Procedures for Returning the Application

If the contractor returns the application, the following apply:

(i) The contractor shall notify the provider via the applicable return letter (sent by mail, the PCV, or e-mail) that the application is being returned, the reason(s) for the return, and how to reapply.

(ii) The contractor shall not enter the application into PECOS. No L & T record shall be created.

(iii) Any application resubmission requires a brand new certification statement page containing a signature and date. The provider cannot simply add its signature to the original certification statement it submitted. (This does not apply to e-signature situations.)

(iv) For paper applications, the contractor shall: (A) keep the original application and supporting documents and return a copy; (B) make a copy or scan of the application and documents and return the originals to the provider; or (C) simply send a letter to the provider (in lieu of sending the originals or a copy thereof) explaining that the application is being returned (though not physically returned) and why. (If the contractor chooses the third approach and the provider requests a copy of its application, the contractor should fax or mail it to the provider.)

See section 10.3 of this chapter for more information regarding the return of applications.

C. Special Situations Concerning Changes of Information and Changes of Ownership

1. Expiration of Timeframe for Reporting Changes - If the contractor returns a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to its PEOG BFL notifying him or her of the return. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

2. Timeframe Not Yet Expired - If the contractor returns a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in section 10.4.1.4.2(C)(1) after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

3 Second Return, Rejection, or Denial – If, per section 10.4.1.4.2, the provider resubmits the change of information or CHOW application and the contractor either returns it again, rejects it, or denies it, the contractor shall send the e-mail referenced in section 10.4.1.4.2(C)(1) regardless

of whether the applicable timeframe has expired. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

D. Reactivations

If the contractor returns a reactivation application, the provider's Medicare billing privileges shall remain deactivated.

E. Revalidations

If the contractor returns a revalidation application, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider's Medicare billing privileges under 42 CFR § 424.540(a)(3) if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If the provider indeed resubmits the application and the contractor returns it again, rejects it, or denies it, the contractor shall – absent another CMS instruction to the contrary - deactivate the provider's billing privileges, assuming the applicable time period has expired.

10.4.1.4.3 - Rejections

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Background

1. Rejection Reasons

a. Section 424.525(a)(1)(i) through (x) – Submission of Complete Information

In accordance with 42 CFR § 424.525(a)(1)(i) through (x), the contractor (including the NSC) may reject the provider's application if the provider fails to furnish complete information on the enrollment application within 30 calendar days from the date the contractor requested the missing information. For purposes of this policy, this includes situations where the provider submitted an application that falls into one of the following categories and, upon the contractor's request to submit a new or corrected complete application, the provider failed to do so within 30 days of the request:

(i) The application is missing data required by CMS or the contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application.

(v) The application is signed by a person unauthorized to do so under this 42 CFR Part 424, subpart P.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS-855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS-855 application. (For example, the provider or supplier submitted a Form CMS-855A application when a Form CMS-855B application was required.)

(Note that certain rejection grounds are inapplicable to PECOS applications (e.g., Form CMS-855 application was completed in pencil, certification statement is missing)).

b. Section 424.525(a)(2) - Documentation

In accordance with 42 CFR § 424.525(a)(2), the contractor (including the NSC) may reject the application if the provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the application.

c. Section 424.525(a)(3) – Application Fee

Consistent with 42 CFR § 424.525(a)(3), the contractor (including the NSC) may reject the application if the institutional provider (as that term is defined in § 424.502) does not submit the application fee in the designated amount or a hardship waiver request (1) with the application at the time of filing and (2) after development for the fee by the contractor. This means that the contractor shall develop for a non-submitted fee rather than return the application. (It need not develop for a waiver, however.) If the institutional provider fails to submit the fee (or a waiver) within 30 days of the request, the contractor can reject the application.

2. Applicability

a. Development

The applications described in subsections (A)(1)(a) through (c) above shall be developed, rather than returned. For instance, if a provider submits an application completed in pencil, the contractor shall request the provider to submit a new application, either in ink or via Internet-based PECOS.

b. Transaction and Form Types

Per § 424.525(e)---and except as otherwise specified in the applicable reason for rejection---§ 424.525(a)(1) through (3) apply to all CMS provider enrollment application submissions, including, but not limited to, the following:

- Form CMS-855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.
- Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.
- Form CMS-20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.
- Any electronic or successor versions of the forms identified in paragraphs § 424.525(e)(1) through (3).)

B. Timeframe

The 30-day clock identified in § 424.525(a) starts on the date the contractor mails, faxes, or e-mails (e.g., via the PCV) the development letter or other request for information to the provider. If the contractor makes a follow-up request for information, the 30-day clock does not start anew; rather, it keeps running from the date the development letter was sent. However, the contractor has the discretion to extend the 30-day timeframe if it determines that the provider is actively working with the contractor to resolve any outstanding issues.

C. Incomplete Responses

The provider must furnish all missing and clarifying data and/or documentation requested by the contractor within the applicable timeframe. If the provider furnishes some, but not all, of the requested information, the contractor is not required to contact the provider again to request the remaining data. It can simply reject the application at the expiration of the aforementioned 30-day period. Consider the following example:

EXAMPLE: A provider submits a Form CMS-855A in which Section 3 is blank. On March 1, the contractor requests that Section 3 be fully completed. On March 14, the provider submits an application with the Final Adverse Action History question completed. However, the report of each adverse action, date, applicable body, and resolution data fields remains blank. The contractor need not make a second request for this data to be furnished. It can reject the application on March 31, or 30 days after its initial request was made.

D. Creation - Paper Applications Only

If the contractor cannot complete the intake or data entry process in PECOS because of missing data and the application is subsequently rejected, the contractor shall disposition the application accordingly in PECOS consistent with existing CMS guidance.

E. Other Impacts of a Rejection

1. Changes of Information and CHOWs

a. Expiration of Timeframe for Reporting Changes - If the contractor rejects a change of information or CHOW submission per this chapter and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to its PEOG BFL notifying him or her of the rejection. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

b. Timeframe Not Yet Expired - If the contractor rejects a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in subsection (E)(1)(a) above after the expiration of said time period unless the provider/supplier has resubmitted the change request/CHOW.

c. Second Rejection, Return, or Denial – If, per subsection (E)(1)(b) above, the provider resubmits the change of information or CHOW application and the contractor either rejects it again, returns it, or denies it, the contractor shall send the e-mail referenced in subsection (E)(1)(a) above regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

F. Reactivations

If the contractor rejects a reactivation application, the provider's Medicare billing privileges shall remain deactivated.

G. Revalidations

If the contractor rejects a revalidation application per this chapter 10, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider/supplier's Medicare billing privileges under 42 CFR § 424.540(a)(3) if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider/supplier's billing privileges after the applicable time period expires unless the provider/supplier has resubmitted the revalidation application. If the provider/supplier indeed resubmits the application and the contractor rejects it again, returns it, or denies it, the contractor shall – absent a CMS instruction to the contrary - deactivate the provider's billing privileges, assuming the applicable time period has expired.

H. Additional Rejection Policies

1. Resubmission after Rejection

If the provider's application is rejected, the provider must complete and submit a new Form CMS-855 or CMS-20134 (either via paper or Internet-based PECOS) and all necessary documentation.

2. Applicability

Unless stated otherwise in this chapter or another CMS directive, this section 10.4.1.4.3 applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, CHOW applications, revalidations, and reactivations).

3. Physicians and Non-Physician Practitioners

Incomplete applications submitted by physicians and non-physician practitioners shall be rejected (unless a denial reason exists) if they fail to provide the requested information within the designated timeframe.

4. Notice

If the contractor rejects an application, it shall notify the provider via letter (sent via fax, mail, the PCV, or e-mail) that the application is being rejected, the reason(s) for the rejection, and how to reapply. Absent a CMS instruction or directive to the contrary, the letter shall be sent to the provider no later than 5 business days after the contractor concludes that the provider's application should be rejected.

5. Copy of Application

Paper Applications - If the contractor rejects an application, it shall either (1) keep the original application and all supporting documents or (2) maintain the scanned submission of the application and documents in PECOS and return the originals to the provider. If the contractor chooses the former approach and the provider requests a copy of its application, the contractor may fax or mail it to the provider.

PECOS – Since the application was submitted electronically via PECOS and all supporting documents were uploaded consistent with section 10.3 of this chapter, the contractor need not return any documents to the provider.

10.4.2 - Denials

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In executing the instructions in section 10.4.2 et seq. of this chapter, the contractor shall also adhere to:

(i) The supplemental and superseding instructions in section 10.6.6 of this chapter concerning final adverse actions (e.g., referrals to PEOG);

(ii) The letter formats and verbiage in section 10.7 et seq. of this chapter;

(iii) The PECOS 2.0 instructions in section 10.3 of this chapter; and

(iv) Any other directive that, per CMS, explicitly pre-empts any instruction(s) in section 10.4.2 et seq. of this chapter.

If any instruction in categories (i) through (iv) above conflict with that in section 10.4.2 et seq., the instruction in (i), (ii), (iii), or (iv) applies. In addition, the contractor shall adhere to any instruction in (i), (ii), (iii), or (iv) above that addresses a denial-related matter not discussed in section 10.4.2 et seq.

10.4.2.1 - Denials – General Principles

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Notification Letters for Denials

If the contractor finds a legal basis for denying an application - and, if applicable under section 10.4.2 et seq., section 10.6.6, or another CMS directive, receives approval from PEOG for said denial - the contractor shall deny the application and notify the provider by letter. Except as stated otherwise in this chapter, the denial letter shall contain:

(i) A legal (i.e., regulatory) basis for each reason for the denial;

(ii) A clear explanation of why the application is being denied, including the facts or evidence that the contractor used in making its determination;

(iii) An explanation of why the provider does not meet the applicable enrollment criteria;

(iv) The appropriate regulatory basis (e.g., 42 CFR § 424.530(a)(1)) for the denial. (The contractor shall not use provisions from this chapter 10 as the basis for denial.)

(v) Procedures for submitting a corrective action plan (CAP, for denials based on 42 CFR § 424.530(a)(1)); and

(vi) Complete and accurate information about the provider's further appeal rights.

In addition, the letter shall follow the format of the applicable model denial letter in section 10.7 et seq. of this chapter.

There is no reenrollment bar for denied applications. Reenrollment bars apply only to revocations.

(NOTE: See section 10.2.2.4(V) of this chapter for instructions regarding the application of 42 CFR § 424.530(a)(1) and (18) to IDTF denials. In the event of any inconsistency, the section 10.2.2.4(V) guidance takes precedence over that in section 10.4.2 et seq.)

B. When Prior PEOG Approval of the Denial Necessary

For cases involving 42 CFR § 424.530(a)(1) (Noncompliance – Not Professionally Licensed Individual Practitioners), § 424.530(a)(2) (Provider or Supplier Conduct), 42 CFR § 424.530(a)(3) (Felony Convictions), § 424.530(a)(4) (False or Misleading Information or Application), § 424.530(a)(6) (Medicare Debt), § 424.530(a)(7) (Payment Suspension), § 424.530(a)(11) (Prescribing Authority), § 424.530(a)(12) (Revoked Under Different Name, Numerical Identifier, or Business Identity), § 424.530(a)(13) (Affiliation that Poses an Undue Risk), § 424.530(a)(14) (Other Program Termination or Suspension),), § 424.530(a)(15) (Patient Harm), and § 424.530(a)(17) (False Claims Act Civil Judgments), the contractor shall obtain approval of both the denial and the denial letter from PEOG via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox prior to sending the denial letter. The contractor shall also obtain prior PEOG approval of the denial and denial letter if otherwise required to do so in this chapter or another CMS directive (i.e., certain denial situations other than those described in this subsection 10.4.2.1(B) require prior PEOG approval, such as those outlined in section 10.6.6). (Note that MDPP denials no longer require prior PEOG approval except in cases where such approval is otherwise mandated per this section 10.4.2.1(B) (e.g., MDPP denials under (a)(3), (a)(4), etc.)

PEOG will notify the contractor of its determination (including, as applicable, whether a reapplication bar under § 424.530(f) is to be imposed) and instruct the contractor as to how to proceed. Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider via certified mail no later than 5 business days after PEOG concludes that the provider's application should be denied. The contractor shall not proceed with finalizing the denial until it receives the above-mentioned guidance from PEOG. If this guidance is delayed, the contractor shall carve the impacted application(s) out of its timeliness reporting; the contractor shall document and report the impacted application(s) in its Monthly Status Reports.

C. When Prior PEOG Approval of the Denial Unnecessary – Timeframe for Sending Letter

Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider/supplier via certified mail no later than 5 business days after the contractor determines that the provider's application should be denied.

D. No Denial Recommendation to State

If the applicant is a certified provider or certified supplier and a denial reason is implicated, the contractor need not submit a recommendation for denial to the state/SOG Location. Except as stated otherwise in this chapter, the contractor can simply: (1) deny the application (though, as explained in this chapter, some denials might require prior PEOG approval); (2) close out the PECOS record; (3) send a denial letter to the provider; and (4) copy the state and the SOG Location on said letter.

E. PECOS Entry

All denied applications and all applicable denial reasons shall be entered into PECOS, including fingerprint and non-covered provider or supplier type denials. For non-covered provider or

supplier type denials, the contractor shall select the "Other" specialty/provider/supplier type option and input the type listed on the application.

10.4.2.2 - Denial Reasons

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Denial Reason 1– Not in Compliance with Medicare Requirements (42 CFR §424.530(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in this Title 42 or on the enrollment application applicable to its provider or supplier type and has not submitted a plan of corrective action as outlined in 42 CFR part 488." Such non-compliance includes, but is not limited to, the following situations:

i. The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

ii. The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

iii. The provider or supplier is not appropriately licensed.

iv. The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.

v. The provider or supplier does not meet CMS regulatory requirements for the specialty that it seeks to enroll as. (See section 10.2.8 of this chapter for examples of suppliers that are not eligible to participate.)

vi. The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

vii. The applicant does not qualify as a provider of services or a supplier of medical and health services. (For instance, the applicant is not recognized by any federal statute as a Medicare provider or supplier (see section 10.2.8 of this chapter.)) An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in § 1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

viii. The provider or supplier does not otherwise meet general enrollment requirements.

(With respect to (v) above – and, as applicable, (iii) and (iv) - the contractor's denial letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider or supplier type. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

NOTE: The contractor must identify in its denial letter the exact provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.

(NOTE: For (a)(1) denials involving an individual practitioner who is not appropriately licensed due to a disciplinary action, PEOG -- rather than the contractor -- will make all denial determinations for this noncompliance requirement).

B. Denial Reason 2– Excluded/Debarred from Federal Program (42 CFR § 424.530(a)(2))

(i) "The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel (such as a billing specialist, accountant, or human resources specialist) furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from Medicare, Medicaid, or any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act."

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(Unless stated otherwise in section 10.6.6 of this chapter or in another CMS directive, the contractor need not review the OIG exclusion list for any "health care or administrative or management services personnel" who are not otherwise required to be reported on the enrollment application.)

C. Denial Reason 3 – Felony Conviction (42 CFR § 424.530(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, director, of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR § 1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries.

(i) Offenses include, but are not limited in scope and severity to:

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit resulting in a conviction of criminal neglect or misconduct.

(D) Any felonies outlined in section 1128 of the Social Security Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier."

While a reenrollment bar is established for revoked providers/suppliers, this does not preclude the contractor from denying reenrollment to a provider/supplier that was convicted of a felony within the preceding 10-year period or that otherwise does not meet all of the criteria necessary to enroll in Medicare.

Note that if an MDPP coach meets the above felony requirements, this would not itself warrant a denial of the MDPP supplier under § 424.535(a)(3). This is because the coach, not the MDPP supplier, has the felony conviction. The MDPP supplier could, however, be denied enrollment under § 424.530(a)(1) (non-compliance with enrollment requirements) for having an ineligible coach.

As explained in section 10.6.6 of this chapter, the contractor shall submit all felonies found on Form CMS-855 and CMS-20134 applications to PEOG for review via ProviderEnrollmentRevocations@cms.hhs.gov. (See section 10.6.6 for more information.)

D. Denial Reason 4– False or Misleading Information on Application (42 CFR § 424.530(a)(4))

"The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program."

E. Denial Reason 5– On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR §424.530(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Denial Reason 6– Medicare Debt (42 CFR § 424.530(a)(6))

1. Background

Consistent with 42 CFR § 424.530(a)(6), an enrollment application may be denied if:

(i) The provider, supplier, or owner thereof (as defined in § 424.502) has an existing Medicare debt:

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all the following criteria are met:

(A) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination, or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination [under § 424.530(a)(6)(ii)], CMS considers the following factors:

(1) The amount of the Medicare debt.

(2) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(3) The percentage of the enrolling provider, supplier, or owner's ownership of the prior entity.

(4) Whether the Medicare debt is currently being appealed.

(5) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred."

In addition, a denial of Medicare enrollment under paragraph (a)(6)(ii) can be avoided if the enrolling provider, supplier, or owner thereof does either of the following: (1) satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt; or (2) repays the debt in full.

2. Contractor's Determination of Overpayment

When processing a Form CMS-855A, CMS-855B, CMS-855I, CMS-855S, or CMS-20134 initial or change of ownership application (if applicable), the contractor shall determine – using a system generated monthly listing – whether the provider, supplier, or any owner listed in Section 5 or 6 of the application has an existing or delinquent Medicare overpayment, as described in section 10.4.2.2(F)(1) above and § 424.530(a)(6). If such an overpayment exists, the contractor shall deny the application, using 42 CFR §424.530(a)(6) as the basis. However, prior PEOG approval is required before proceeding with the denial. The contractor shall under no circumstances deny an application under § 424.530(a)(6) without receiving PEOG approval to do so.

3. Examples

Example #1: Dr. X, a sole proprietor, has a $70,000 overpayment. Three months later, he joins Group Y and becomes a 50 percent owner thereof. Group Y submits an initial enrollment application two months thereafter. Group Y's enrollment could be denied because Dr. X is an owner.

Example #2: Dr. John Smith's practice ("Smith Medicine") is set up as a sole proprietorship. He incurs a $50,000 overpayment. He terminates his Medicare enrollment. Six months later, he tries to enroll as a sole proprietorship; his practice is named "JS Medicine." A denial is warranted because § 424.530(a)(6) applies to physicians and the $50,000 overpayment was attached to him as the sole proprietor.

Example #3 - Same scenario as example #2, but assume that his new practice is an LLC of which he is only a 30 percent owner. A denial is still warranted because he is an owner of the enrolling supplier and the $50,000 overpayment was attached to him.

Example #4 - Jane Smith is a nurse practitioner in a solo practice. Her practice ("Smith Medicine") is set up as a closely-held corporation, of which she is the 100 percent owner. Smith Medicine is assessed a $20,000 overpayment. She terminates her Medicare enrollment. Nine months later, she submits a Form CMS-855I application to enroll herself, Jane Smith as a new individual provider. The business will be established as a sole proprietorship. A denial is not warranted because the $20,000 overpayment was attached to Smith Medicine, not to Jane Smith.

In each of these examples, however, denial could be avoided if (1) the party with the overpayment is on a Medicare-approved plan of repayment or (2) the overpayments in question are currently being offset or being appealed.

4. Additional Considerations Involving § 424.530(a)(6)

The contractor shall also observe the following with respect to § 424.530(a)(6):

a. In determining whether an overpayment exists, the contractor need only review its own records; it need not contact other contractors to determine whether the person or entity has an overpayment in those contractor jurisdictions.

b. The instructions in this section 10.4.2.2(F) apply only to (i) initial enrollments and (ii) new owners in a change of ownership.

c. The term "owner" under § 424.502 means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

d. If the person or entity had an overpayment at the time the application was filed but repaid it in full by the time the contractor performed the review described in this section 10.4.2.2(F), the contractor shall not deny the application based on § 424.530(a)(6).

G. Denial Reason 7– Medicare or Medicaid Payment Suspension (42 CFR § 424.530(a)(7))

(i) The provider or supplier, or any owning or managing employee or organization of the provider or supplier, is currently under a Medicare or Medicaid payment suspension as defined in §§ 405.370 through 405.372 or in § 455.23 of this chapter.

(ii) CMS may apply the provision in this paragraph (a)(7) to the provider or supplier under any of the provider's, supplier's, or owning or managing employee's or organization's current or former names, numerical identifiers, or business identities or to any of its existing enrollments.

(iii) In determining whether a denial is appropriate, CMS considers the following factors:

(A) The specific behavior in question.

(B) Whether the provider or supplier is the subject of other similar investigations.

(C) Any other information that CMS deems relevant to its determination.

H. Denial Reason 8– Home Health Agency (HHA) Capitalization (42 CFR § 424.530(a)(8))

An HHA submitting an initial application for enrollment:

a. Cannot, within 30 days of a CMS or Medicare contractor request, furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement in 42 CFR § 489.28(a); or

b. Fails to satisfy the initial reserve operating funds requirement in 42 CFR § 489.28(a).

I. Denial Reason 9– Hardship Exception Denial and Fee Not Paid (42 CFR § 424.530(a)(9))

"The institutional provider's (as that term is defined in 42 CFR § 424.502) hardship exception request is not granted, and the institutional provider does not submit the required application fee within 30 days of notification that the hardship exception request was not approved."

(This denial reason should only be used when the institutional provider fails to submit the application fee after its hardship request was denied. The contractor shall use § 424.530(a)(1) as a basis for denial when the institutional provider: (a) does not submit a hardship exception request and fails to submit the application fee within the prescribed timeframes; or (b) submits the fee, but it cannot be deposited into a government-owned account.)

J. Denial Reason 10– Temporary Moratorium (42 CFR § 424.530(a)(10))

"The provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." (This denial reason applies to initial enrollment applications and practice location additions.)

K. Denial Reason 11 – Prescribing Authority (42 CFR § 424.530(a)(11))

"1. A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause; or

2. The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor."

(Except as otherwise stated in this chapter or in another CMS directive, the contractor need not verify whether an individual's DEA certificate was surrendered in response to a show cause order.)

NOTE: With respect to (a)(11), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

L. Denial Reason 12 (42 CFR § 424.530(a)(12) - Revoked Under Different Name, Numerical Identifier, or Business Identity)

"The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In making its determination, CMS considers the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);
(ii) Geographic location;
(iii) Provider or supplier type;
(iv) Business structure; or
(v) Any evidence indicating that the two parties [the revoked provider/supplier and the newly-enrolling provider/supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

NOTE: With respect to (a)(12), PEOG – rather than the contractor – will make all determinations regarding whether a provider or supplier was revoked under a different name, numerical identifier or business identity.

M. Denial Reason 13 (42 CFR § 424.530(a)(13) - Affiliation that Poses an Undue Risk)

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 (specifically, the factors listed in 42 CFR § 424.519(f)) that poses an undue risk of fraud, waste, and abuse to the Medicare program."

An affiliation is defined as any of the following:

(i) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
(ii) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
(iii) An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of § 424.519 only, sole proprietorships), either under contract or through

some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.
(iv) An interest in which an individual is acting as an officer or director of a corporation.
(v) Any reassignment relationship under § 424.80.

NOTE: With respect to (a)(13), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has an affiliation per 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse.

N. Denial Reason 14 (42 CFR § 424.530(a)(14) – Other Program Termination or Suspension)

"(1) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program; or (2) the provider or supplier's license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling."

In determining whether a denial under § 424.530(a)(14) is appropriate, CMS considers the following factors:

a. The reason(s) for the termination, suspension, or revocation;

b. Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one state's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other state licensing boards, or has had any other final adverse actions (as that term is defined in § 424.502) imposed against it; and

c. Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(14), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has a termination or suspension from another program or has a license that is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling.

O. Denial Reason 15 (42 CFR § 424.530(a)(15) – Patient Harm)

"The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm

(B) The nature of the physician's or other eligible professional's conduct

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree: (i) license restriction(s) pertaining to certain procedures or practices; (ii) required compliance appearances before state oversight board members; (iii) license restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge); (iv) administrative/monetary penalties; and (v) formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon."

Section 424.530(a)(15) does not apply to actions or orders pertaining exclusively to either of the following: (i) required participation in rehabilitation or mental/behavioral health programs; or (ii) required abstinence from drugs or alcohol and random drug testing.

NOTE: With respect to (a)(15), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

P. Denial Reason 17 – False Claims Act Judgment (42 CFR § 424.530(a)(17))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted)

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502)

(F) Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(17), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

Q. Denial Reason 18 – Standard or Condition Violation (42 CFR § 424.530(a)(18))

(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (c).

(Similar to current practice with respect to § 424.530(a)(1), the contractor can make denial determinations under § 424.530(a)(18) without prior PEOG approval. The contractor's denial letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

(See section 10.4.2.3 for more information regarding § 424.530(a)(18).)

10.4.2.3 – Additional Denial Policies

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Post-Denial Submission of Enrollment Application

A denied provider may not submit a new enrollment application until:

(i) If the initial denial was not appealed, the provider's appeal rights have lapsed;

(ii) If the initial denial was appealed, the provider has received notification that the determination was upheld; or

(iii) The reapplication bar has expired, if applicable.

The contractor shall return an application submitted before the aforementioned have occurred.

B. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR § 424.530(c), if the denial was due to adverse activity (e.g., exclusion, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel of the provider or supplier furnishing services payable by a federal health care program, the denial may

be reversed (with PEOG approval) if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

C. Denials - Changes of Information and Changes of Ownership (CHOWs)

1. Expiration of Timeframe for Reporting Changes

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to the CMS MedicareProviderEnrollment@cms.hhs.gov mailbox notifying PEOG of the denial. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

2. Timeframe Not Yet Expired

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in subsection (C)(1) above after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

3. Second Rejection, Return, or Denial

If, per subsection (C)(2) above, the provider resubmits the change of information or CHOW application and the contractor either denies it again, returns it, or rejects it, the contractor shall send the e-mail referenced in subsection (C)(1) above regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

D. Reactivations

If the contractor denies a reactivation application, the provider's Medicare billing privileges shall remain deactivated or revoked.

E. Revalidations

If the contractor denies a revalidation application, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider's Medicare billing privileges if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If, per the previous sentence, the provider resubmits the application and the contractor denies it again, returns it, or rejects it, the contractor shall - unless an existing CMS instruction or directive states otherwise – revoke the provider's billing privileges, assuming the applicable time period has expired.

F. Appeals of Denials

For information regarding the provider enrollment appeals process, see section 10.6.18 of this chapter.

G. Use of 424.530(a)(1)

1. (A)(1) Versus (A)(5)

If a denial is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.530(a)(5) (rather than § 424.530(a)(1)) as the denial reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(18)

If a denial is warranted due to non-compliance with one of the standards and conditions referenced in § 424.530(a)(18) – and except as otherwise directed in this chapter (e.g., section 10.2.2.4(V)) -- the contractor shall use § 424.530(a)(18) (rather than § 424.530(a)(1)) as the denial reason. No CAP rights are therefore involved.

10.4.2.3.4 – Denial Based on Survey Failure

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

(The instructions in this section 10.4.2.3.4 apply only if both of the following requirements are met:

(i) The situation involves a certified provider/supplier initial enrollment denial based on the provider/supplier's failure of its state/accreditation survey (e.g., section 10.4.2.3.4 is inapplicable to revocations, changes of information involving a survey, etc.); and.

(ii) The certified provider/supplier type in question has "transitioned" (as that term is described in this chapter).

Except as otherwise stated, section 10.4.2.3.4 takes precedence over any other instruction in this chapter to the contrary. (For instance, if a SNF fails its survey and the state notifies the contractor thereof, the contractor shall follow the instructions in this section 10.4.2.3.4 rather than those in section 10.2.1.14(B)(3)(a) of this chapter.) All other denials (e.g., survey denials for non-transitioned providers; denials for transitioned providers for reasons other than a survey failure) shall be handled consistent with the instructions in this chapter.)

A. Traditional Process – Survey Failure

The longstanding process for state/accreditation survey failures typically involved the following:

(i) The SOG Location notifies the provider/supplier of the survey failure

(ii) The provider/supplier is given up to two additional opportunities for resurvey within 6 months of the SOG notification in (i) above

(iii) As applicable, no provider agreement, tie-in notice (CMS-2007), final denial notice, etc. from the SOG Location is issued unless or until the provider/supplier passes or fails the remaining survey(s) or the aforementioned 6-month period expires

(iv) Depending on the results of (iii), the SOG Location issues a tie-in approval/denial notice to the contractor

(v) The contractor finalizes the application

(vi) The SOG Location handles any resulting reconsideration.

Regarding paragraph (A)(ii) above: (1) the applicant may submit no more than two additional requests for survey/certification; and (2) no more than 6 months may elapse between the date of the SOG Location's first denial and the CMS's receipt of the second request. Note, however, that isolated cases can arise when a subsequent survey is completed within the 6-month period but the SOG Location does not receive the results until after the 6-month period expires. This is acceptable because the actual survey would have occurred timely. Thus, references to a "6-month period" in this section 10.4.2.3.4 includes isolated instances where the SOG Location is awaiting survey results beyond the expiration of this period.

B. Revised Process for Transitioned Certified Providers/Suppliers

Event 1 – Provider/Supplier Fails Initial Survey

(i) The state notifies the SOG Location and the contractor (typically via the CMS-1539) of the survey failure and the specific requirements the provider/supplier failed.

(ii) Within 5 business days of receiving this notification copy from the state, the contractor shall send to the provider/supplier the denial letter in section 10.7.5.1.1 of this chapter. (Notwithstanding any other instruction in this chapter to the contrary, this particular letter need not be sent via certified mail.) The state, accreditation organization (if applicable), and SOG Location shall be copied on the letter.

(iii) The letter shall include the reason(s) for the survey failure (from the CMS-1539) and reconsideration rights for said failure; the SOG Location will handle any reconsideration.

(iv) The 6-month clock commences on the date of the letter in (B)(ii) above.

(v) Once this letter is sent, no further action by the contractor is required at this time and the provider/supplier need not submit a new or revised application because of the survey failure. The enrollment application is not finalized but instead remains pending until the provider/supplier passes the survey or the six-month period has expired.

Event 2 – The 6-Month Period - Reconsiderations

(i) If the provider/supplier submits a reconsideration and the survey failure is overturned because of a successful survey, the SOG Location will notify the provider/supplier thereof. (The SOG

Location will also notify the contractor of the reversal via a CMS-1539 (or other approval notice).) The contractor shall follow the instructions in paragraph (i) in Event 3 below.

(ii) If the survey failure is upheld on reconsideration, the SOG Location will notify the provider/supplier and the contractor thereof. The contractor need not take further action at this time. During the above-referenced 6-month period, the state will perform no more than two additional surveys.

Event 3 – Final Decision

The state or SOG Location will notify the contractor of the final outcome of the 6-month period (e.g., survey is finally passed, provider fails subsequent survey). This could occur either before or after the exact date on which the 6-month period expired. The contractor is not required to internally track this 6-month period but need only wait for the state's or SOG Location's notification of the final outcome.

(i) Notice of Approval

If the state or SOG Location sends notice of its approval of the provider/supplier (e.g., subsequent survey passed; failure of the first survey was overturned on reconsideration), the contractor shall complete its processing of the application consistent with the instructions in this chapter regarding transitioned providers/suppliers. (To illustrate, if the provider is an HHA, the contractor shall follow the instructions in section 10.2.1.6(B).) In sending the appropriate approval letter, however, the contractor shall delete all references therein to provider agreement reconsiderations. This is because the provider/supplier has no further appeals rights related to the provider agreement.

(ii) Notice of Denial

If the state or SOG Location sends notice of its denial of the provider/supplier (e.g., the provider failed a subsequent survey(s); the provider did not file a reconsideration request regarding the first failed survey and/or no second survey was performed), the contractor shall follow the current denial instructions in this chapter for transitioned providers/suppliers.

10.4.3 – Voluntary and Involuntary Terminations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Voluntary Terminations of Certified Providers and Certified Suppliers

For information regarding certified provider/supplier voluntary terminations, see section 10.6.1.3 of this chapter.

B. Voluntary Terminations of Non-Certified Suppliers

The contractor shall adhere to the following when processing voluntary terminations of non-certified suppliers.

1. Timeframes – The contractor shall process such voluntary terminations in accordance with the timeframes in section 10.5 et seq. of this chapter.

2. Submission – Non-certified suppliers may only submit voluntary termination requests via the paper application process or PECOS. They cannot do so via letter.

3. Reassignments/PTANs - When processing a voluntary termination of a reassignment, the contractor shall contact the group to confirm that: (1) the group member PTAN is being terminated from all locations; and (2) if multiple group member PTANs exist for multiple group locations, each PTAN is terminated. However, if a group has one PTAN with multiple addresses, the contractor need not contact the group to confirm the termination.

4. PECOS and Deactivations - The contractor shall identify the voluntary termination action in PECOS as a deactivation with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per 42 CFR § 424.540(a)(7), and unless stated otherwise in this chapter or in another CMS directive, the effective date of the deactivation (for system purposes) shall be the day after the date on which the supplier voluntarily withdrew from Medicare

5. Reassignments - When processing a voluntary termination of a reassignment, the contractor shall terminate non-certified suppliers effective the day after that which the supplier requested on its termination application. (Note that this is different from a voluntary termination of the provider/supplier itself as addressed in subsection (B)(4) above.)

6. Special Payments - Upon receipt of a non-certified supplier voluntary termination request, the contractor may ask the supplier to complete the "Special Payments" portion of Section 4 of the Form CMS-855/20134 so that future payments can be sent thereto. If the supplier has no special payments address already on file, the addition should be included in the same transaction as the termination (i.e., one transaction incorporating both items). If the supplier wants to change its existing special payments address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The supplier is not required to submit a Form CMS-588 in conjunction with a termination.

C. Involuntary Terminations – Certified Providers/Suppliers

In the event an instruction in section 10.6.1 et seq. of this chapter contradicts guidance in this section 10.4.3(C), the section 10.6.1 et seq. guidance takes precedence.

1. Notification from State or SOG Location

If the contractor receives a notice from the state or SOG Location that involuntarily terminates a certified provider/supplier's Medicare participation because the provider/supplier no longer meets the conditions of participation, the contractor need not send a letter to the provider/supplier stating that its Medicare participation has been terminated. The state or SOG Location will issue such a letter and afford appeal rights. The contractor shall follow the applicable instructions in section 10.4.7 et seq. of this chapter with respect to revoking the provider/supplier's enrollment, since the provider/supplier is no longer compliant with Medicare enrollment regulations. **(NOTE:** The contractor must identify in its revocation letter the <u>exact</u> provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.)

The contractor shall record the revocation in PECOS using the status reason of "Non-Compliance: Provider/Supplier Type Requirements Not Met." The contractor shall not identify the involuntary termination action in PECOS as a Deactivation with a status reason of "Voluntarily Withdrawal from the Medicare Program." In addition, the contractor shall end-date the entity's enrollment record in PECOS in the same manner as it would upon receipt of a termination notice from the SOG Location.

2. Revocation Letter

Per subsection (C)(1) above, the contractor shall issue a revocation letter to the certified provider/supplier using 42 CFR § 424.535(a)(1) as the legal basis for the revocation. The letter shall also contain the effective date of the revocation, appeal rights, and the length of the reenrollment bar as determined by CMS and indicated to the contractor. (See section 10.7 et seq. of this chapter for the applicable revocation letter.) The contractor shall e-mail a copy of the letter to the SOG Location using the same e-mail address it normally uses when communicating with the SOG Location's survey and certification staff.

3. Additional Information

For more information on voluntary terminations, refer to:

- Section 1866(b)(1) of the Social Security Act
- 42 CFR § 489.52(b)
- Pub. 100-07, chapter 3, section 3046 (SOM)

10.4.4 – Changes of Information

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. General Information

Unless as stated otherwise in this chapter, the following apply:

(i) The instructions in this section 10.4.4 apply to Part A and Part B enrollments.

(ii) In the event an instruction in sections 10.6.1 et seq. or 10.6.22 et seq. of this chapter contradicts that in this section 10.4.4, the section 10.6.1 et seq. or 10.6.22 et seq. guidance takes precedence (e.g., transitioned certified provider/supplier change of information instructions in section 10.6.1.2 of this chapter).

(iii) Except as otherwise specified in this chapter or another CMS directive, if an enrolled provider/supplier is adding, deleting, or changing information under its existing tax identification number, it must report the change using the applicable Form CMS-855 or CMS-20134. (Letterhead is impermissible.) The provider/supplier shall: (a) furnish the changed data in the applicable section(s) of the form; and (b) sign and date the certification statement.

(iv) The timeframes for reporting changes are generally addressed in § 424.516.

B. Time Requirements to Report Changes of Information via a Form CMS-855/20134 Application

(For purposes of the regulatory provisions referenced in this section 10.4.4(B) (e.g., § 424.57(c)(2)):

- A practice location "change" includes location additions, deletions, and relocations.
- All practice location changes – regardless of the provider or supplier type involved – must be reported within 30 days of the change.)

1. Physicians/Non-Physicians/Groups

Pursuant to § 424.516(d), change of information requirements apply to physicians, non-physician practitioners, and physician and non-physician practitioner organizations (i.e., clinic/group practices). These supplier types must report the following changes within 30 days: (1) a change of ownership; (2) adverse legal action; and (3) a change in practice location. All other changes must be reported within 90 days.

2. DMEPOS Suppliers

Per 42 CFR §§ 424.57(c)(2) and 424.516(c), DMEPOS suppliers must report any change to their enrollment information within 30 days.

3. IDTFs

Per 42 CFR §§ 410.33(g)(2) and 424.516(b), IDTFs must report any change in adverse legal actions, ownership, location, and general supervision within 30 days. All other changes must be reported within 90 days.

4. MDPP Suppliers

Per 42 CFR §§ 424.205(d)(5) and 424.516(e), an MDPP supplier must update its enrollment application within 30 days of any change of ownership, practice location, change to its coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), or change in final adverse action history. All other changes must be reported within 90 days.

5. All Other Provider/Supplier Types

Consistent with 42 CFR § 424.516(e), all other provider/supplier types not specifically referenced in § 424.516(b) through (e) are subject to the following reporting timeframes:

(i) Changes of ownership or control (including changes in authorized official(s) or delegated official(s)); change of practice location – 30 days

(ii) All other changes – 90 days

(In addition, and per § 424.516(e)(3), an air ambulance supplier must report a revocation or suspension of its license or certification to the contractor within 30 days of the revocation/suspension. The following FAA certifications must be reported: (a) specific pilot certifications including, but not limited to, instrument and medical certifications; and (b) airworthiness certification.)

C. Signatories and Notifications

1. Signer Not on Record - If the signer has never been reported in Section 6 of the Form CMS-855 or CMS-20134, Section 6 must be completed in full with information about the individual. (This policy applies regardless of whether the provider/supplier already has a Form CMS-855/20134 on file.) The contractor shall conduct all required validations concerning the individual.

2. Notifications – For changes of information that do not require state agency or SOG Location approval (e.g., Form CMS-855I changes, Form CMS-855B changes not involving ambulatory surgical centers or portable x-ray suppliers, minor Form CMS-855A/B certified provider/supplier changes), the contractor shall:

(i) Furnish written, e-mail, PCV, or fax confirmation to the provider that the change has been made; and

(ii) Document PECOS (per sections 10.3 and 10.6.19 of this chapter) with the date and time the confirmation was made. If, however, the transaction only involves an area code/ZIP code change, the contractor need not send confirmation to the provider that it has processed the change.

3. Confirmation of Change in Practice Location Address

In cases where a provider submits a Form CMS-855 or Form CMS-20134 request to change its practice location address, the contractor shall contact the location currently associated with the provider in PECOS or MCS to verify that the provider/supplier is no longer there and did in fact move.

D. Change in Special Payments Address

Note that the instructions in this subsection (D) are in addition to, and not in lieu of, those in section 10.6.23 and vice versa.

1. Submitted Change - If the provider/supplier submits a change to its special payments address, the contractor shall verify the change by contacting the individual physician/practitioner (Form CMS-855I changes), an authorized or delegated official (Form CMS-855A, Form CMS-855B, and Form CMS-20134 changes), or the contact person listed in Section 13 (for Form CMS-855A, Form CMS-855B, Form CMS-20134, and Form CMS-855I changes). If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

2. Revalidation - When processing a revalidation application, the contractor shall (unless another CMS directive instructs otherwise) follow the instructions in sections 10.4.4(D) and 10.4.4(C)(3) above, respectively, if the practice location address or special payment address on the application is different from that currently associated with the provider in PECOS or MCS.

E. Provider or Supplier Changing Specialty Type

With the exception of individual physicians and certain situations described in section 10.3 of this chapter, providers and suppliers who wish to change their enrolled provider/supplier type must terminate their current enrollment and submit an initial enrollment application (Screening and an application fee (if applicable) applies for the new enrollment.)

F. Changes Involving Complete Form CMS-855 or CMS-20134 Applications

A provider must submit a complete Form CMS-855 or CMS-20134 application if it (1) submits any change request and (2) does not have an established enrollment record in PECOS. (For purposes of this requirement, the term "change request" includes EFT changes.) It is immaterial whether: (1) the provider or another party (e.g., local government changes street name) was responsible for triggering the changed data; or (2) the signer of the change request or EFT form already has a signature on file with the contractor.

If the contractor receives a change request from a provider that is not in PECOS, the contractor shall develop for the entire application consistent with the procedures described in this chapter (i.e., the contractor shall treat the transaction as a request for additional information). Consistent with existing policies for requesting additional data, the provider has 30 calendar days from the date of the contractor's request to furnish a complete Form CMS-855 or CMS-20134. During this period, the contractor should "hold" (i.e., not process) the change request until the entire application arrives; no L & T record shall be created in PECOS at this point.

If the provider fails to submit a complete application within the aforementioned 30-day period, the contractor shall follow the instructions in section 10.4.1.4.3 of this chapter.

If the provider submits the application, the contractor shall process it in accordance with the instructions in this chapter and all other applicable CMS directives. This includes:

(i) Processing the complete application consistent with the timeframes for initial applications outlined in this chapter.

(ii) Validate all data elements on the Form CMS-855 or CMS-20134 consistent with the instructions in this chapter pertaining to initial applications. The contractor shall not approve the change request until it has verified all data on the complete Form CMS-855 or CMS-20134 consistent with the instructions in this chapter.

(iii) Creating a record in PECOS prior to approving the change request. (The receipt date should be the date on which the complete application was received, not the date on which the initial change request was received.) The transaction should be treated as an initial enrollment in PECOS; internally, the contractor shall treat it as a change of information. As the complete application will presumably incorporate the changed data reported on the original Form CMS-

855 or CMS-20134 change request, the contractor shall not take two separate counts (one initial and one change request) for the transaction. (NOTE: Any PECOS 2.0 policies or procedures that are contrary to those in this subparagraph (iii) take precedence over the latter.)

G. Incomplete or Unverifiable Changes of Information

(The contractor shall follow the instructions in this section 10.4.4(G) if it cannot process the submitted change request to completion.)

There can be instances where a provider has an enrollment record in PECOS and submits a change request but: (1) fails to timely respond to the contractor's request for additional or clarifying information; or (2) the changed information cannot be validated. The contractor in these situations shall reject the change request in accordance with section 10.4.1.4.3 of this chapter. Moreover, if the changed information is of such materiality that the contractor cannot determine whether the provider still meets all enrollment requirements, the contractor shall refer the matter to its PEOG BFL for guidance. Examples include but are not limited to: (i) change in the provider's lone practice location; (ii) change in ownership; or (iii) change in EFT information.

H. Change of EFT Information

(Note that the instructions in this subsection (H) are in addition to, and not in lieu, those in section 10.6.23 and vice versa.)

If the provider submits a Form CMS-588 request to change the bank name, depository routing transit number, or depository account number, the contractor shall contact the individual physician/practitioner (for Form CMS-855I enrollees), an authorized or delegated official on record (for Form CMS-855A, CMS-855B, and Form CMS-20134 enrollees), or the Section 13 contact person on record (for Form CMS-855A, Form CMS-855B, Form CMS-20134 and Form CMS-855I enrollees) to verify the change. If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

I. Special Instructions for Certified Providers, ASCs, and Portable X-ray Suppliers

1. Timeframe for State Review

In situations where state and/or SOG Location review of the change of information is required (see sections 10.6.1.2 and 10.6.22.1), the contractor may (via any means) advise the provider that it may take several months for the request to be approved.

2. Post-Recommendation Changes

If an applicant submits a change request after the contractor recommends approval of the provider's initial Form CMS-855 application but before the state or SOG Location (as applicable) notifies the contractor that, respectively, it recommends approval of or approves the initial application, the contractor shall process the newly-submitted data as a separate change of information. The contractor shall not take the changed information/corrected pages and,

immediately upon receipt, send them directly to the state/SOG Location for incorporation into the existing application.

In entering the change request into PECOS, the contractor shall use the date on which it received the change request in its mailroom as the actual receipt date in PECOS; the contractor shall not use the date on which the contractor received the aforementioned state/SOG Location approval/recommendation. The contractor shall explain the situation in PECOS.

J. Critical Access Hospital (CAH) Addition of New Provider-Based Locations

Regulations found at 42 CFR § 485.610(e)(2) and in the State Operations Manual state that the CAH's provider-based location must meet certain distance requirements from the main campus of another hospital or CAH.

The contractor shall contact the appropriate SOG Location while processing the Form CMS-855A to verify that the CAH's new provider-based location is more than 35 miles (15 miles in the case of mountainous terrain or an area with only secondary roads) from the main campus of another hospital or CAH. The contractor may not make a recommendation for approval without receiving a response from the SOG Location.

If the SOG Location finds that CAH's new provider-based location meets the distance requirements, the contractor shall continue processing the application normally. If the SOG Location determines that the location does not meet the distance requirements, the contractor shall reject the application and issue to the CAH the applicable rejection letter outlined in section 10.7 et seq.

The SOG Location will provide the CAH with three options if the location does not meet the distance requirements:

1. The CAH keeps the new provider-based location, which will cause an involuntary termination in 90 days (as outlined in the Pub. 100-07, chapter 3, section 3012).
2. The CAH terminates the new provider-based location and continue its enrollment as a CAH.
3. The CAH keeps the new provider-based location but converts to a hospital (as outlined in Pub. 100-07, chapter 2, sections 2256G and 2256H).

For each option, the contractor shall keep the CAH's enrollment in an approved status in PECOS. For Option #1 above, the contractor will receive notice from the SOG Location of the termination, which will lead to revocation of the CAH's enrollment. For Option #2, the CAH's enrollment remains approved and the contractor shall expect no further communication from the SOG Location. If the CAH chooses Option #3 to convert to a hospital, the contractor will receive a Form CMS-855A to terminate the CAH's enrollment and a new Form CMS-855A to enroll as a hospital.

10.4.5 – Revalidations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Consistent with section 6401(a) of the Patient Protection and the Affordable Care Act (ACA), all existing providers and suppliers are required to revalidate their enrollment information under new enrollment screening criteria. Providers and suppliers are normally required to revalidate their Medicare enrollment every 5 years (every 3 years for DMEPOS suppliers). However, CMS reserves the right to perform off-cycle revalidations as deemed necessary.

Except as otherwise stated in this chapter or another CMS directive, the contractor shall follow the guidance in sections 10.4.5 through 10.4.5.3 of this chapter when processing revalidation applications. This guidance takes precedence over all other instructions in this chapter concerning revalidation processing unless, again, another CMS directive specifies otherwise. The contractor shall note, however, that some of the instructions in section 10.4.5 et seq. may not apply to PECOS revalidation applications. This is because, as stated in section 10.3(C) of this chapter:

(1) PECOS automatically handles revalidation tracking and revalidation requests and prevents the submission of PECOS revalidation applications outside of the revalidation window.
(2) PECOS establishes timeframes and then queues mailings based on revalidation history and enrollment dates (although CMS can modify timeframes and request off-cycle revalidations at any time; this includes those for large group revalidations.) All PECOS revalidation requests will be staggered so that revalidations are submitted and processed within 7 months of the provider's due date. This will eliminate the potential for unsolicited revalidation applications submitted outside of the 7-month window and permit a more structured and streamlined revalidation process.
(3) Failure to respond to a revalidation request would result in an automatic pend, deactivation, etc.

Accordingly, the contractor can disregard those instructions in section 10.4.5 et seq. that obviously do not apply to a particular situation.

10.4.5.1 – Revalidation Solicitations

(Rev. 12524; Issued: 03-01-24; Effective: 04-01-24; Implementation: 06-03-24)

A. Background

Under previous practice, CMS identified the providers and suppliers required to revalidate during each cycle. CMS communicated when new lists became available through the appropriate channels, at which time the contractor obtained the list from the CGI Share Point Ensemble website. With the advent of PECOS 2.0, PECOS will automatically: (i) determine when a provider/supplier is due to periodically revalidate its enrollment; and (ii) send a revalidation notice to the provider/supplier. Note that this new process of revalidation solicitation applies both to providers/suppliers that currently submit applications via (or otherwise utilize) PECOS or via paper. For the former group, solicitations will be sent via the PCV. For the latter, solicitations will be e-mailed via PECOS, and the affected provider/supplier may submit its revalidation application via paper; it is not required to use PECOS.

B. Sending Revalidation Letters

Based on the due date identified in PECOS, PECOS will send a revalidation notice (using the applicable letter in section 10.7 et seq. of this chapter) between 90 to 105 days prior to the provider/supplier's revalidation due date. The initial revalidation letter will include a generic provider enrollment signature.

C. Interaction with Change Request

If the contractor receives a change of information (COI) application from the provider after PECOS has mailed to the provider a revalidation notice, the contractor shall process it as a COI with no merger of the two applications; the applications shall be processed separately.

If the provider submits an application marked as a revalidation but that only includes enough information to be considered a COI, the contractor shall (1) develop for a complete application containing the missing data elements and (2) treat it as a revalidation.

D. Interaction with a Change of Ownership (CHOW)

PECOS will not commence revalidation action regarding a provider/supplier that is undergoing a CHOW that: (1) the contractor is currently processing; or (2) is pending review with the state agency.

E. Reassignment Applications Received After Revalidation Letter Mailed

If a reassignment application has been received after a revalidation letter has been sent to the affected provider/supplier, the contractor shall process the reassignment application. The supplier need not report the newly established reassignment/employment arrangement on the revalidation application, and the contractor shall not develop for this information; this is because the arrangement was established after the revalidation notice was issued. However, the contractor shall maintain the reassignment/employment arrangement information in the enrollment record when processing the revalidation application; this information shall not be overridden. If the supplier fails to respond to the revalidation request, all reassignments shall be end-dated, including the newly established reassignment. Consider the following illustration:

EXAMPLE: Dr. Doe submits a reassignment application to add a new reassignment to Browns Medical Center after receiving a revalidation request. He submits his revalidation application to his contractor but does not include the reassignment for Browns Medical Center because the contractor is still processing the reassignment application and has not yet approved the reassignment. The contractor finalizes the reassignment changes and then proceeds with processing the revalidation application. The contractor shall not develop for the new reassignment to Browns Medical Center and shall maintain the reassignment in the provider's enrollment record when processing the revalidation application.

F. Revalidation Extension Requests

The contractor shall only accept extension requests from a provider that was not given the full 7 months' advance notice prior to their revalidation due date. The contractor shall not accept extension requests from providers for any other reason.

The provider/supplier may submit its request in writing (fax/e-mail/PCV permissible) or via phone, though the individual provider, authorized/delegated official, or appropriate contact person shall make the request. (See section 10.3 of this chapter for information regarding contact persons for PECOS applications.)

G. Additional Letter Data

In addition to the PCV e-mailing revalidation correspondence, the contractor – in any circumstance required per this chapter -- shall print and mail the following PCV-generated letters: (1) revalidation notification letters (e.g., the first letter came back as undeliverable (see subsection (B)(2) above)); (2) stay of enrollment letters; and (3) deactivation letters.

(NOTE: As a general rule, the PCV can, among other things: (1) automatically send emails (e.g., revalidation); (2) send e-mails upon request (e.g., development); (3) generate letters/store letters; (4) send letters to a print queue; and (5) accept document uploads,)

10.4.5.2 – Non-Responses to Revalidation and Extension Requests
(Rev. 12524; Issued: 03-01-24; Effective: 04-01-24; Implementation: 06-03-24)

A. Phone Calls

The contractor may (but is not required to) continue to contact providers via telephone or e-mail to communicate non-receipt of revalidation applications.

B. Stay of Enrollment and Non-Responses to Revalidation Requests

(The contractor shall follow existing guidance regarding the application of stays of enrollment in revalidation situations, including that in section 10.4.9(D) of this chapter.)

No later than 5 business days after sending the applicable deactivation letter per existing guidance -- and if the deactivated supplier is a physician – the contractor shall search his/her associate record to determine if he/she serves as a supervising physician on any independent diagnostic testing facility (IDTF) enrollment. If he/she does, the contractor shall disassociate him/her as the supervising physician for that entity. If he/she is the only supervising physician n file for the IDTF, the contractor shall develop for an active supervising physician to bring the IDTF into compliance. The contractor shall give the IDTF 30 days to respond. Failure to provide an active supervising physician in the designated timeframe shall result in revocation of the IDTF's billing privileges for non-compliance with the IDTF standards.

10.4.5.3 – Receipt and Processing of Revalidation Applications
(Rev. 12524; Issued: 03-01-24; Effective: 04-01-24; Implementation: 06-03-24)

The provider may submit its revalidation application via paper or PECOS, though the latter is encouraged to allow for more expedited processing.

For paper applications, the contractor shall input the relevant data in PECOS consistent with

longstanding practice and with the policies in this chapter, including those in section 10.3.

Note that some of the instructions in this section 10.4.5.3 et seq. may be inapplicable to PECOS (e.g., developing for missing sections of the Form CMS-855 revalidation application). Also, the stay of enrollment instructions in sections 10.4.5.2 and 10.4.9 take precedence over those in this section 10.4.5.3 in the event of any conflict.

A. General Situations

1. Unsolicited Applications

An unsolicited revalidation application is one received outside of the PECOS revalidation request addressed in section 10.4.5.1. The contractor shall return such applications using the applicable sample return letter in section 10.7 et seq. within 20 business days of receipt. If the application was received more than 7 months prior to the provider/supplier's revalidation due date, the contractor shall use § 424.526(a)(8) as the return basis. If § 424.526(a)(8) does not apply to the situation, the contractor shall use § 424.526(a)(7) as the basis, for the application was inapplicable to or not needed for the transaction involved.

If applicable, the contractor shall also submit a request to CMS to have the application fee returned to the provider.

2. Signatures

The contractor may only accept revalidation applications signed by the individual provider or the authorized or delegated official.

3. Sub-Units

Any certified provider sub-unit that has a separate provider agreement must revalidate on a separate Form CMS-855A. It cannot revalidate via the main provider's Form CMS-855A. If the sub-unit has a separate CMS Certification Number (CCN) but not a separate provider agreement (e.g., hospital psychiatric unit, HHA branch), the sub-unit can disclose the revalidation on the main provider's Form CMS-855A; this is because the sub-unit is a practice location of the main provider and not a separately enrolled entity. Separate fees, too, are not required.

4. Collapse of PTANs

If the provider requests to collapse its PTANs per a revalidation, the contractor shall process said requests if appropriate (based on payment localities, etc.).

5. Voluntary Withdrawal

(This subsection (A)(5) does not apply to certified providers/suppliers. See section 10.6.1.3 of this chapter for instructions concerning certified provider/supplier voluntary terminations.)

If a non-certified supplier wishes to voluntarily withdraw from Medicare (including deactivating all active PTANs), the contractor shall accept this request via phone, U.S. mail, or fax from the individual supplier or the authorized/delegated official (on letterhead); the contractor shall not require the non-certified supplier to complete a Form CMS-855 or CMS-20134 application. If the contractor makes the request via telephone, the contractor shall document the telephone conversation in PECOS and take the appropriate action in PECOS.

B. Development Required

(Note that some of the instructions in this subsection (B) will be inapplicable to PECOS applications. See section 10.3 for more information.)

1. General Instructions

If a revalidation application requires development (e.g., missing application fee, clarification or documentation needed, missing reassignments), the contractor shall notify the provider via mail, telephone, the PCV, fax, or e-mail. The contractor shall develop for all of the required information in one development request. The provider has 30 days to respond to the contractor's request. For paper applications, the provider may submit the information via mail, fax, or e-mail containing scanned documentation; this includes missing signatures and dates. For PECOS applications, the provider must submit the information via PECOS. (Note that the provider may submit a full Form CMS-855I or Sections 1, 2, 4, & 15 of the Form CMS-855I to report missing reassignments any time prior to their revalidation due date; this includes post-revalidation application approval.)

If the contractor can verify licensure and/or educational requirements (e.g., non-physician practitioner's degree or diploma) online, the contractor shall not require the provider to submit this documentation. If the supporting documentation currently exists in the provider's file, the provider need not submit that documentation again with their revalidation application; the contractor may utilize the existing documentation for verification. Residency information is not required as part of a revalidation. In addition, the contractor need not develop for data that is missing or needs clarification on the provider's revalidation application if the provider accurately disclosed (meaning no clarification is needed) the information (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, though with the exception of the following items:

(i) Adverse legal action data
(ii) LBN
(iii) Tax identification number (TIN)
(iv) NPI-legacy number combinations
(v) Supplier/Practitioner type
(vi) DBA name
(vii) Effective dates of sale/transfer/consolidation or indication of acceptance of assets/liabilities

The contractor shall not require providers to include the PTAN(s) in Section 2 or 4 of the revalidation application---provided that the provider included the information needed (NPI, TIN, LBN, DBA, etc.) for the contractor to appropriately make the association. If the PTAN was not

submitted but is needed to make the connection, the contractor shall use the shared systems, PECOS, or its provider file(s) as a resource before developing with the provider.

The contractor shall not develop for the EFT form if the provider has the 05/10 or 09/13 version of the Form CMS-588 on file. If provider submits an EFT form with a bank letter or voided check, the contractor may verify that the LBN matches and develop to process the application accordingly. Note that the instructions in section 10.6.23 apply to revalidations.

If the supporting documentation currently exists in the provider's file, the provider need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a previously submitted enrollment application (or documentation currently uploaded in PECOS) qualifies as a processing alternative, unless stated otherwise in this chapter or any CMS directive. In addition, per the instructions in this chapter, the contractor shall document in PECOS that it found the missing information elsewhere in the enrollment package, with previously submitted applications, or with documentation currently uploaded in PECOS. (This excludes information that the contractor must verify at the current point in time (e.g., a license without a primary source verification method).) In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

If a revalidation response is received for a single reassignment within an enrollment record that has multiple reassignments, the contractor shall develop with the contact person (or the individual provider if a contact is not listed) for the remaining reassignments not accounted for. If no response is received within 30 days, the contractor shall revalidate the single reassignment and deactivate the reassignments within the enrollment records that were not revalidated.

If other missing information is not received within 30 days, the contractor shall deactivate the provider within 25 days after the development due date and notify the provider of the deactivation using the applicable sample letter in section 10.7 et seq. of this chapter. After deactivation, the provider must submit an entirely new application in order to reactivate their PTANs. The contractor may use any supporting documentation received (if needed) for subsequent application submissions.

The deactivation date shall be consistent with the latter of: (1) the revalidation due date; or (2) the date on which the deactivation occurred due to non-response or incomplete response to a development request for all provider business structures (e.g., organizations, sole proprietors, sole owners, etc.).

2. Illustrations

Consider the following examples that address the instructions in section 10.4.5.3(B)(1):

SCENARIO #1 - PECOS issues a revalidation notice to the provider and includes reassignments and/or employment arrangements for Groups A, B & C. The provider submits the revalidation application but only addresses the reassignment for Group A. The contractor develops with the contact person for the missing reassignments and/or employment arrangements for Groups B & C. The provider responds with the reassignment information for Groups B & C prior to the development due date. Since the revalidation application remains in progress, the provider may

submit a full Form CMS-855I or Sections 1, 2, 4, & 15 of the Form CMS-855I to report the missing reassignment information (even post-revalidation application approval). Here, the contractor processes the revalidation application to completion, and the provider experiences no break in billing.

SCENARIO #2 - The contractor issues a revalidation notice to the provider and includes reassignments and/or employment arrangements for Groups A, B & C. The provider submits the revalidation application to the contractor but only addresses the reassignment for Group A. The contractor develops with the contact person for the missing reassignments and/or employment arrangements for Groups B & C. No response is received within 30 days, and the revalidation due date has passed. In this situation, Group A's reassignment is revalidated, and the contractor shall deactivate Group B & C's reassignments and/or employment arrangements effective with the date on which the contractor took deactivation action due to non-response or incomplete response to a development request. The approval letter shall identify the reassignments and/or employment arrangements that were revalidated and those that were terminated with the effective date of the reassignment or termination. The provider must submit a full application (Form CMS-855R) to reactivate the reassignment. The reactivation effective date is based on the receipt date of the CMS-855R.

In Scenario #2, therefore: (i) the provider experiences a break in billing but the contractor only deactivates the non-response reassignments and/or employment arrangements; and (ii) the contractor revalidates the other reassignments and/or employment arrangements.)

Contractor-initiated development letters, however, shall include a provider enrollment analyst's name and phone number for provider contacts.

C. Revalidation Received After a Deactivation Occurs

1. General Guidance

The contractor shall require a deactivated provider to submit a new, full application to reactivate their enrollment record. The contractor shall process the application as a reactivation. The provider shall maintain their original PTAN; however, the contractor shall reflect a gap in coverage (between the deactivation and the reactivation) on the existing PTAN using A/R codes in MCS and based on the application's receipt date. The provider will not receive reimbursement for dates of service in which they were non-compliant with Medicare requirements (deactivated for non-response to revalidation). The contractor shall reactivate group members (with the group enrollment) who had their reassignment associations terminated when the contractor deactivated the group. The effective dates assigned to the reassigned providers should align with the group's effective date per standard reactivation instructions.

2. Certified Providers and Certified Suppliers

Unless CMS instructs otherwise, the contractor shall allow a certified provider/supplier to maintain its original PTAN and effective date when the reactivation application is processed. (As stated in § 424.540(c), a deactivation does not terminate a certified provider/supplier agreement.) In addition, when processing the revalidation application after a deactivation occurs, the

contractor shall not require the deactivated certified provider/supplier to obtain a new state survey or accreditation as a condition of revalidation.

D. Finalizing the Revalidation Application

Prior to processing the revalidation application to completion, the contractor shall:

(i) Ensure that a site visit (if applicable to the provider in question) occurs.

(ii) Ensure that the provider meets all applicable federal regulatory requirements regarding licensure, certification, and/or educational requirements.

(iii) Revalidate the provider's information based on the data in PECOS.

(iv) Verify the practice locations, although the contractor need not contact each location separately. The contractor shall: (1) verify the location(s) by contacting the contact person listed on the application; and (2) note the validation accordingly in the contractor's verification documentation per the instructions in this chapter.

(v) Ensure that the appropriate record type and finalization status are identified in PECOS.

(vi) Ensure that an enrollment record is not marked as revalidated in PECOS if responses have been received for some PTANs but not all PTANs have been addressed (meaning that no action has been taken on the non-response PTANs, e.g., end-dated). If all PTANs have been addressed (e.g., revalidated, end-dated), the enrollment can be marked as revalidated.

(vii) Ensure that PECOS and the claims systems remain consistent. The contractor shall not directly update the shared systems without first updating PECOS when processing a revalidation (unless instructed otherwise in another CMS directive).

(viii) When processing is complete, issue an approval letter to the contact person (or the provider if no contact person is listed) via mail, fax, the PCV, or e-mail. (For PECOS If the provider has reassignments that were terminated due to non-response, the approval letter shall contain the reassignments that were terminated due to non-response and the effective date of termination (i.e., the revalidation due date or the development due date).

E. Revalidation Reporting

Unless CMS requests it, the contractor need no longer submit reports to CMS regarding its revalidation activities, for the revalidation data is captured in PECOS.

10.4.6 – Reactivations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Form CMS-855 or CMS-20134 Reactivations – Screening Levels

1. Limited

The contractor shall process reactivation applications from providers in the "limited" level of categorical screening in accordance with existing instructions.

2. Moderate

The contractor shall process reactivation applications from providers in the "moderate" level of categorical screening (including existing HHAs and DMEPOS suppliers) in accordance with the screening procedures for this category. A site visit is thus needed prior to the contractor's final decision regarding the application.

3. High

The contractor shall process reactivation applications from providers in the "high" level of categorical screening in accordance with the screening procedures for this category. A site visit is thus needed prior to the contractor's final decision regarding the application.

B. Form CMS-855B and CMS-855I Non-Certified Supplier Reactivations

If the contractor approves a Part B non-certified supplier's reactivation application, the reactivation effective date shall be the date the contractor received the application that was processed to approval. In addition, upon reactivating a Part B non-certified supplier, the contractor shall issue a new PTAN; for PECOS applications (and as indicated in section 10.3 of this chapter), PECOS will automatically issue a new PTAN.

C. Form CMS-855A or CMS-855B Certified Provider or Supplier Reactivations

With the exception of HHAs, reactivation of a certified provider/supplier does not require a new state survey, provider agreement, or participation agreement. Per 42 CFR § 424.540(b)(3)(i), an HHA must undergo a new state survey or obtain accreditation by an approved accreditation organization before it can be reactivated.

D. Reactivations - Deactivation for Reasons Other Than Non-Submission of a Claim

To reactivate its billing privileges, the provider or supplier must submit a complete Medicare enrollment application if the provider or supplier was deactivated: (i) for failing to timely notify the contractor of a change of information; or (ii) under § 424.540(a)(4) and (a)(5).

E. Reactivation Effective Date

Per 42 CFR § 424.540(d)(2), the effective date of a reactivation of billing privileges under this section is the date on which the contractor received the provider's or supplier's reactivation submission that the contractor processed to approval. Under 42 CFR § 424.540(e), however, the provider or supplier may not receive payment for services or items furnished while deactivated. This means that the contractor shall not add a retroactive back-billing period (e.g., 30 days) to

the reactivation effective date. To illustrate, suppose the contractor establishes a reactivation effective date under § 424.540(d)(2) of October 30, the date the contractor received the ultimately approved reactivation submission. The contractor under § 424.540(e) cannot establish an effective date earlier than October 30 to allow for additional retroactive billing.

F. Miscellaneous Policies

1. Previous Withdrawn Status

A provider that voluntarily withdraws (or, in the case of a certified provider/supplier, voluntarily or involuntarily withdraws from Medicare enrollment) is ineligible for reactivation. Such a provider must complete an initial enrollment application and, if applicable, pay an application fee.

2. Deactivation for Non-Billing

For providers deactivated for non-billing, the provider must submit a complete Form CMS-855 or CMS-20134 enrollment application via paper or PECOS Web.

3. Contractor Timeliness Standards

For Form CMS-855 or CMS-20134 reactivation applications, the timeliness requirements in section 10.5 et seq. of this chapter pertaining to initial enrollment applications apply. Except as otherwise stated in this chapter or another CMS directive, the contractor shall validate all of the information on the application as it would with an initial application.

10.4.7 – Revocations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In executing the instructions in section 10.4.7 et seq. of this chapter, the contractor shall also adhere to:

(i) All supplemental and any superseding instructions in section 10.6.6 of this chapter concerning final adverse actions (e.g., referrals to PEOG);

(ii) The letter formats and verbiage in section 10.7 et seq. of this chapter;

(iii) The PECOS 2.0 instructions in section 10.3 of this chapter; and

(iv) Any other directive that, per CMS, explicitly pre-empts any instruction(s) in section 10.4.7 et seq. of this chapter.

If any instruction in categories (i) through (iv) above conflict with that in section 10.4.7 et seq., the instruction in (i), (ii), (iii), or (iv) applies. In addition, the contractor shall adhere to any instruction in (i), (ii), (iii), or (iv) above that addresses a revocation-related matter not discussed in section 10.4.7 et seq.

10.4.7.1 – Revocations – Background and General Requirements
(Rev. 12550; Issued: 03-21-24; Effective: 04-21-24; Implementation: 04-21-24)

A. Introduction

Medicare revokes currently enrolled providers/suppliers' Medicare billing privileges and corresponding provider/supplier agreements pursuant to federal regulations at 42 CFR § 424.535. (A Medicare revocation is a "termination" as defined at 42 CFR § 455.101.) A revocation of Medicare billing privileges does not affect a provider's ability to submit claims to non-Medicare payers using their NPI.

If the contractor determines that a provider's billing privileges should be revoked or receives information from PEOG that a provider's billing privileges should be revoked, it shall undertake activities to process the revocation, apply the revocation in PECOS, notify the provider, and afford appeal rights. This section 10.4.7.1 includes, but is not limited to, information concerning the contractor's responsibilities to:

(i) Prepare a draft revocation letter

(ii) E-mail the letter to the appropriate PEOG mailbox with additional pertinent information regarding the basis for revocation

(iii) Receive PEOG's determination and follow PEOG's instructions regarding the case

(iv) If PEOG authorizes the revocation: (a) revoke the provider's billing privileges effective on the appropriate date; (b) establish the applicable reenrollment bar; (c) update PECOS with the appropriate reenrollment bar length; (d) assess an overpayment, as applicable; and (e) send the revocation letter (including affording appeal rights) to the provider via certified mail.

B. Administrative Requirements

This section 10.4.7.1(B) addresses (in greater specificity than section 10.4.7.1(A)) certain contractor administrative activities pertaining to revocations. As stated in section 10.4.7.1(A), however, the contractor shall take into account the instructions in sections 10.6.6 and 10.7 et seq.

1. Processing Timeframes

If the contractor receives approval from PEOG (or receives an unrelated request from PEOG) to revoke a provider's billing privileges, the contractor shall complete all steps associated with the revocation no later than five (5) business days from the date it received PEOG's approval/request. The contractor shall notify PEOG that it has completed all revocation steps no later than three (3) business days after completion.

2. Revocation Letters - Contents

i. General Information

When the contractor discovers a basis for revoking a provider's enrollment under 42 CFR § 424.535 - and, if applicable under section 10.6.6 of this chapter or another CMS directive, receives PEOG's approval for the revocation - the contractor shall revoke billing privileges and notify the provider by letter. The revocation letter shall contain:

(a) A legal (i.e., regulatory, such as § 424.535(a)(3) or §424.535(a)(9)) basis for each reason for revocation (the contractor shall not use provisions from this chapter as the basis for revocation);

(b) A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence that the contractor used in making its determination;

(c) An explanation of why the provider does not meet the applicable enrollment criteria;

(d) The effective date of the revocation;

(e) Procedures for submitting a CAP (if revoked under § 424.535(a)(1));

(f) Complete and accurate information about the provider's appeal rights;

(g) Any other information contained in or required by the applicable model letter in section 10.7 et seq.

ii. One Letter Per Enrollment

The contractor shall issue a unique revocation letter per enrollment. For example, regarding revocation letters for solely owned organizations, when revoking a physician/non-physician practitioner's billing privileges and those of his/her solely owned organization, the contractor shall issue **two** revocation letter: one for the individual and the other for the solely owned organization. The contractor shall not issue one letter to convey revoked Medicare billing privileges for both the individual and the solely owned organization.

3. Revocation Letters – PEOG Approval

Using the guidance in this section 10.4.7.1(B) et seq., section 10.6.6, and section 10.7 et seq., the contractor shall determine whether it must submit its draft revocation letter to PEOG for approval prior to sending it to the provider.

i. Prior PEOG Approval Required

If prior PEOG approval of the letter is required, the contractor shall submit the letter to the appropriate PEOG mailbox for PEOG review. PEOG will examine the letter for technical correctness and determine matters such as: (1) whether the revocation affects the revoked provider's other locations; (2) the length and application of the reenrollment bar; and (3) the revocation effective date. PEOG will notify the contractor of the outcome of its review and instruct the contractor how to proceed.

The contractor shall not begin finalizing the revocation until it receives guidance from PEOG.

The contractor may not alter an approved revocation letter; if it needs to revise said letter, the contractor shall submit the letter to PEOG for a new review via the process described above.

Unless CMS has directed otherwise, the contractor shall document and report the impacted application/enrollment in its Monthly Status Reports.

ii. When PEOG Approval of Revocation Letter is Unnecessary

The contractor need not obtain prior PEOG approval of the revocation and the revocation letter if the revocation involves any of the following situations:

- § 424.535(a)(1) (for (a)(1) noncompliance issues other than Noncompliance – Not Professionally Licensed Individual Practitioners OR except as otherwise required in this chapter or another CMS directive)
- § 424.535(a)(6)
- § 424.535(a)(11)

4. Issuing the Revocation Letter to the Provider

The contractor shall send revocation letters by USPS certified mail. (The contractor may e-mail a follow-up copy of the letter after issuing it via USPS certified mail.) The contractor shall date and mail the letter on the same business day.

10.4.7.2 – Revocation Effective Dates

(Rev. 12550; Issued: 03-21-24; Effective: 04-21-24; Implementation: 04-21-24)

A. Effective Dates

The contractor shall apply a revocation effective date based upon federal regulations at § 424.535(g). In general, and as discussed below, these dates are either prospective or retroactive.

1. Revocations with Retroactive Effective Dates (§ 424.535(g)(2))

The following revocation reasons require a retroactive effective date per § 424.535(g):

(i) Federal exclusion or debarment

(ii) Felony conviction

(iii) License suspension, revocation, or voluntary surrender in lieu of further disciplinary action

(iv) Determination that the provider or supplier is no longer operational

(v) Termination from a federal health care program other than Medicare (for example, Medicaid)

(vi) Termination of a provider agreement under 42 CFR part 489; or

(vii) Violation of provider or supplier standard as described in 42 CFR §§ 424.535(a)(23) and § 424.535(g)(2)

A revocation based upon any of these reasons is effective with (as applicable to the specific revocation reason):

- The date of the exclusion, debarment, felony conviction, license suspension/revocation/voluntary surrender in lieu of further disciplinary action, or federal health care program (other than Medicare) termination;
- The date that CMS or the contractor determined that the provider is no longer operational;
- The date the provider agreement is terminated (under 42 CFR part 489) or, as applicable the date CMS establishes under 42 CFR § 489.55; or
- The date of the specific provider or supplier standard or condition violation as described in § 424.535(g)(2)

To illustrate, for a revocation involving a licensure revocation/suspension, the revocation effective date (and the date listed on the revocation letter) shall be the date of the actual license revocation/suspension.

Additionally, and as described in 424.535(g)(3), if the action that triggered the revocation occurred before the provider's or supplier's enrollment, the revocation effective date is the enrollment effective date that CMS assigned to the provider or supplier. To illustrate, for a revocation involving an adverse legal action that occurred on February 1 (of which CMS was not aware) and the provider was enrolled effective April 1, the revocation effective date would be April 1 rather than February 1. Strictly for purposes of applying § 424.535(g)(3) -- and notwithstanding any guidance to the contrary in section 10.6.2 of this chapter – the effective date of enrollment is the date that was established under §§ 424.520 or 424.521, whichever is earlier.

2. Revocations with Prospective Effective Dates (§ 424.535(g)(1))

The contractor shall use a prospective effective date (i.e., the date that is 30 days after CMS or the CMS contractor mails notice of its determination to the provider) for revocations not based upon one of the reasons listed in §§ 424.535(g)(2) and section 10.4.7.2(A) above (e.g., § 424.535(a)(8) -- abuse of billing).

B. Revocations Based Upon More than One Reason

When a revocation involves more than one reason, the contractor shall determine whether any of the grounds require a retroactive effective date (listed in §§ 424.535(g) and section 10.4.7.2(B) above; if a retroactive date is indeed implicated, the contractor shall apply the appropriate retroactive date.

10.4.7.3 – Revocation Reasons
(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

Sections 10.4.7.3(A) through (V) list the revocation reasons in 42 CFR § 424.535. Section 10.4.7.3(W) discusses extensions of revocations per 42 CFR § 424.535(i).

(NOTE: See section 10.2.2.4(V) of this chapter for instructions regarding the application of 42 CFR § 424.535(a)(1) and (23) to IDTF revocations. In the event of any inconsistency, the section 10.2.2.4(V) guidance takes precedence over that in section 10.4.7 et seq.)

A. Revocation Reason 1 – Noncompliance (42 CFR § 424.535(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in this Title 42 or in the enrollment application applicable to its provider or supplier type and has not submitted a plan of corrective action as outlined in 42 CFR Part 488. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter."

(Title 42 includes the principal provider enrollment regulations in 42 CFR Part 424, subpart P; the IDTF enrollment standards in 42 CFR § 410.33; the OTP enrollment standards in 42 CFR § 424.67; etc.)

Noncompliance includes but is not limited to: (1) the provider/supplier no longer has a physical business address or mobile unit where services can be rendered; (2) the provider/supplier does not have a place where patient records are stored to determine the amounts due such provider or other person; and/or (3) the provider/supplier no longer meets or maintains general enrollment requirements. Noncompliance also includes situations when the provider/supplier has failed to pay any user fees as assessed under 42 CFR Part 488.

Other situations (some of which were mentioned in the previous paragraph) in which § 424.535(a)(1) may be used as a revocation reason include, but are not limited to, the following:

- The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

- The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

- The provider or supplier is not appropriately licensed. (NOTE: For (a)(1) revocations involving an individual practitioner who is not appropriately licensed due to a disciplinary action, PEOG -- rather than the contractor -- will make all determinations to revoke for this noncompliance requirement).

- The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.

- The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.

- The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

- The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider/supplier's notification from CMS or its contractor to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information. (This revocation reason will not apply if CMS has instructed the contractor to use deactivation reason § 424.540(a)(3) in lieu thereof.)

- The provider or supplier does not otherwise meet general enrollment requirements.

(Concerning the last bullet above – and, as applicable, bullets 3, 4 and 5 – the contractor's revocation letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider/supplier type.)

Special Instructions Regarding Certified Providers/Suppliers – The SOG Location may involuntarily terminate a certified provider/supplier if the latter no longer meets CMS requirements, conditions of participation, or conditions of coverage. When this occurs, CMS terminates the provider'/supplier's provider agreement and notifies the contractor thereof. Upon receipt of the CMS notice (and except as otherwise stated in this chapter), the contractor shall follow the revocation procedures in this chapter (including, as applicable, those in section 10.6.6)), using § 424.535(a)(1) as the revocation basis; the contractor shall not process the involuntary termination as a deactivation based upon a voluntary withdrawal from Medicare.

Note that the contractor need not (but certainly may) contact the SOG Location to obtain further details of the termination.

B. Revocation Reason 2 – Provider or Supplier Conduct (42 CFR § 424.535(a)(2))

"(i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel furnishing services payable by a federal health care program, of the provider or supplier is:

(A) Excluded from the Medicare, Medicaid, and any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Is debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76.

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier."

If the contractor finds an excluded party (and unless section 10.6.6 states otherwise, in which case the latter section takes precedence), the contractor shall notify its PEOG BFL immediately. PEOG will notify the Contracting Officer's Representative (COR) for the appropriate Unified Program Integrity Contractor (UPIC). The COR will, in turn, contact the OIG for further investigation.

C. Revocation Reason 3 – Felony Conviction (42 CFR § 424.535(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR §1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries. [Under § 424.535(a)(3)(ii),] [o]ffenses include, but are not limited in scope and severity to:

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
- Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

[Under § 424.535(a)(3)(iii),] revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses."]

[Under § 424.535(a)(3)(iv),] the individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.]

The expiration of a reenrollment bar issued pursuant to 42 CFR § 424.535(c) does not preclude CMS or its contractors from denying reenrollment to a provider that (i) was convicted of a felony within the preceding 10-year period or (ii) otherwise does not meet all criteria necessary to enroll in Medicare.

D. Revocation Reason 4 – False or Misleading Information on Application (42 CFR § 424.535(a)(4))

"The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be

subject to either fines or imprisonment, or both, in accordance with current laws and regulations.)"

E. Revocation Reason 5 - On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR § 424.535(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Revocation Reason 6 - Hardship Exception Denial and Fee Not Paid (42 CFR §424.535(a)(6))

(i) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(ii) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(iii) Either of the following occurs:

- CMS is not able to deposit the full application amount into a government-owned account; or

- The funds are not able to be credited to the United States Treasury;

(iv) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(v) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

G. Revocation Reason 7 – Misuse of Billing Number (42 CFR § 424.535(a)(7))

"The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers that enter into a valid reassignment of benefits as specified in 42 CFR § 424.80 or a change of ownership as outlined in 42 CFR § 489.18."

H. Revocation Reason 8 – Abuse of Billing Privileges (42 CFR § 424.535(a)(8))

"Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following factors:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502) and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination."

(**NOTE**: Concerning (a)(8), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider has a pattern or practice of submitting non-compliant claims; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

I. Revocation Reason 9 – Failure to Report (42 CFR § 424.535(a)(9))

"The provider or supplier failed to comply with the reporting requirements specified in 42 CFR § 424.516(d) or (e), § 410.33(g)(2), or § 424.57(c)(2) [which pertain to the reporting of changes in adverse actions and practice locations]."

With respect to § 424.535(a)(9) (and except as otherwise stated in section 10.6.6):

- If the provider reports a change in practice location more than 30 days after the effective date of the change, the contractor shall not pursue a revocation on this basis. However, if the contractor independently determines – through an on-site inspection under 42 CFR § 424.535(a)(5)(ii) or via another verification process - that the provider's address has changed but the provider has not notified the contractor thereof within the aforementioned 30-day timeframe, the contractor may pursue a revocation (e.g., seeking PEOG's approval to revoke).

- If an IDTF reports a change in ownership, change of location, change in general supervision or change in adverse legal action more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

- If a DMEPOS supplier reports a change of information more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

J. Revocation Reason 10 – Failure to Document or Provide CMS Access to Documentation (42 CFR § 424.535(a)(10))

"The provider or supplier did not comply with the documentation requirements specified in 42 CFR § 424.516(f). A provider that furnishes any covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to maintain documentation for 7 years."

K. Revocation Reason 11 - Home Health Agency (HHA) Capitalization (42 CFR § 424.535(a)(11))

"An HHA fails to furnish - within 30 days of a CMS or contractor request - supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR § 489.28(a)."

L. Revocation Reason 12 – Other Program Termination (42 CFR § 424.535(a)(12))

"The provider or supplier is terminated, revoked, or otherwise barred from participation in a particular State Medicaid Agency or any other federal health care program."

In making its determination, CMS considers the following factors listed in 42 CFR § 424.535(a)(12):

"(A) The reason(s) for the termination or revocation;

(B) Whether the provider or supplier is currently terminated, revoked, or otherwise barred from more than one program (for example, more than one state's Medicaid program) or has been subject to any other sanctions during its participation in other programs; and;

(C) Any other information that CMS deems relevant to its determination."

Under § 424.535(a)(12)(ii), "Medicare may not revoke [a provider/supplier's Medicare billing privileges] unless and until the provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal."

M. Revocation Reason 13 - Prescribing Authority (42 CFR § 424.535(a)(13))

"(i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked or is surrendered in response to an order to show cause; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician's or other eligible professional's ability to prescribe drugs."

N. Revocation Reason 14 – Improper Prescribing Practices (42 CFR § 424.535(a)(14))

"CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part B or D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed;

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s);

(E) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in § 424.502);

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted - that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act - and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient."

(**NOTE**: Concerning (a)(14), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider/supplier has a pattern or practice of prescribing Part B or D drugs; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

O. Revocation Reason 15 – False Claims Act Judgment (42 CFR § 424.535(a)(15))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted)

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502)

(F) Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(15), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

P. Revocation Reason 17 – Debt Referred to the United States Department of Treasury (42 CFR § 424.535(a)(17))

"The provider or supplier has failed to repay a debt that CMS appropriately refers to the United States Department of Treasury." In determining whether a revocation is appropriate, CMS considers the following factors:

"(i)(A) The reason(s) for the failure to fully repay the debt (to the extent this can be determined);

(B) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined);

(C) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined);

(D) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions;

(E) The amount of the debt; and

(F) Any other evidence that CMS deems relevant to its determination."

(NOTE: With respect to (a)(17):

- Section 424.535(a)(17)(ii) excludes from paragraph (a)(17)(i)'s purview those cases where: (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired.
- PEOG – rather than the contractor – will make all (a)(17) determinations.

Q. Revocation Reason 18 – Revoked Under a Different Name, Numerical Identifier or Business Identity (42 CFR § 424.535(a)(18))

"The provider or supplier is currently revoked [from Medicare] under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired." In making its determination, CMS considers the following factors:

"(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);

(ii) Geographic location;

(iii) Provider or supplier type;

(iv) Business structure; or

(v) Any evidence indicating that the two parties [the revoked provider or supplier and newly enrolling provider or supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

(NOTE: Concerning (a)(18), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier was revoked under a different name, numerical identifier, or business identity.)

R. Revocation Reason 19 – Affiliation that Poses an Undue Risk (42 CFR § 424.535(a)(19))

1. Specific Reason

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse to the Medicare program." In making this determination, CMS considers the following factors listed in 42 CFR § 424.519(f)(1) through (6):

"(1) The duration of the affiliation

(2) Whether the affiliation still exists and, if not, how long ago it ended

(3) The degree and extent of the affiliation

(4) If applicable, the reason for the termination of the affiliation

(5) Regarding the affiliated provider/supplier's disclosable event [under § 424.519(b)]:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt: (A) the amount of the debt; (B) whether the affiliated provider or supplier is repaying the debt; and (C) to whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that CMS deems relevant to its determination."

2. Definition of Affiliation

For purposes of § 424.519 only, 42 CFR § 424.502 defines "affiliation" as:

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of [§ 424.519 only], sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

- An interest in which an individual is acting as an officer or director of a corporation.

- Any reassignment relationship under § 424.80."

(NOTE: Concerning (a)(19), PEOG -- rather than the contractor -- will make all determinations regarding whether a provider/supplier has an affiliation per § 424.519 that poses an undue risk of fraud, waste, and abuse.)

S. Revocation Reason 20 – Billing from a Non-Compliant Location (42 CFR § 424.535(a)(20))

"CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider/supplier's enrollments (involving the non-compliant location or other locations) should be revoked, CMS considers the following factors [enumerated in § 424.535(a)(20)(i) through (vii)]:

- The reason(s) for and the specific facts behind the location's non-compliance;

- The number of additional locations involved;

- The provider or suppliers possibly history of final adverse actions or Medicare or Medicaid payment suspensions;

- The degree of risk the location's continuance poses to the Medicare Trust Funds;

- The length of time that the location was considered non-compliant;

- The amount that was billed for services performed at or items furnished from the non-compliant location; and,

- Any other evidence that CMS deems relevant to its determination."

(NOTE: Concerning (a)(20), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier has performed services or furnished items from a location that did not comply with Medicare enrollment requirements.)

T. Revocation Reason 21 – Abusive Ordering, Certifying, Referring, or Prescribing of Part A or B Services, Items or Drugs (42 CFR § 424.535(a)(21))

"The physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements." In making its determination, CMS considers the following factors [enumerated in § 424.535(i) through (ix)]:

- Whether the physician or eligible professional's diagnosis supports the order, certification, referral or prescription in question;

- Whether there are instances where the necessary evaluation of the patient for whom the order, certification, referral or prescription could have not occurred (for example: the patient was deceased or out of state at the time of the alleged office visit);

- The number and types of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state(s) in which he or she practices and the reason(s) for the action(s);

- Whether the physician or eligible professional has any history of final adverse actions (as defined by 42 CFR § 424.502);

- The length of time over which the pattern or practice has continued;

- How long the physician or eligible professional has been enrolled in Medicare;

- The number of type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that resulted in a final judgement against the physician or eligible professional or the physician or eligible professional paid a settlement to the plaintiff(s) (to the extent this can be determined);

- Whether any State Medicaid Agency (SMA) or other public health insurance program has restricted, suspended, revoked or terminated the physician's or eligible professional's ability to practice medicine and reason for any such restriction, suspension, revocation or termination; and

- Any other information that CMS deems relevant to its determination.

(NOTE: Concerning (a)(21), PEOG – rather than the contractor – will make all determinations regarding whether a physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items, or drugs that is abusive, threatening to the safety of Medicare beneficiaries, or fails to meet Medicare requirements).

U. Revocation Reason 22 – Patient Harm (42 CFR § 424.535(a)(22))

The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates,

or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors [enumerated in § 424.535(a)(22)(i)(A) through (E)):

(A) The nature of the patient harm.
(B) The nature of the physician's or other eligible professional's conduct.
(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(i) License restriction(s) pertaining to certain procedures or practices.

(ii) Required compliance appearances before State medical board members.

(iii) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(iv) Administrative or monetary penalties.

(v) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician/other eligible professional's conduct and the degree of harm thereto or impact upon."

(Per 42 CFR § 424.535(a)(22)(ii), paragraph (a)(22) does not apply to actions or orders pertaining exclusively to either of the following:

- Required participation in rehabilitation or mental/behavioral health programs; or
- Required abstinence from drugs or alcohol and random drug testing.)

V. Revocation Reason 23 – Standard or Condition Violation (42 CFR § 424.535(a)(23))

(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g). (See section 10.2.2.4(V) for more information. The instructions in that section supersede those in this section 10.4.7.3(V).)

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (c).

(The contractor can make revocation determinations under § 424.535(a)(23) without prior PEOG approval. The contractor's revocation letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

(See section 10.4.7.5(A) for more information regarding § 424.535(a)(23).)

W. Extension of Revocation

If a provider's Medicare enrollment is revoked under § 424.535(a), CMS may revoke any and all of the provider's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types. In determining whether to revoke a provider's other enrollments, CMS considers the following factors:

(i) The reason for the revocation and the facts of the case;

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments;

(iii) The number and type(s) of other enrollments; and

(iv) Any other information that CMS deems relevant to its determination.

10.4.7.4 – Reenrollment Bar

(Rev. 12550; Issued: 03-21-24; Effective: 04-21-24; Implementation: 04-21-24)

If any inconsistency exists between an instruction in this section 10.4.7.4 and a directive in section 10.6.6, the latter instruction takes precedence. In addition, the contractor shall adhere to any instruction in section 10.6.6 that addresses a reenrollment bar matter not discussed in section 10.4.7.4.

A. Background

As stated in 42 CFR § 424.535(c), if a provider/supplier has their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation. In addition, CMS may impose a reenrollment bar of up to 20 years if the provider/supplier is being revoked from Medicare for the second time.

Per § 424.535(c), the reenrollment bar does not apply if the revocation: (i) is based on § 424.535(a)(1); and (ii) stems from a provider/supplier's failure to respond timely to a revalidation request or other request for information. If both of these conditions are met, no reenrollment bar will be applied.

The contractor shall update PECOS to reflect that the individual cannot participate in Medicare for the applicable length of the reenrollment bar. Except as otherwise stated in this chapter, PEOG (rather than the contractor) determines reenrollment bars that exceed 3 years.

In addition, CMS may add up to 3 more years to the provider/supplier's reenrollment bar if it determines that the provider/supplier is attempting to circumvent its existing reenrollment bar.

B. Establishment of Length

The following serves merely as general, non-binding guidance regarding the establishment of the length of reenrollment bars. It is crucial to note that every situation must and will be judged on its own merits, facts, and circumstances. It should not be assumed that a particular timeframe will always be applied to a specific revocation reason in all cases. CMS retains the discretion to apply a reenrollment bar period that is different from that indicated below (though which in no case will be greater than 10 to 20 years).

- § 424.535(a)(1) (Noncompliance) – 1 year
- §424.535(a)(6) (Grounds Related to Screening) – 1 year
- §424.535(a)(11) (Initial Reserve Operating Funds) – 1 year
- §424.535(a)(23) (Provider/Supplier Standards) – 1 year

The following revocation reasons will receive reenrollment bar lengths per CMS discretion:

- §424.535(a)(1) (Noncompliance- Not Professionally Licensed Individual Practitioners)
- §424.535(a)(2) (Provider or supplier conduct)
- §424.535(a)(3) (Felonies)
- §424.535(a)(4) (False or misleading information)
- §424.535(a)(5) (On-site review)
- §424.535(a)(7) (Misuse of billing number)
- §424.535(a)(8) (Abuse of billing privileges)
- §424.535(a)(9) (Failure to Report)
- §424.535(a)(10) (Failure to document or provide CMS access to documentation)
- §424.535(a)(12) (Other program termination)
- §424.535(a)(13) (Prescribing authority)
- §424.535(a)(14) (Improper Prescribing Practices)
- §424.535(a)(15) (False Claims Act Civil Judgment)
    - §424.535(a)(17) (Debt Referred to the United States Department of Treasury)
    - §424.535(a)(18) (Revoked Under a Different Name, Numerical Identifier or Business Identity)
    - §424.535(a)(19) (Affiliation that Poses an Undue Risk)
    - §424.535(a)(20) (Billing from a Non-Compliant Location)

- §424.535(a)(21) (Abusive ordering, certifying, referring, or prescribing of Part A or B services, items, or drugs)
- §424.535(a)(22) (Patient Harm)

C. Applicability of Bar

1. Revocation Reasons Other Than § 424.535(a)(1), (a)(5), (a)(6), (a)(9), (a)(10), (a)(11), and (a)(23)

In general, and unless stated otherwise above, any reenrollment bar at a minimum applies to: (1) all practice locations under the provider's PECOS or legacy enrollment record; and (2) any effort to reestablish any of these locations (i) at a different address and/or (ii) under a different business or legal identity, structure, or TIN. If the contractor receives an application and is unsure whether a revoked provider is attempting to reestablish a revoked location, it shall contact its PEOG BFL for guidance. Instances where the provider might be attempting to do so include - but are not limited to – the following:

SCENARIO 1 - John Smith was the sole owner of Group Practice X, a sole proprietorship. Six months after X was revoked under § 424.535(a)(9), the contractor receives an initial application from Group Practice Medicine, LLC, of which John Smith is the sole owner/member.

SCENARIO 2 - Jack Jones and Stan Smith were 50 percent owners of World Home Health Agency, a partnership. One year after World Home Health was revoked under § 424.535(a)(7), the contractor receives an initial application from XYZ Home Health, a corporation owned by Jack Jones and his wife, Jane Jones.

SCENARIO 3 - John Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ's lone location was at 1 Jones Street. XYZ's billing privileges were revoked after it was determined that the site was non-operational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has two locations in the same city in which 1 Jones Street is located. John Smith is listed as a 75 percent owner.

2. Revocation Reasons § 424.535(a)(1), (a)(5), (a)(6), (a)(9), (a)(10), (a)(11), and (a)(23)

For these revocation reasons, any reenrollment bar applies only to the specific enrollment that was the subject of the reenrollment bar.

D. Discussing Provider Enrollment Appeals Process in Revocation Letter

(If a conflict exists between the instructions in this section 10.4.7.4(D) and those in either (i) those in section 10.6.18 or (ii) the language in the applicable model letter in section 10.7 et seq., the guidance in section 10.6.18 or the model letter takes precedence.)

In the revocation letter, the contractor shall include information concerning the provider's appeal rights. The following table summarizes where the provider must send a corrective action plan (CAP) and/or reconsideration request.

	CAP requests should be sent to:		Reconsideration request should be sent to:	
Revocation Regulation	**Institutional***	**Non-institutional**	**Institutional***	**Non-Institutional**
424.535(a)(1) related to an enrollment requirement (i.e., 425.516)	Alone or in combination: CMS	MAC	CMS	MAC
424.535(a)(1) Licensure	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(1) DME or IDTF	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(2) Exclusion	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(2) Debarment	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(3)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(4)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(5)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(6)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(7)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(9)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(10)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(11)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(12)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(13)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(14)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(15)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(17)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(18)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(19)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(20)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(21)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(22)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(23)	No CAP rights	No CAP rights	CMS	CMS

* Institutional providers:

- Ambulance Service Supplier
- Ambulatory Surgery Centers
- CLIA Labs
- Community Mental Health Center
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)

- Critical Access Hospitals
- End Stage Renal Disease (ESRDs)
- Federally Qualified Health Centers (FQHCs)
- Histocompatibility Laboratories
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals and Hospital Units
- Independent Diagnostic Testing Facilities (IDTFs)
- Intensive Cardiac Rehabilitation
- Indian Health Service Facility
- Mammography Screening Centers
- Mass Immunization/Flu Roster Billers
- Medicare Diabetes Prevention Programs (MDPPs)
- Opioid Treatment Centers (OTPs)
- Organ Procurement Organizations (OPOs)
- Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
- Pharmacies
- Portable X-Ray Suppliers (PXRSs)
- Radiation Therapy Centers
- Rehabilitation Services
- Religious Non-Medical Health Care Institutions (RNCHIs)
- Rural Health Clinics (RHCs)
- Skilled Nursing Facilities (SNFs)

The CMS defines "institutional provider" in 42 CFR § 424.502 to mean any provider/supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (except physician and non-physician practitioner organizations), or Form CMS-855S, or the associated Internet-based PECOS enrollment application. (Note that MDPP suppliers no longer fall within this regulatory definition of institutional provider. Per 42 CFR § 424.205(b)(5), the provider enrollment application fee is inapplicable to all MDPP suppliers that submit a Form CMS-20134 enrollment application. Solely for purposes of appeal submissions, however, MDPP suppliers are included in the bulleted list above.)

10.4.7.5 – Additional Revocation Policies

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Use of § 424.535(a)(1)

1. (A)(1) Versus (A)(5)

If a revocation is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.535(a)(5) (rather than § 424.535(a)(1)) as the revocation reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(23)

If a revocation is warranted due to non-compliance with one of the standards and conditions referenced in § 424.535(a)(23) – and except as otherwise stated in this chapter (e.g., section 10.2.2.4(V)) -- the contractor shall use § 424.535(a)(23) (rather than § 424.535(a)(1)) as the revocation reason. No CAP rights are therefore involved.

B. Submission of Claims for Services Furnished Before Revocation

Per 42 CFR § 424.535(h), a revoked provider or supplier (other than a home health agency (HHA)) must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter. A revoked HHA must submit all claims for items and services within 60 days after the later of: (1) the effective date of the revocation, or (2) the date that the HHA's last payable episode ends.

Nothing in § 424.535(h) impacts the requirements of 42 CFR § 424.44 regarding the timely filing of claims.

C. Reporting Revocations/Terminations to the State Medicaid Agencies and Children's Health Program (CHIP)

(If the instructions in this section 10.4.7.5(C) conflict with those in another CMS directive, the latter takes precedence.)

Section 6401(b)(2) of the Patient Protection and Affordable Health Care Act (i.e., the Affordable Care Act) was enacted on March 23, 2010. It requires that CMS establish a process for making available to each State Medicaid Plan or Child Health Plan the name, NPI, and other identifying information regarding any revoked or denied Medicare provider/supplier. Accordingly, CMS provides a monthly revoked and denied provider list to all contractors via the Share Point Ensemble site.

The contractor shall:

- Access this list on the 5th day of each month via the Share Point Ensemble site

- Review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS

- Document any appeal actions a provider/supplier may have submitted after the provider/supplier's revocation or denial

- Update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation or denial

The contractor shall not make any other modifications to the format of this form or its contents.

The following are the only authorized entries to be made on the report:

Appeal Submitted:
Yes - (Definition: An appeal has been received. (This includes either a CAP or Reconsideration request or notification of an ALJ or DAB action.))
No - (Definition: No appeal of any type has been submitted)

Appeal Type:
CAP
Reconsideration
ALJ
DAB

Appeal Status:
Under Review
Revocation Upheld
Revocation Overturned
Denial Upheld
Denial Overturned
CAP accepted
CAP denied
Reconsideration Accepted
Reconsideration Denied

If a contractor is reporting that no appeal has been submitted, the appeal type and status columns will be noted as N/A.

If an appeal action has been submitted to PEOG for certified providers/suppliers, the contractor shall access the PEOG appeals log via the Share Point Ensemble site to determine the appeal status to include on the spreadsheet.

The contractor shall submit their completed reports by the 20th of each month to the CGI Share Point Ensemble site.

D. Opting-Out after Revocation

Revoked suppliers cannot order, certify, or prescribe Part A or B services, items, or drugs to Medicare beneficiaries if they opt-out of Medicare after revocation. For example, if Dr. Thompson is Medicare-revoked, he cannot opt-out and order back and knee orthoses for his patients.

E. Overpayments Based Upon Revocations

The contractor shall commence procedures to collect overpayment after the timeframe for the appeal of the revocation has expired or within 10 days of the final appeal determination at the first level of appeal. Overpayments are processed in accordance with 42 CFR Part 405, subpart C.

If a revocation has a prospective effective date, the contractor shall assess an overpayment back to the date that is the more recent of the following:

- The date when Medicare claims are determined to be ineligible for payment; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

The date when Medicare claims are determined to be ineligible for payment may, but will not always, match the inactive date of the enrollment as reflected in PECOS and in MCS or FISS. Again, in determining an overpayment, the contractor shall use the starting date upon which claims are ineligible for reimbursement, not the date the enrollment is inactive according to PECOS and MCS or FISS.

In accordance with 42 CFR § 424.565, if a physician, non-physician practitioner, physician organization, or non-physician practitioner organization fails to comply with the reporting requirements specified in 42 CFR § 424.516(d)(1)(ii), the contractor may assess an overpayment back to a date that is the more recent of the following:

- The date of the final adverse action or change in practice location; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

F. Other Sources of Potential Bases for Revocations

When CMS instructs the contractor to take revocation action, PEOG communicates such direction; neither the UPIC, the state agency, CMS Field Office, nor CMS Regional Office (RO) (including SOG Location) personnel can direct a contractor to revoke a provider/supplier. However, some of these entities may refer a potential revocation to PEOG. This section 10.4.7.5(E) discusses the operational aspects of these referrals.

1. UPICs

a. Background

If, through its investigations, the UPIC believes that a particular provider/supplier's Medicare billing privileges should be revoked, it shall develop a case file - including the reason(s) for revocation and the data described in subsection (E)(1)(b) below - and submit the file and all supporting documentation to PEOG.

PEOG will review the case file and:

- Return the case file to UPIC for additional development, or
- Consider approving the UPIC's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the applicable contractor to revoke the provider/supplier; and (2) notify the applicable contracting officer's representative (COR).

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

b. Contents of Request

The revocation request shall contain the following information:

- Provider/supplier name; administrative location(s); community setting(s), if applicable type (e.g., DMEPOS supplier); Provider Transaction Access Number (PTAN); National Provider Identifier (NPI); applicable Medicare Administrative Contractor
- Name(s), e-mail address(es), and phone number(s) of investigators
- Tracking number
- Provider/supplier's billing status (Active? Inactive? For how long?)
- Whether the provider/supplier is a Fraud Prevention System provider/supplier
- Source/Special Project
- Whether the provider/supplier is under a current payment suspension
- Legal basis for revocation
- Relevant facts
- Application of facts to revocation reason
- Any other notable facts
- Effective date (per 42 CFR § 424.535(g))
- Supporting documentation
- Photos (which should be copied and pasted within the document)

2. CMS Field Office or RO Revocations

If a CMS Field Office (FO) or (RO) believes that Revocation Reason 8 (see 42 CFR § 424.535(a)(8) is appropriate in a certain case), the FO/RO will develop a case file - including the reason(s) for revocation - and submit the file and all supporting documentation to PEOG. The case file must include the name, all known identification numbers (including the NPI and associated PTAN(s)), and locations of the provider/supplier, as well as detailed information to substantiate the revocation action.

If PEOG concurs with the FO/RO's revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) accordingly notify the FO/RO.

(See section 10.4.3 of this chapter for information on the contractor's responsibilities concerning involuntary terminations received from the SOG Location.)

3. OIG Identified Revocations

PEOG is responsible for actions based on HHS OIG Identified revocations.

G. MDPP Supplier Revocation for Use of an Ineligible Coach

1. Background

Section 424.205(h)(1)(v) established a new revocation reason for MDPP suppliers. It permits revocation if the MDPP supplier knowingly permitted an ineligible coach to furnish MDPP services to beneficiaries, despite being previously removed from the MDPP supplier's roster through a CAP.

If a contractor or UPIC suspects this scenario, it shall develop a case file - including the revocation reason(s) - and submit the file and all supporting documentation to PEOG. The contractor shall provide PEOG with the information described in section 10.4.7.5(E)(1)(b).

PEOG will review the case file and:

- Return the case file to the contractor for additional development, or
- Consider approving the contractor's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) notify the applicable COR.

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

2. Effective Dates

An MDPP supplier revoked under § 424.205(h)(1)(v) does not have CAP rights. The revocation becomes effective 30 days after the contractor sends notice of the revocation.

3. Reenrollment Bar

As stated in § 424.205(h), if an MDPP supplier has its billing privileges revoked, it is barred from participating in Medicare from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of

the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation.

10.4.8 – Deactivations

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Bases for Contractor Action

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor shall – without prior approval from its PEOG BFL - deactivate a provider/supplier's entire enrollment record and Medicare billing privileges when:

(i) The provider/supplier fails to respond to a revalidation request.

(ii) The provider/supplier fails to respond timely to a revalidation development request.

(iii) The provider/supplier is enrolled in an approved status with neither an active reassignment nor practice location for 90 days or longer. (The deactivation basis shall be 42 CFR § 424.540(a)(4), which permits deactivation if the provider/supplier is not in compliance with all enrollment requirements. See sections 10.4.8(B) and (D) below for more information on this new deactivation ground.)

(iv) The provider/supplier deactivates an EFT agreement and remains enrolled but does not submit a new EFT agreement within 90 days. (The deactivation basis shall be 42 CFR § 424.540(a)(4).)

(v) The provider/supplier is deceased, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the provider's/supplier's death; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(6) below.)

(vi) The provider or supplier is voluntarily withdrawing from Medicare, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the voluntary withdrawal; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(7) below.)

(vii) The provider's or supplier's license has expired and the provider or supplier has not billed while the license was expired. (The deactivation basis shall be 42 CFR § 424.540(a)(4).)

The contractor shall not take deactivation action except as specified and permitted in this chapter or other CMS directives. CMS particularly reiterates that – consistent with existing policy -- the contractor shall not on its own volition deactivate any provider/supplier for non-billing under § 424.540(a)(1). All § 424.540(a)(1) deactivations can only be implemented at CMS' explicit direction.

B. Regulatory Reasons for Deactivation in § 424.540(a)

1. Grounds

Section 424.540(a) lists eight deactivation grounds:

Section 424.540(a)(1) - The provider/supplier does not submit any Medicare claims for 6 consecutive calendar months. The 6-month period will begin the 1st day of the 1st month without a claim submission through the last day of the 6th month without a submitted claim.

Section 424.540(a)(2) - The provider/supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under Title 42. (For example, a provider/supplier type falling within the purview of § 424.516(e)(1) and (2) failed to report a change in ownership or control within (i) 30 calendar days of when the change occurred, or (b) 90 calendar days of when the change occurred for all other information on the enrollment application.)

If the provider/supplier submits a change of information and (a) it appears the change was not reported within 90 days of the change, (b) the contractor did not previously take administrative action against the provider/supplier, and (c) no revocation action is applicable, the contractor should process the change of information without deactivating the provider/supplier's enrollment.

Section 424.540(a)(3) - The provider/supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

Section 424.540(a)(4) - The provider/supplier is not in compliance with all enrollment requirements. (See section 10.4.8(D) below for more information.)

Section 424.540(a)(5) - The provider's/supplier's practice location is non-operational or otherwise invalid. (See section 10.4.8(D) below for more information.)

Section 424.540(a)(6) - The provider/supplier is deceased.

Section 424.540(a)(7) - The provider/supplier is voluntarily withdrawing from Medicare.

Section 424.540(a)(8) - The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

C. Effective Dates

(See § 424.540(d) for regulations concerning deactivation effective dates.)

The effective dates of a deactivation are as follows:

a. Non-Billing (§ 424.540(a)(1)) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the deactivation is imposed.

b. Section 424.540(a)(2), (3), and (4) (see subsection (B) above) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/

supplier became non-compliant (e.g., the day after the expiration of the 90-day period in which the provider was required to report a change of information).

c. Section 424.540(a)(5) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider's/supplier's practice location became non-operational or otherwise invalid.

d. Section 424.540(a)(6) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of death of the provider/supplier.

e. Section 424.540(a)(7) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/supplier voluntarily withdrew from Medicare.

f. Section 424.540(a)(8) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of the sale. (Note that PEOG will ultimately determine this effective date during its review of the case per subsection (F) below.)

(See subsection 10.4.8(E) below for additional information on § 424.540(a)(7). See subsection 10.4.8(F) below for additional information on § 424.540(a)(8)).

D. Sections 424.540(a)(4) and (a)(5)

(This section 10.4.8(D) is inapplicable to the situations described in section 10.4.8(A)(iii) and (iv). These two scenarios do not require any referral to PEOG; the contractor can take deactivation action on its own volition.)

The grounds for deactivation under § 424.540(a)(4) and (a)(5) mirror the revocation reasons described in, respectively, § 424.535(a)(1) and (a)(5). When sending a potential § 424.535(a)(1) and (a)(5) revocation case to PEOG for review per section 10.4.7.1(A) of this chapter, PEOG will determine whether a revocation or a deactivation (under § 424.540(a)(4) or (a)(5)) is appropriate. The contractor shall not deactivate a provider or supplier under § 424.540(a)(4) or (a)(5) unless PEOG specifically directs the contractor to do so.

E. Section 424.540(a)(7)

See section 10.6.1.3 of this chapter for information regarding certified provider/supplier voluntary terminations and section 10.4.3(B) for information on non-certified supplier voluntary terminations.

F. Section 424.540(a)(8)

See section 10.6.1.1.5 of this chapter for information regarding seller CHOWs.

G. Miscellaneous

1. Except for deactivations under § 424.540(a)(8) (see § 424.550(b)(1)) and § 424.540(a)(7)**, t**he deactivation of Medicare billing privileges does not affect a provider/supplier's participation agreement.

2. Prior to deactivating an HHA's billing privileges for any reason (including under the "36-month rule"), the contractor shall refer the matter to its PEOG BFL for review and approval. The only exception for PEOG BFL review and approval is a deactivation due to failure to comply with a revalidation request.

3. Notwithstanding any other instruction to the contrary in this chapter, the provider/supplier may submit a rebuttal for deactivations imposed pursuant to § 424.540(a)(7) or (8). For these two rebuttal reasons, the contractor shall abide by the rebuttal policies in section 10.4.8.1. Note, however, that any such rebuttal only applies to the deactivation of billing privileges and not to the provider agreement termination.

10.4.8.1 – Deactivation Rebuttals

(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Background

Pursuant to 42 CFR § 424.546, a provider/supplier whose Medicare billing privileges have been deactivated under 42 CFR § 424.540(a) may file a rebuttal. A rebuttal is an opportunity for the provider/supplier to demonstrate that it meets all applicable enrollment requirements and that its Medicare billing privileges should not have been deactivated. Only one rebuttal request may be submitted per enrollment deactivation. Additional rebuttal requests submitted for the same deactivated enrollment for which a rebuttal has already been received shall be dismissed.

If an application is received for a deactivated provider/supplier while a rebuttal submission is pending or during the rebuttal submission timeframe, the contractor shall process the application consistent with current processing instructions. If the rebuttal determination is issued and overturns the deactivation prior to an application being approved, the contractor shall return the application received while the rebuttal determination was pending unless: (1) the submitted application is required to reactivate the provider/supplier's enrollment; or (2) if there are new changes being reported. If an application (1) is received while a rebuttal submission is pending, (2) is approved prior to the issuance of a rebuttal determination, and (3) results in the provider's or supplier's enrollment being reactivated without a gap in billing privileges, the contractor shall stop processing the rebuttal submission and issue an applicable moot letter.

B. Notification Letters for Deactivations

If a basis is found to deactivate a provider's or supplier's Medicare billing privileges under one of the regulatory authorities in 42 C.F.R. § 424.540, the contractor shall deactivate the provider/supplier unless another CMS directive applies. If a revocation authority is applicable, the contractor shall follow the instructions in sections 10.4.7 and 10.4.8 et seq. of this chapter in lieu of deactivating the enrollment. If no revocation authority applies, the contractor shall send notification of the deactivation using the applicable model deactivation notice. The contractor shall send a notification letter for every deactivated enrollment. The contractor shall ensure the deactivation notice contains sufficient details so it is clear why the provider's or supplier's Medicare billing privileges are being deactivated. The contractor shall send the deactivation notification letter via hard-copy mail and via e-mail (if a valid email address is available); the contractor should also send the notice via fax if a valid fax number is available. All notifications

shall be saved in PDF format, and all notification letters shall be mailed on the same date listed on the letter.

C. Rebuttal Submissions

1. Requirements and Submission of Rebuttals

Pursuant to 42 C.F.R. § 424.546(b), to be accepted and processed, the rebuttal submission must:

(1) Be in writing;

(2) Specify the facts or issues concerning the rebuttal with which the provider or supplier disagrees, and the reasons for disagreement;

(3) Include all documentation the provider or supplier wants CMS to consider in its review of the deactivation;

(4) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 C.F.R. 498.10);

- If the legal representative is an attorney, the attorney must include a statement that he/she/they have the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority.
- If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.
- Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.
- Signatures may be original or electronic. Valid signatures include handwriting (wet) signatures in ink and digital/electronic signatures. Digital or electronic signatures such as those created by digital signature options, created in software, such as Adobe) and email signatures shall be accepted. Contractors shall contact ProviderEnrollmentAppeals@cms.hhs.gov for questions regarding electronic and digital signatures.

(5) Be received by the contractor within 15 calendar days from the date of the deactivation notice. The contractor shall accept a rebuttal submission via hard-copy mail, e-mail, and/or fax;

If the rebuttal submission is not appropriately signed or if a statement from the attorney or written notice of representation is not included in the submission, the contractor shall send a development request for a proper signature or the missing statement/written notice (using the

applicable model letter) before dismissing the rebuttal submission. The contractor shall allow 15 calendar days from the date of the development request letter for the rebuttal submitter to respond to the development request.

If a rebuttal submission: (1) is not appropriately signed and no response is received to the development request (if applicable); (2) is untimely (as described above); (3) does not specify the facts or issues with which the provider/supplier disagrees and the reasons for disagreement and no response is received to the development request; or (4) is a duplicative submission, the contractor shall dismiss the rebuttal submission using the applicable Rebuttal Dismissal Model Letter. For those rebuttal submissions that are improperly signed and/or do not specify the facts or issue with which the provider or supplier disagrees and the reasons for disagreement, the contractor shall send a development request via hard-copy mail, email, if available, to the provider/supplier requesting a proper signature and/or clarification on the facts or issues with which the provider or supplier disagrees and the reasons for disagreement using the applicable Rebuttal Development Model Letter. Sending the development letter via fax is optional. The contractor shall grant an additional 15-calendar days from the date of the development request letter for the provider or supplier to submit an acceptable rebuttal submission. If no response is received or the rebuttal submission is still deficient after the development request and the 15-calendar day timeframe has expired, the contractor shall dismiss the rebuttal submission using the applicable Rebuttal Dismissal Model Letter.

The contractor may make a good cause determination to accept any rebuttal that has been submitted beyond the 15 calendar-day filing timeframe. Good cause may be found where there are circumstances beyond the provider's or supplier's control that prevented the timely submission of a rebuttal. These uncontrollable circumstances do not include the provider/supplier's failure to timely update its enrollment information, specifically its various addresses. If the contractor believes good cause exists to accept an untimely rebuttal submission, the contractor shall send a request approval email to ProviderEnrollmentAppeals@cms.hhs.gov within five calendar days of making the good cause determination. This email shall detail the contractor's reasoning for finding good cause. Processing timeliness standards shall begin on the date the contractor receives a response from CMS.

2. Time Calculations for Rebuttal Submissions

If the 15th calendar day from the date on the deactivation notice falls on a weekend or federally-recognized holiday, the rebuttal shall be accepted as timely if the contractor received it by the next business day.

It is the provider's or supplier's responsibility to timely update his/her/their/its enrollment record to reflect any changes to the provider's or supplier's enrollment information including, but not limited to, its correspondence address. Failure to timely update a correspondence address or other addresses included in its Medicare enrollment record does not constitute an "in fact" showing that the deactivation notice was received after the presumed receipt date (as described above).

3. Processing Rebuttal Submissions

The contractor shall send an acknowledgement letter via hard-copy mail to the return address on the rebuttal submission within 10 calendar-days of receipt of the accepted rebuttal request using the Rebuttal Acknowledgment Model Letter, including a rebuttal tracking number and the provider's or supplier's NPI. The acknowledgement letter shall also be sent via email if a valid email address is available (either in the enrollment record or rebuttal submission). It is optional for the contractor to send the acknowledgement letter via fax if a valid fax number is available. If a rebuttal determination is issued within 10 calendar-days of the date of receipt of the rebuttal submission then the contractor is not required to issue a receipt acknowledgement letter.

The contractor shall process all accepted rebuttal submissions within 30 calendar-days of the date of receipt. If, while reviewing the rebuttal submission, the provider or supplier wishes to withdraw its rebuttal, the request to withdraw must be submitted to the contractor in writing before the rebuttal determination is issued. If a provider or supplier submits a written request to withdraw its rebuttal submission prior to the issuance of a rebuttal determination then the contractor shall issue a letter using the applicable Rebuttal Withdrawn Model Letter and no rebuttal determination shall be issued.

The contractor's review of the rebuttal submission shall only consist of whether the provider or supplier met the enrollment requirements and if billing privileges were deactivated appropriately. All materials received by the provider/supplier shall be considered by the contractor in its review.

4. Reason-Specific Instructions

a. § 424.540(a)(1)

For deactivations under § 424.540(a)(1), the contractor shall review submitted documentation and internal systems to confirm whether billing occurred during the 6-month period preceding the date of deactivation, starting with the first day of the first month 6 months prior to the date of deactivation. If it is confirmed that billing occurred within 6 months, the contractor shall issue a favorable rebuttal determination. If no billing occurred during the 6-month period prior to the date of deactivation, the contractor shall issue an unfavorable rebuttal determination. Consider the following illustration:

EXAMPLE: Dr. Awesome has been enrolled in Medicare since 2010. A review of billing data reveals that Dr. Awesome has not submitted any Medicare claims since January 2019. Dr. Awesome's enrollment is deactivated, under 42 C.F.R. § 424.540(a)(1), effective January 1, 2020. Dr. Awesome timely submits a rebuttal in response to the deactivation. Upon review by the contractor, it is confirmed that Dr. Awesome had not submitted claims since January 2019. Therefore, an unfavorable rebuttal determination would therefore be appropriate in this scenario, for the deactivation was appropriate.

b. § 424.540(a)(2)

For deactivations under § 424.540(a)(2), the contractor shall review the submitted documentation and internal records to determine whether the change of information was properly submitted within the required timeframe. The required timeframe to submit updated information is described at 42 C.F.R. §§ 424.550, 410.33(g)(2), 424.57(c)(2), and 424.516(d). If information

was submitted properly and timely, the contractor shall approve the rebuttal submission, issue a favorable rebuttal determination, and reinstate the provider 's or supplier's Medicare billing privileges to an approved status. If it was not submitted properly and timely, the contractor shall deny the rebuttal request and issue an unfavorable rebuttal determination, as the deactivation was appropriate. In making this determination, the contractor shall consider, at minimum, the following.

- Whether the deactivation was implemented after the required timeframe to report a change of enrollment information elapsed;
- Whether the letter notifying the provider/supplier of the deactivation was sent to the correct address as instructed in section 10.7 et seq. of this chapter; and
- Whether the enrollment changes were received in an enrollment application that was processed to completion within the required timeframe.

Consider the following illustration:

EXAMPLE: Dr. Happy has reassigned his benefits to a physician group, Smile, LLC. Smile, LLC is Dr. Happy's only reassignment and only practice location. Smile, LLC's enrollment and corresponding billing privileges are revoked effective January 1, 2018. Dr. Happy's enrollment is deactivated on February 1, 2018 for failing to update his enrollment record with respect to his practice location. Dr. Happy timely submits a rebuttal in response to the deactivation of his individual enrollment. Upon review by the contractor of the submitted documentation and internal records, it is discovered that Dr. Happy submitted a change of information application received by the contractor on February 28, 2018 that sought to update his practice location. However, this application was ultimately rejected due to his failure to timely respond to a development request.

In this scenario, the deactivation was correctly implemented after 30 days of the change of enrollment information – the change in practice location. However, an enrollment application updating Dr. Happy's practice location that was processed to completion was not received within 30 days of the change of enrollment information. Though the contractor received an application within 30 days of the change of enrollment information, that application was not processed to completion. Thus, an unfavorable rebuttal determination would be appropriate in this scenario, as the deactivation was appropriately implemented.

c. § 424.540(a)(3)

For deactivations under § 424.540(a)(3), the contractor shall review all submitted documentation and internal records to determine whether the provider or supplier furnished complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information. In making this determination, the contractor shall consider, at minimum, the following:

- Whether the deactivation was implemented after 90 days of the revalidation request.
- Whether the letter notifying the provider or supplier of the requirement to revalidate was sent to the correct address as instructed in section 10.7 of this chapter.

- Whether a revalidation application was timely received and was processed to completion.

Consider the following scenario:

EXAMPLE: On January 1, 2022, the contractor appropriately and timely informs Dr. Great that the contractor must receive a revalidation application from Dr. Great by April 15, 2022. The contractor receives a revalidation application from Dr. Great on March 1, 2022. The contractor requests that Dr. Great furnish further information needed to process the revalidation application. Dr. Great does not respond to the development request within 30 days as requested. The contractor rejects the March 1, 2022 revalidation application and subsequently deactivates Dr. Great's enrollment on April 16, 2022 under 42 C.F.R. § 424.540(a)(3). Dr. Great timely files a rebuttal in response to the deactivation. Upon review of the submitted documentation and internal records, the contractor confirms that Dr. Great was appropriately and timely notified of the requirement to revalidate and that it did not receive a revalidation application within 90 days of the revalidation request that could be processed to completion. Accordingly, an unfavorable rebuttal determination would be appropriate in this scenario, as the deactivation was appropriately implemented.

d. § 424.540(a)(4) and (5)

For deactivations under § 424.540(a)(4), the contractor shall review all submitted documentation and internal records to determine whether the provider or supplier was, in fact, compliant with all enrollment requirements at the time of the deactivation

For deactivations under § 424.540(a)(5), the contractor shall review all submitted documentation and internal records to determine whether the provider's or supplier's practice location was operational or otherwise valid at the time of the deactivation.

If the provider or supplier was indeed compliant or operational at the time of the deactivation, the contractor shall approve the rebuttal request and reinstate the provider's or supplier's Medicare billing privileges to an approved status; prior PEOG review of the rebuttal or approval of the rebuttal request is not required.

e. § 424.540(a)(6)-(8)

Although rebuttals under § 424.540(a)(6)-(8) these three deactivation grounds are uncommon, the provider or supplier may submit one. Upon receipt of a rebuttal submission, the contractor shall review all submitted documentation and internal records to determine whether the deactivation pursuant to the regulatory basis in question was appropriate. If it was not, the contractor shall approve the rebuttal request and reinstate the provider/supplier's Medicare billing privileges to an approved status; prior PEOG review of the rebuttal or approval of the rebuttal request is not required. If the rebuttal was not submitted properly and timely, the contractor shall dismiss the rebuttal request.

D. Determination

The contractor shall render a determination regarding a rebuttal submission using the appropriate Model Rebuttal Decision Letter. If the contractor is unable to render a determination, the contactor shall use the appropriate Model Letter for the specific situation. All determinations (including dismissals and withdrawals) related to rebuttal submissions shall be sent (1) via hard-copy mail to the return address on the rebuttal submission; (2) via hard-copy mail to the correspondence mailing address on the enrollment records (if different from return address on rebuttal submission); and (3) by e-mail if a valid e-mail address is available (submitted as part of the rebuttal submission and/or listed in the enrollment record correspondence mailing address). The contractor may also send via fax if a valid fax number is available. All documentation shall be saved in PDF format. All notification letters shall be mailed on the same date listed on the letter.

If the contractor issues a rebuttal determination favorable to the provider or supplier, it shall make the necessary modification(s) to the provider's or supplier's Medicare billing privileges within 10 business days of the date on the favorable determination letter. This may include the elimination of the deactivation altogether so that there is no gap in billing privileges or a change in the deactivation effective date. If the contactor issues a rebuttal determination unfavorable to the provider or supplier, the provider's or supplier's Medicare billing privileges shall remain deactivated until a reactivation application is received and processed to completion.

If a rebuttal determination overturns the deactivation, the contractor shall return any application(s) received while the rebuttal submission was being reviewed or during the rebuttal submission timeframe that has not been processed to completion, unless the application is needed to reactivate the enrollment or if there are new changes being reported. If the contractor confirms that the application is not needed and that no new changes are being reported, the contractor shall use the following return reason in the Returned Application Model Letter found at 10.7.7.A of this chapter in response to the scenario described above: "A rebuttal decision has been issued; therefore, the submitted Form CMS [855/588/20134] is not needed."

If additional information/documentation is needed prior to reinstating the provider or supplier as part of a favorable rebuttal determination (e.g., deactivation due to non-response to revalidation and a complete application or missing information is needed to finalize the revalidation), the contractor shall document these next steps in its rebuttal determination letter. The contractor shall not reinstate the provider or supplier until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the rebuttal determination, the contractor shall contact the provider/supplier to again request the additional information/documentation within 10 calendar days of not receiving a response.

If no response is received within 30 calendar days of the second request for additional information/documentation, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

E. No Further Review

Pursuant to 42 C.F.R. § 424.546(f), a determination made regarding a rebuttal request is not an initial determination and is not subject to further review. Thus, no additional appeal rights shall be included on any rebuttal determination letter.

F. External Monthly Reporting for Rebuttals

Using the provider enrollment rebuttals reporting template, the contractor shall complete all columns listed for all rebuttal submissions received and processed by the contractor. No column shall be left blank (except Column K, as described below). If the contractor is unable to complete all columns for a given rebuttal submission, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within five business days of discovery to seek further guidance.

The reports shall use only the formats identified below. All dates shall be formatted as mm/dd/yyyy (e.g. 01/13/2021). The reports shall be sent to CMS via email at ProviderEnrollmentAppeals@cms.hhs.gov no later than the 15th of each month. If this day falls on a weekend or a holiday, the report shall be submitted the following business day. The report shall include the prior month's rebuttal submissions, as well as outcomes for all submissions previously received that were not yet completed and reported to CMS (e.g., the February report shall cover all January rebuttals).

IMPORTANT: All submissions shall remain on the monthly report until a final outcome/decision has been reported to CMS.

- **Column A:** The response in Column A labelled, "Provider/Supplier Name (As it appears in PECOS)" shall be the provider's or supplier's Legal Business Name, exactly as it is spelled and formatted in the PECOS enrollment record (including capitalization, abbreviations, and punctuation).

- **Column B:** The response in Column B labelled, "NPI" shall be the provider's or supplier's NPI. If the provider/supplier has more than one NPI, the contract shall list each NPI, separated by a semi-colon.

- **Column C:** The response in Column C labelled, "EID (if applicable)" shall be the provider's or supplier's EID. If there is no EID associated with the provider/supplier, the response shall be "N/A".

- **Column D:** The response in Column D labelled, "PTAN(s) (if applicable)" shall include the provider's or supplier's PTAN. If the provider/supplier has more than one PTAN, each PTAN shall be separated by a semicolon (e.g. L5988; 190002033). If the provider/supplier does not have a PTAN, the response shall be "N/A".

- **Column E:** The response in Column E labelled, "Contractor (Including Jurisdiction)," shall be in one of the following formats. No other formats are acceptable.

    - CGS J15
    - FCSO
    - NGS J6

- NGS JK
- Noridian JE
- Noridian JF
- Novitas JH
- Novitas JL
- NPE East
- NPE West
- NSC
- Palmetto JJ
- Palmetto JM
- WPS J5
- WPS J8

- **Column F:** The response in Column F labelled, “Regulatory Authority for Deactivation,” shall be in the following format. If the response is “Other (see Comments)” the Contractors shall use Column K to provide explanatory notes (e.g. when a rebuttal is submitted in response to an enrollment action that does not afford rebuttal rights, describe the enrollment action in Column K). No other formats are acceptable:

  - 424.540(a)(1)
  - 424.540(a)(2)
  - 424.540(a)(3)
  - 424.540(a)(4)
  - 424.540(a)(5)
  - 424.540(a)(6)
  - 424.540(a)(7)
  - 424.540(a)(8)
  - Other (see Comments)

- **Column G:** The response in Column G labelled, “Date Rebuttal Received” shall be the date on which the Contractor received the rebuttal. The date shall be formatted as mm/dd/yyyy (e.g. 10/25/2021).

- **Column H:** The response in Column H labelled, “Date Receipt Acknowledgement Sent to Provider/Supplier/Legal Representative,” shall be “Not yet sent” if a receipt acknowledgement email/letter has not been sent to the provider/supplier/legal representative at the time the monthly report is sent to CMS. The response shall be “N/A” if a receipt acknowledgement email/letter is not required for that case (i.e., rebuttal determination is issued within 10-calendar days of the date of receipt of the rebuttal submission). Dates shall be formatted as mm/dd/yyyy (e.g. 06/15/2020).

- **Column I:** The response in Column I labelled, “Date Rebuttal Determination Issued” shall be the date on which the Contractor issues the rebuttal determination. The date shall be formatted as mm/dd/yyyy (e.g. 09/19/2019). If a final rebuttal determination has not yet been issued, the contractors shall enter "In Process" as the response.

- **Column J:** The response in Column J labelled, “Final Decision Result,” shall be one of

the following. No other formats are acceptable.

- **Not Actionable:** Rebuttal is no longer actionable (moot) because the basis for the deactivation has been resolved (e.g. deactivation was rescinded).
- **Favorable:** (to provider/supplier) Contractor has determined that an error was made in the implementation of the deactivation. Therefore, the initial determination was overturned and the enrollment record has been placed in approved status.
- **Unfavorable:** (to provider/supplier) Contractor upholds the initial determination resulting in the enrollment remaining deactivated.
- **Dismissed:** The rebuttal submission does not meet the rebuttal submission requirements (e.g. missing proper signature and did not timely respond to development request).
- **Withdrawn:** Provider/supplier/representative has submitted written notice of its intent to withdraw its rebuttal before the contractor issued a determination and the contractor has acknowledge the withdrawal.
- **In Process:** A final decision has not been issued. The Contractor is still processing the submission.

- **Column K:** The response in Column K labelled, "Comments," shall include any information related to the deactivation, rebuttal submission, or rebuttal determination that provides context for CMS in reporting the rebuttal and outcome. This column may be left blank if no additional information is necessary.

10.4.9 – Stay of Enrollment

(Rev. 12524; Issued: 03-01-24; Effective: 04-01-24; Implementation: 06-03-24)

(In the event of any inconsistency between the instructions in this section 10.4.9 and other instructions in chapter 10, the 10.4.9 instructions take precedence if a stay of enrollment situation is involved.)

A. Background

In the Calendar Year 2024 Physician Fee Schedule final rule (CMS-1784-F), CMS established a new provider enrollment status in 42 CFR § 424.541 labeled a "stay of enrollment." The purpose was to create a CMS action that would be less burdensome on providers/suppliers (hereafter collectively "provider," except as otherwise noted) than a deactivation or revocation. It represents a middle ground between (1) a deactivation and (2) non-action on CMS' part. It gives CMS greater flexibility to take appropriate, fair, and reasonable measures commensurate with the degree of the provider's non-compliance.

A stay of enrollment (or simply "stay") is a preliminary, interim status---prior to any subsequent deactivation or revocation---that would represent, in a sense, a "pause" in enrollment, during which the provider would nonetheless remain enrolled in Medicare. In this vein, CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment.

Unless CMS explicitly instructs the contractor to do so (such as per section 10.4.9(D) below), the contractor shall not: (i) initiate or impose a stay; or (ii) refer a potential stay case to PEOG if the contractor believes a certain situation it has encountered may warrant one.

B. Regulatory Requirements for Imposition -- Two-Step Test under § 424.541(a)(1)

As outlined in § 424.541(a)(1)(i) and (ii), there are two requirements for a stay's implementation. Specifically, the provider:

- Is non-compliant with at least one enrollment requirement in Title 42; **and**

- Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application (hereafter occasionally and collectively referenced as "the applicable CMS form" or "ACF".)

Examples of how this bright-line, two-pronged test would be met include:

- A provider failed to timely report a change in its address from 10 Smith Street to 20 Smith Street.
- A supplier did not respond to a revalidation request.
- A DMEPOS supplier did not report the deletion of a managing employee.
- A physician did not timely report a change in his/her practice location's zip code.
- An MDPP supplier failed to timely report a change in the address of an organizational owner.
- An IDTF failed to comply with a supplier standard in § 410.33(g) but compliance can be reached by submitting an ACF.

In these illustrations, the provider failed to adhere to a reporting, revalidation, or supplier standard requirement in Title 42 (the first prong of the § 424.541(a)(1) test) but could resume compliance by submitting the applicable CMS form (the second prong). (It is important to understand that if the type of non-compliance involved cannot be corrected via the submission of an ACF, a stay cannot be imposed.) These are merely examples, however, and there are many scenarios in which a stay could apply.

Examples of when the stay of enrollment test would not be met include:

- A provider's owner has been convicted of a felony.
- A physician has lost his/her state medical license.

Although the first prong of the § 424.541(a)(1) test --- non-compliance --- has been met in these situations, the provider cannot correct the non-compliance simply by submitting an ACF.

C. Important Facets of a Stay as Outlined in § 424.541

Section 424.541 also contains the following provisions:

1. Enrollment Status (§ 424.541(a)(2)(i)) – As previously mentioned, the provider remains enrolled in Medicare during the stay.

2. Claims (§ 424.541(a)(2)(ii)):

Per § 424.541(a)(2)(ii)(A) – and except as stated in § 424.541(a)(2)(ii)(B) -- claims submitted by the provider with dates of service within the stay period will be rejected.

Under § 424.541(a)(2)(ii)(B), claims submitted by the provider with dates of service within the stay period are eligible for payment (assuming all other requirements for claim payment are met) if:

- CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42 (§ 424.541(a)(2)(ii)(B)(1)); and
- The stay ends before its original expiration date. (To illustrate, suppose CMS imposes a stay period of 30 days. The claims described in § 424.541(a)(2)(ii)(B) would be payable if the provider resumes compliance on or before the 30th day of the stay.)

To reiterate, the requirements of both § 424.541(a)(2)(ii)(B)(1) and (2) must be met for payments to be made pursuant to § 424.541(a)(2)(ii)(B).

3. Maximum Duration of the Stay (§ 424.541(a)(3)) - A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay. **For purposes of this requirement, the postmark date is the date on which the letter is mailed. For instance, suppose the letter is mailed on June 1. The stay period commences on June 1, which is also the stay's effective date.**

Again, a stay has a maximum length of 60 days and cannot be extended. Note, however, that CMS can impose a stay of less than 60 days. It is not required that each assigned stay period be 60 days.

4. End-Date of the Stay (§ 424.541(a)(5)) – A stay ends on the earlier of the following dates:

- The date on which CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42, OR
- The day after the imposed stay period expires.

For purposes of § 424.541(a)(5) ONLY:

++ The term "has resumed compliance" means the provider has submitted the ACF that CMS requested the provider to submit in the stay notification letter. (See section 10.4.9(C)(5)(f) below for more information.) To illustrate, assume a provider receives a stay notification letter on March 1 because the provider had failed to timely report an address change via the Form CMS-855B. The letter requests the provider to submit this ACF. The provider does so on March 10. The stay thus ends on March 10. Note that the contractor need not have begun processing the ACF for a stay to be lifted. Even if the application is later returned, rejected, or denied, the stay ceases on the date the application is submitted.

++ For paper ACFs, the ACF is considered "submitted" on the date the contractor receives the ACF (e.g., in its mailroom).

5. Additional Considerations

a. Adverse Action - A stay is not considered an adverse legal action of any kind.

b. Deactivations and Revocations - **CMS always reserves the right to impose:**

(i) **A deactivation or revocation instead of a stay, even in cases of minor non-compliance. It should not be assumed that a stay will always be the first step in such situations**.

(ii) **A deactivation prior to the expiration of the stay, in which case the deactivation ends the stay**

c. Multiple Stays and Extensions – CMS will neither extend a stay period beyond 60 days nor apply a subsequent stay based on the same non-compliance (e.g., the provider failed to reach compliance within the imposed/assigned stay period (e.g., within 15 days), so CMS immediately applies another stay). Yet CMS may impose a stay multiple times against the provider for separate instances of non-compliance (e.g., one stay in June 2024, another stay in December 2025, and so forth).

d. Timeliness – Normal timeliness standards (as outlined in section 10.5 of this chapter) and processing alternatives (outlined in chapter 10) apply when the contractor is processing the ACF.

e. Applicable Forms and Transactions – As stated in § 424.541(a)(1), the types of ACFs for stay purposes are the Form CMS-855A, Form CMS-855B, Form CMS-855I, Form CMS-855S, Form CMS-20134, Form CMS-855O (though the CMS-855O will not involve claim submissions, retroactive payments, etc.), and Form CMS-588. The applicable transactions are limited to changes of information and revalidations. For purposes of the stay, however, the term "changes of information" can include, at CMS' discretion, reassignment situations under the Form CMS-855I.

f. Compliance – Except as stated or instructed otherwise by CMS, and strictly and solely for purposes of lifting/ending a stay, compliance under §§ 424.541(a)(2)(ii)(B)(1) and (a)(5) is reached when the provider submits the ACF. **Once the stay expires, though, compliance under Title 42 is only resumed consistent with existing policies (e.g., the contractor approves the change of information).**

g. Ordering/Certifying – A stay has no effect on a physician/practitioner's ability to order/certify/refer/prescribe services, items, or drugs.

h. Stay Periods – Except as instructed otherwise by CMS, all assigned stay periods for revalidation non-responses (see subsection (D)(1) below) will be 30 days (rather than 60

days). For the PEOG-directed stays described in subsection (D)(2) below, PEOG will notify the contractor of the assigned stay period for that specific case.

6. General Stay Process for Revalidations

In general – and subject to the more specific scenarios described in section 10.4.9(D)(1) -- the stay process will work as follows in situations where the provider fails to submit a revalidation application in response to a CMS/contractor revalidation request:

Implementing the Stay - Within 10 days after the expiration of the period in which the provider had to submit the revalidation application, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(A); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

Removing the Stay if the Provider Submits the Revalidation Application During the Stay - Within 10 days after the revalidation application is submitted, the contractor shall change the PECOS status to "Approved – Remove Stay of Enrollment."

Failure to Respond During the Allotted Timeframe – Within 10 days of the allotted timeframe described below, the contractor shall deactivate the provider in accordance with CMS directives.

(This also includes the contractor turning on and turning off claim rejection edits as warranted (e.g., implementing the edits when the stay is imposed).)

Note that the above general process will be largely similar in cases where CMS directs the contractor to impose a stay in a specific case, the principal exception being the timeframe for contractor action in certain situations. These cases are addressed in subsections (D)(2)(a) through (D)(2)(c) below.

D. Case Studies

This section 10.4.9(D) contains more detailed scenarios addressing how the stay process will typically operate and the contractor's required activities therein. (Except as otherwise indicated, all days are calendar days.)

1. Non-Response to Revalidation Request

These scenarios assume the provider (Smith Health Care) failed to submit the requested revalidation application within the required revalidation timeframe (RRT) – the last day of which, for purposes of our examples, is February 27.

Scenario A – Revalidation Application Submitted During Stay Period and Is Approved

Step 1 –No later than 10 days after the expiration of the RRT, the contractor shall: (a) send to Smith via regular mail the letter identified in section 10.7.20(A); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed. Thus, if the letter is mailed March 5, the PECOS status should be changed effective March 5, which will be the effective date of the stay. This means Smith has until April 4 (or 30 days) to submit the

revalidation application. Claims for services furnished beginning March 5 to the end of the stay will be rejected except as stated in § 424.541(a)(2)(ii)(B).

(If the contractor receives the revalidation application from Smith after the RRT expires but before it mails the stay notification letter, the contractor can process the application as normal without imposing a stay.)

Step 2 – Smith submits the revalidation application on March 16.

Step 3 – No later than 10 days after the revalidation application is submitted, the contractor shall change the PECOS status to "Approved – Remove Stay of Enrollment" effective on the submission date (March 16 if the application was submitted via PECOS). Claims for services furnished between March 5 and March 16 (i.e., the duration of the stay) are therefore payable.

Step 4 – The contractor processes the revalidation application to approval and takes all standard actions related thereto (e.g., sends approval letter, switches PECOS record to "Approved"). No further action needed.

Scenario B – Revalidation Application Not Submitted at All

Assume that Step 1 is the same as Step 1 in Scenario A.

Step 2 – Smith fails to submit the revalidation application by April 4, the last day of the stay period. The contractor need take no action regarding the lifting of the stay (e.g., notifying the provider of the stay's cessation).

Step 3 – Within 10 days of the April 4 date (i.e., by April 14), the contractor shall: (a) change the PECOS status to "Deactivated" effective the day after the RRT expired (or February 28); and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

Note that the deactivation effective date is retroactive to the date of the non-compliance (again, February 28), or the date by which Smith was required to submit the revalidation application to CMS. This means that even though the stay was lifted effective April 5 and claims furnished on or after that date are thus payable, this will effectively be negated by the retroactive deactivation in a manner akin to how retroactive deactivations currently operate.

Due to the provider's failure to submit the application during the stay period, claims for services furnished during the stay (March 5 – April 4) are not payable.

Scenario C – Revalidation Application Submitted During the Stay but Is Rejected

Assume Steps 1, 2, and 3 are the same as Steps 1, 2, and 3 in Scenario A.

Step 4 – The contractor determines that the revalidation application should be rejected.

Step 5 – The contractor shall:

- Process the rejection consistent with existing procedures.

- Within 10 days of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the day after the RRT expired (or February 28); and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

Scenario D – Revalidation Application Not Submitted During the Stay but Is Submitted After the Stay Period Expires

Assume Step 1 is the same as Step 1 in Scenario A. (Note that the stay expired on April 4.)

Step 2 - Smith submits the revalidation application on April 7.
Step 3

Step 3A - If the contractor receives the revalidation application before it mails the deactivation letter (as described in Step 3 of Scenario B), the contractor can process the application as normal without imposing a deactivation.

Step 3B – If the contractor receives the revalidation application after it mails the deactivation letter, it shall process the application as a reactivation application.

2. PEOG-Directed Stays

The situations in this subsection (D)(2) only apply when PEOG directs the contractor via e-mail to impose a stay. Except as otherwise instructed, the contractor need not notify PEOG that it has imposed the stay, whether the provider submitted the ACF, whether and when a deactivation was imposed, etc.

a. Ownership Discrepancies

PEOG may notify the contractor via e-mail to apply a stay against a particular provider due to incorrect enrollment information pertaining to ownership; the provider must correct this data by submitting an ACF. In such cases, the contractor shall follow the general stay procedures, steps, and scenarios outlined in subsection (D)(1) above except as follows:

- Step 1 of Scenarios A, B, C, and D - Within **5** days of receiving this e-mail, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(B); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

- Step 3 of Scenarios B and D - Within **5** days after the expiration of the 30-day stay period, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 5 of Scenario C - Within **5** days of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was

mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

To illustrate the first three exceptions, suppose the contractor receives an e-mail from PEOG on August 1 directing it to impose a stay on Provider X because X's ownership data is incorrect. If this were a revalidation situation, the contractor would have 10 days (or until August 11) to complete Step 1. Here, however, the contractor must complete Step 1 by August 6.

Now assume the contractor finishes Step 1 on August 4. The stay begins that day and ends on September 3. Provider X fails to submit the ACF during that period. The contractor must complete Step 3 by September 8 (rather than September 13). If X timely submitted the ACF but the contractor rejects it and sends the rejection letter on September 20, the contractor must complete Step 5 of Scenario C by September 25.

In sum, the only material differences between the general procedures in subsections (D)(1) and (D)(2)(a) are:

- The timeframes for contractor action (10 days vs. 5 days)
- (D)(1) addresses revalidations --- for which no prior notification from PEOG is needed to impose a stay --- whereas (D)(2)(a) applies only to ownership discrepancies and requires said notification from PEOG.
- In (D)(1) cases, any deactivation effective date is retroactive to the day after the RRT's expiration. For (D)(2)(a) situations, the deactivation effective date is retroactive to the date of the stay notification letter.

b. Immediate Imposition

Situations could occur when PEOG directs the contractor via e-mail to immediately impose a stay. Here, and except if PEOG directs otherwise:

- Step 1 of Scenarios A, B, C, and D - Within **1 business day** of receiving this e-mail, the contractor shall: (a) send to the provider via regular mail the letter identified in section 10.7.20(B); and (b) switch the PECOS status to "Approved – Stay of Enrollment" effective the date the letter is mailed.

- Step 3 of Scenarios B and D - Within **1 business day** after the expiration of the 30-day stay period, the contractor shall -- (a) Change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) Take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 5 of Scenario C - Within **1 business day** of sending the rejection letter, the contractor shall: (a) change the PECOS status to "Deactivated" effective the date the stay notification letter was mailed; and (b) take all other measures normally associated with a deactivation (e.g., send deactivation letter).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

Aside from the above timeframes, the contractor shall follow the general procedures, steps, and scenarios outlined in subsection (D)(1) above.

c. All Other PEOG-Directed Stays

For all PEOG-directed stays other than those described in subsections (D)(2)(a) and (b), the following apply:

- As with revalidations, the contractor has 10 days to undertake the actions described in Steps 1, 3 (Scenarios B and D), and 5 (Scenario C).

- Step 3B of Scenario D - If the contractor receives the ACF after it mails the deactivation letter, it shall request the submission of or develop for a reactivation application.

E. Other Scenarios

The contractor may encounter stay situations not explicitly identified in subsection (D) above. In such situations, the contractor shall -- to the maximum extent possible -- still follow the general processes and basic steps outlined in the (D)(1) and (2) scenario(s) most applicable to the case the contractor is handling. If the contractor nonetheless needs additional guidance, it shall contact its PEOG BFL for guidance.

F. Letters

The contractor shall send all stay notification letters via hard-copy mail and via e-mail (if a valid email address is available); the contractor should also send the notice via fax if a valid fax number is available. All notifications shall be saved in PDF format, **and all notification letters shall be mailed on the same date listed on the letter.**

G. Rebuttals

See section 10.4.9.1 of this chapter for information concerning rebuttals of stays of enrollment.

H. NPE and DME MAC Interaction

The NPEs and the DME MACs shall interact, coordinate, and communicate with each other in stay situations consistent with CMS instructions and in instances generally akin to those involving deactivations. This could include, for example:

- The NPE notifying the applicable DME MAC of the imposition or lifting of a stay and any subsequent deactivation.
- Upon being informed of a stay by the NPE, the DME MAC holding payment for services furnished during the stay period.

10.4.9.1 – Stay of Enrollment Rebuttals
(Rev. 12524; Issued: 03- 01-24; Effective: 04-01-24; Implementation: 06-03-24)

Note that the MAC will handle all non-DMEPOS supplier stay rebuttals consistent with the instructions in this section 10.4.9.1 and all other CMS guidance. DMEPOS supplier stay rebuttals will be handled by the PEOG appeals and rebuttals contractor.

A. Background

Pursuant to 42 CFR § 424.541(b), a provider/supplier (hereafter "provider") under a stay of enrollment may file a rebuttal. A rebuttal is an opportunity for the provider to demonstrate that it met all applicable enrollment requirements and that the stay should not have been imposed. Only one rebuttal request may be submitted per enrollment stay. Additional rebuttal requests submitted for the same stay for which a rebuttal has already been received shall be dismissed.

If the applicable CMS form (ACF) (see section 10.4.9) is received for a "stayed" provider while a rebuttal submission is pending or during the rebuttal submission timeframe, the contractor shall process the ACF consistent with current instructions.

B. Rebuttal Submissions

1. Requirements and Submission of Rebuttals

Pursuant to 42 C.F.R. § 424.541(b), to be accepted and processed, the rebuttal submission must—

(6) Be in writing;

(7) Specify the facts or issues concerning the rebuttal with which the provider disagrees, and the reasons for disagreement;

(8) Include all documentation the provider wants CMS to consider in its review of the stay;

(9) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR § 424.502), or a legal representative (as defined in 42 C.F.R. § 498.10).

- If the legal representative is an attorney, the attorney must include a statement that he/she/they have the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority.
- If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.
- Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a

signed statement authorizing that individual from the group to act on his/her/their behalf.

- Signatures may be original or electronic. Valid signatures include handwriting (wet) signatures in ink and digital/electronic signatures. Digital or electronic signatures such as those created by digital signature options, created in software, such as Adobe) and email signatures shall be accepted. Contractors shall contact ProviderEnrollmentAppeals@cms.hhs.gov for questions regarding electronic and digital signatures.

(10) Be received by the contractor within 15 calendar days from the date of the stay notification letter to the provider. The contractor shall accept a rebuttal submission via hard-copy mail, e-mail, and/or fax.

If the rebuttal submission is not appropriately signed or if a statement from the attorney or written notice of representation is not included in the submission, the contractor shall send a development request for a proper signature or the missing statement/written notice (using the applicable model letter) before dismissing the rebuttal submission. The contractor shall allow 15 calendar days from the date of the development request letter for the rebuttal submitter to respond to the development request.

If a rebuttal submission--(1) Is not appropriately signed and no response is received to the development request (if applicable); (2) Is untimely (as described above); (3) Does not specify the facts or issues with which the provider disagrees and the reasons for disagreement and no response is received to the development request; or (4) Is a duplicative submission, the contractor shall dismiss the rebuttal submission using the applicable rebuttal dismissal model letter. (The contractor can use the same rebuttal dismissal letters applicable to deactivation letters, modifying them to apply to the stay situation.) For those rebuttal submissions that are improperly signed and/or do not specify the facts or issues with which the provider disagrees and the reasons for disagreement, the contractor shall send a development request via hard-copy mail, email, if available, to the provider requesting a proper signature and/or clarification on the facts or issues with which the provider disagrees and the reasons for disagreement using the applicable rebuttal development model letter. Sending the development letter via fax is optional. The contractor shall grant an additional 15-calendar days from the date of the development request letter for the provider to submit an acceptable rebuttal submission. If no response is received or the rebuttal submission is still deficient after the development request and the 15-calendar day timeframe has expired, the contractor shall dismiss the rebuttal submission using the applicable rebuttal dismissal model letter.

The contractor may make a good cause determination to accept any rebuttal that has been submitted beyond the 15 calendar-day filing timeframe. Good cause may be found where there are circumstances beyond the provider's control that prevented the timely submission of a rebuttal. These uncontrollable circumstances do not include the provider's failure to timely update its enrollment information, specifically its various addresses. If the contractor believes good cause exists to accept an untimely rebuttal submission, the contractor shall send a request approval email to ProviderEnrollmentAppeals@cms.hhs.gov within five calendar days of making the good cause determination. This email shall detail the contractor's reasoning for

finding good cause. Processing timeliness standards shall begin on the date the contractor receives a response from CMS.

2. Time Calculations for Rebuttal Submissions

If the 15th calendar day from the date of the stay notification letter falls on a weekend or federally-recognized holiday, the rebuttal shall be accepted as timely if the contractor received it by the next business day.

It is the provider's responsibility to timely update their enrollment record to reflect any changes to their enrollment information including, but not limited to, their correspondence address. Failure to timely update a correspondence address or other addresses included in their Medicare enrollment record does not constitute an "in fact" showing that the stay notice was received after the presumed receipt date (as described above).

3. Processing Rebuttal Submissions

The contractor shall send an acknowledgement letter via hard-copy mail to the return address on the rebuttal submission within 10 calendar-days of receipt of the accepted rebuttal request using the rebuttal acknowledgment model letter, including a rebuttal tracking number and the provider's NPI. The acknowledgement letter shall also be sent via email if a valid email address is available (either in the enrollment record or rebuttal submission). It is optional for the contractor to send the acknowledgement letter via fax if a valid fax number is available. If a rebuttal determination is issued within 10 calendar-days of the date of receipt of the rebuttal submission, the contractor is not required to issue a receipt acknowledgement letter.

The contractor shall process all accepted rebuttal submissions within 30 calendar days of the date of receipt. If, while reviewing the rebuttal submission, the provider wishes to withdraw its rebuttal, the request to withdraw must be submitted to the contractor in writing before the rebuttal determination is issued. If a provider submits a written request to withdraw its rebuttal submission prior to the issuance of a rebuttal determination, the contractor shall issue a letter using the applicable rebuttal withdrawn model letter and no rebuttal determination shall be issued.

All materials received from the provider shall be considered by the contractor in its review.

4. Reason-Specific Instructions

i. General

As explained in section 10.4.9, CMS may impose a stay if the following two requirements are met:

- The provider is non-compliant with at least one enrollment requirement in Title 42; **and**
- The provider can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information

or revalidation application (hereafter collectively referenced as "the applicable CMS form" or "ACF".)

In its review, therefore, the contractor shall, as a general principle, ascertain whether the provider (1) was indeed non-compliant and (2) can remedy the non-compliance by submitting an ACF. The contractor can review section 10.4.8.1(C)(4) (which addresses deactivation rebuttals) and apply the same basic principles discussed in those illustrations to their factually corresponding stay rebuttal situations.

Note that for stay rebuttals other than that discussed in Example (ii)(A) below, the contractor may need additional information (beyond that referenced in section 10.4.9(A)) regarding PEOG's decision to impose a stay. In such cases, the contractor shall contact ProviderEnrollmentRevocations@cms.hhs.gov and clearly outline the requested data. The 30-day timeframe for processing the rebuttal stops between the times the contractor sends the request and receives the information from PEOG.

C. Determination

The contractor shall render a determination regarding a rebuttal submission using the appropriate model rebuttal decision letter. If the contractor is unable to render a determination, the contactor shall use the appropriate model letter for the specific situation. All determinations (including dismissals and withdrawals) related to rebuttal submissions shall be sent (1) via hard-copy mail to the return address on the rebuttal submission; (2) via hard-copy mail to the correspondence mailing address on the enrollment records (if different from return address on rebuttal submission); and (3) by e-mail if a valid e-mail address is available (submitted as part of the rebuttal submission and/or listed in the enrollment record correspondence mailing address). The contractor may also send via fax if a valid fax number is available. All documentation shall be saved in PDF format. All notification letters shall be mailed on the same date listed on the letter.

If the contractor issues a rebuttal determination favorable to the provider, it shall make the necessary modification(s) to the provider's enrollment within 5 calendar days of the date of the favorable determination letter. This will involve a rescission of the stay regardless of whether the stay has already been lifted or is still in effect. If the contractor confirms that the ACF is not needed and that no new changes are being reported, the contractor shall use the following return reason in the returned application model letter found in section 10.7.7 of this chapter: "A rebuttal decision has been issued; therefore, the submitted Form CMS [855/588/20134] is not needed." If new changes were being reported as part of the ACF, the contractor shall process those changes.

If the contactor issues a rebuttal determination unfavorable to the provider or supplier, the stay (irrespective of whether it has been lifted) remains intact. Hence, if a stay existed from March 1 to March 10 and the stay was upheld on April 1, the record shall still reflect that the provider was under a stay between March 1 – 10.

D. No Further Review

Pursuant to § 424.541(b)(6), a determination made regarding a stay rebuttal request is not an initial determination and is not subject to further review. Thus, no additional appeal rights shall be included on any rebuttal determination letter.

E. External Monthly Reporting for Stay Rebuttals

(This data shall be reported in a template separate from that concerning deactivation rebuttals per section 10.4.8.1.)

Using the provider enrollment rebuttals reporting template, the contractor shall complete all columns listed for all stay rebuttal submissions received and processed by the contractor. No column shall be left blank (except Column K, as described below and as applicable). If the contractor is unable to complete all columns for a given rebuttal submission, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within five business days of discovery to seek further guidance.

The reports shall use only the formats identified below. All dates shall be formatted as mm/dd/yyyy (e.g., 01/13/2021). The reports shall be sent to CMS via email at ProviderEnrollmentAppeals@cms.hhs.gov no later than the 15th of each month. If this day falls on a weekend or a holiday, the report shall be submitted the following business day. The report shall include the prior month's rebuttal submissions, as well as outcomes for all submissions previously received that were not yet completed and reported to CMS (e.g., the February report shall cover all January rebuttals).

IMPORTANT: All submissions shall remain on the monthly report until a final outcome/decision has been reported to CMS.

- **Column A:** The response in Column A labelled, "Provider/Supplier Name (As it appears in PECOS)" shall be the provider's or supplier's legal business name, exactly as it is spelled and formatted in the PECOS enrollment record (including capitalization, abbreviations, and punctuation).

- **Column B:** The response in Column B labelled "NPI" shall be the provider's or supplier's NPI. If the provider/supplier has more than one NPI, the contract shall list each NPI, separated by a semi-colon.

- **Column C:** The response in Column C labelled, "EID (if applicable)" shall be the provider's or supplier's EID. If there is no EID associated with the provider/supplier, the response shall be "N/A".

- **Column D:** The response in Column D labelled, "PTAN(s) (if applicable)" shall include the provider's or supplier's PTAN. If the provider/supplier has more than one PTAN, each PTAN shall be separated by a semicolon (e.g., L5988; 190002033). If the provider/supplier does not have a PTAN, the response shall be "N/A".

- **Column E:** The response in Column E labelled, "Contractor (Including Jurisdiction)," shall be in one of the following formats. No other formats are acceptable.

    - CGS J15
    - FCSO
    - NGS J6

- NGS JK
- Noridian JE
- Noridian JF
- Novitas JH
- Novitas JL
- NPE East
- NPE West
- Palmetto JJ
- Palmetto JM
- WPS J5
- WPS J8

- **Column F:** The contractor shall briefly describe the non-compliance that led to the stay (e.g., revalidation non-response).

- **Column G:** The response in Column G labelled, "Date Rebuttal Received" shall be the date on which the Contractor received the rebuttal. The date shall be formatted as mm/dd/yyyy (e.g. 10/25/2021).

- **Column H:** The response in Column H labelled, "Date Receipt Acknowledgement Sent to Provider/Supplier/Legal Representative," shall be "Not yet sent" if a receipt acknowledgement email/letter has not been sent to the provider/supplier/legal representative at the time the monthly report is sent to CMS. The response shall be "N/A" if a receipt acknowledgement email/letter is not required for that case (i.e., rebuttal determination is issued within 10-calendar days of the date of receipt of the rebuttal submission). Dates shall be formatted as mm/dd/yyyy (e.g. 06/15/2020).

- **Column I:** The response in Column I labelled, "Date Rebuttal Determination Issued" shall be the date on which the Contractor issues the rebuttal determination. The date shall be formatted as mm/dd/yyyy (e.g. 09/19/2019). If a final rebuttal determination has not yet been issued, the contractors shall enter "In Process" as the response.

- **Column J:** The response in Column J labelled, "Final Decision Result," shall be one of the following. No other formats are acceptable.

    - **Not Actionable:** Rebuttal is no longer actionable (moot) because the basis for the stay has been resolved (e.g., CMS rescinded the stay).
    - **Favorable:** (to provider/supplier) Contractor has determined that an error was made in the implementation of the stay. Therefore, the initial determination was overturned and the stay has been rescinded.
    - **Unfavorable:** (to provider/supplier) Contractor upholds the initial stay determination.
    - **Dismissed:** The rebuttal submission does not meet the rebuttal submission requirements (e.g. missing proper signature and did not timely respond to development request).
    - **Withdrawn:** Provider/supplier/representative has submitted written notice of its intent to withdraw its rebuttal before the contractor issued a determination and the

contractor has acknowledged the withdrawal.
    - **In Process:** A final decision has not been issued. The contractor is still processing the submission.

- **Column K:** The response in Column K labelled, "Comments," shall include any information related to the stay, rebuttal submission, or rebuttal determination that provides context for CMS in reporting the rebuttal and outcome. This column may be left blank if no additional information is necessary.

10.5- Timeliness and Accuracy Standards

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Sections 10.5(A) through 10.5(B)(4) of this chapter address the timeliness and accuracy standards applicable to the processing of Form CMS-855, Form CMS-20134 applications (initial and change of information and revalidation) and opt-out affidavits. Even though the provisions of 42 CFR § 405.818 contain processing timeframes that differ than those in sections 10.5(A) through 10.5(B)(4), the contractor shall adhere to the standards specified in sections 10.5(A) through 10.5(B)(4).

The term "PECOS applications" means web-based applications. For special instructions regarding the processing of applications submitted via PECOS 2.0, see section 10.3 of this chapter. The PECOS instructions in section 10.3 take precedence over those in this section 10.5.

Note that the date of receipt of a PECOS application is the date the contractor received it, not the date on which the application required the contractor's manual intervention per section 10.3.

The processing of an application or opt-out affidavit generally includes, but is not limited to, the following activities:

- For paper applications - Receipt of the application or opt-out affidavit in the contractor's mailroom and forwarding it to the appropriate office for review. (This is the intake process.)

- For PECOS applications - Electronic receipt of the application.

- For paper applications – Completing the intake process.

- Ensuring that the information on the application or opt-out affidavit is verified.

- Requesting and receiving clarifying information.

- Site visit (if necessary).

- Requesting fingerprints (if necessary).

- For certified providers/suppliers (and as applicable to the transaction and/or provider/supplier type), formal notification to the state and/or CMS Survey & Operations

Group (SOG) Location of the contractor's approval, denial, or recommendation for approval of the application.

(Note: The timeliness metrics discussed in this section are a combination of Part A applications and Part B applications and opt-out affidavits.)

For purposes of sections 10.5(A) and 10.5(B) below:

- The term "site visit" means that the provider or supplier requires an on-site review to determine whether the provider or supplier is operational based on the provider/supplier type.

- The term "development" means that the contractor needs to contact the provider or supplier for additional information. (A development request (via letter, fax, email, the PCV, or telephone contact for development) to the provider or supplier is considered to be the first development request.)

- The term "fingerprinting" means that 5 percent or greater owners (including partners who own at least 5 percent) of a provider or supplier is required to submit fingerprints for an additional level of screening.

A. Standards for Initial and Change of Information Applications and Opt-Out Affidavits

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term "initial applications" also includes:

- Form CMS-855 or Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the new owner.

- "Complete" Form CMS-855 or Form CMS-20134 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, or (c) as a Form CMS-855 or Form CMS-20134 reactivation.

- Opt-out affidavits submitted for an eligible practitioner's first opt-out period.

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term "changes of information" also includes:

- Form CMS-855 and Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the old owner.

- Form CMS-588 changes submitted without a need for an accompanying complete Form CMS-855 or Form CMS-20134 application.

- Reassignment applications that are not part of an initial, revalidation, or reactivation application (e.g., adding a new reassignment, changing an existing reassignment).

- Form CMS-855 and Form CMS-20134 voluntary terminations.

- Opt-out early termination requests (of initial opt-out affidavits), changes of information and cancellation requests.

Initial and change of information application and opt-out timeliness standards shall be reported together. Likewise, initial, change of information, and opt-out affidavit accuracy shall be reported together.

1. Paper Initial and Change of Information Applications and Opt-Out Affidavits - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 65 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 100 calendar days of receipt.

b. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 30 calendar days of receipt.

The contractor shall process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 65 calendar days of receipt.

2. Paper Initial and Change of Information Applications and Opt-Out Affidavits – Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in sections 10.5(A)(1) through 10.5(A)(2) of this chapter) and all other applicable CMS directives.

3. PECOS Initial and Change of Information Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with existing instructions; site visit (if required) and/or requesting fingerprints (if necessary).

a. PECOS Initial and Change of Information Applications That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Initial and Change of Information Applications That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Initial and Change of Information Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications in full accordance with all the instructions in this chapter (excluding the timeliness standards identified in section 10.5(A)(3) above) and all other applicable CMS directives.

B. Standards for Revalidation Applications

For purposes of sections 10.5(B)(1) through 10.5(B)(3)(b) of this chapter, the term “revalidation applications” includes complete Form CMS-855 or Form CMS-20134 revalidation applications submitted by enrolled providers.

1. Paper Revalidation Applications that Require Site Visits, Development and/or Fingerprinting - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting – Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that require site visits, development and/or fingerprinting within 65

calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 100 calendar days of receipt.

b. Paper Revalidation Applications that do not Require Site Visits, Development, and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that do not require site visits, development and/or fingerprinting within 30 calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 65 calendar days of receipt.

2. Paper Revalidation Applications - Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 revalidations in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in section 10.5(B)(1) above) and all other applicable CMS directives.

3. PECOS Revalidation Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with existing instructions; site visit (if required) and/or requesting fingerprints (if necessary). Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. PECOS Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of all Form CMS-855 and Form CMS- 20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Revalidation Applications That Do Not Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Revalidation Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications in full accordance with all of the instructions in this chapter (with the

exception of the timeliness standards identified in sections 10.5(B)(1) and 10.5(B)(3)(b) above) and all other applicable CMS directives.

C. General Timeliness Principles

Unless stated otherwise in this chapter or in another CMS directive, the principles discussed below apply to all applications discussed in sections 10.5(A)(1) through 10.5(B)(3) of this chapter (e.g., change of ownership (CHOW) applications submitted by old and new owners, CMS-588 forms).

1. Clock Stoppages

The processing timeliness clock temporarily stops when the situations identified in section 10.5(C)(1) occur:

- Referring an application to the Office of Inspector General (OIG) or the Unified Program Integrity Contractor (UPIC).
- Waiting for a final sales agreement (e.g., CHOW, acquisition/merger).
- Contacting: (i) the SOG Location, and/or state agency regarding a provider-based or CHOW determination; (ii) the SOG Location or state agency with a question regarding the application of a CMS policy; (iii) contacting the SOG Location or state agency.
- Referring a provider or supplier to update their information in the National Plan & Provider Enumeration System.
- Contacting CMS' Provider Enrollment & Oversight Group (PEOG) for the following reasons: questions regarding the application or CMS policy; an adverse legal action review; affiliations/overpayments found on the monthly report or PECOS; Advanced Provider Screening criminal alerts; delayed site visits; referrals to PEOG (if required under this chapter) for final review of certain certified provider/supplier applications.
- Referring a provider to the Social Security Administration to resolve a discrepancy involving a social security number or to the Internal Revenue Service to resolve a tax identification number or individual tax identification number issue.
- Contacting another contractor for any type of PECOS update (i.e.: locked associates).
- Contacting the PECOS Maintainer for resolutions to system issues (i.e.: RightNow tickets).
- Practice location and special payment address changes as well as specialty changes with future dates.
- If fingerprints are required, the timeliness clock stops when the fingerprint request is issued and resumes when the contractor receives the results. (If additional information is

developed at the same time as the fingerprint request is issued, no action shall be taken on the developed information until after the fingerprint results are received.)

- Any other clock stoppage expressly permitted in this chapter or by CMS

Should a dependent application be needed to continue processing, the processing clock stops when the development is issued and resumes once the development is received.

Consistent with section 10.6.19(I), the contractor shall document in PECOS any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. The contractor will thus be able to furnish explanatory documentation to CMS should the applicable time limits be exceeded. To illustrate, assume that a contractor received an initial Form CMS-855I application on March 1. On March 30, the contractor sent a question to CMS and received a response on April 7. The processing time clock stops from March 31 to April 7. The contractor should document PECOS to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

2. Calendar Days

Unless otherwise stated in this chapter, all days in the processing time clock are "calendar" days, not "business days." If the final day of a metric falls on a weekend or holiday, this remains the day by which the application must be processed. If the contractor cannot finish processing the application until the next business day, it should document in PECOS that the final day of the metric fell on a Saturday/Sunday/holiday and furnish any additional explanation as needed.

3. Date-Stamping – Paper Applications Only

All incoming correspondence must be date-stamped on the day it was received in the contractor's mailroom. This includes, but is not limited to:

- Any Form CMS-855 or Form CMS-20134 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- Letters from providers. (The first page of the letter must be date-stamped.)

- Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)

- Data that the provider furnishes (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because some contractors interleaf the new/changed pages within the original application. Thus, it is necessary to determine the sequence in which the application and the additional pages were received.)

(Note: PECOS applications are considered "date stamped" on the date the application was received.)

The timeliness clock begins on the date on which the application/envelope is date-stamped in the contractor's mailroom, not the date on which the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the above bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

In addition, and unless stated otherwise in this chapter or in another CMS directive, all incoming enrollment applications (including change requests) must be submitted via mail (unless circumstances require submission via fax or email).

4. When the Processing Cycle Ends

For (1) Form CMS-855A applications, and (2) Form CMS-855B applications submitted by ambulatory surgical centers (ASCs) or portable x-ray suppliers, the processing cycle ends on the date that the contractor enters a final status in PECOS (e.g., denied, returned, rejected, approval recommended) rather than the date on which the contractor sends formal notification of approval recommended, etc., to the state or SOG Location. (Note that accompanying applications (e.g., Form CMS-855I reassignment application submitted with a Form CMS-855B for an ASC) would also end their processing cycle).

In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the state), the cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

For (1) Form CMS-855I applications, (2) Form CMS-855B applications from suppliers other than ASCs and portable x-ray suppliers, (3) Form CMS-20134 and (4) Form CMS-855S applications the processing cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

5. PECOS Applications

See section 10.3 of this chapter for additional information on the processing of PECOS applications.

10.6 -Additional Topics Pertaining to Medicare Enrollment

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

In reviewing the instructions in this section 10.6 et seq., the contractor shall be mindful of the PECOS 2.0 guidance in section 10.3 of this chapter. Note that the latter instructions take precedence over the former with respect to PECOS matters.

10.6.1 – Certified Providers/ Certified Suppliers

(Rev. 11125; Issued 11-18-21; Effective: 12-03-21; Implementation: 01-03-22)

All references to the SOG Location (formerly the "RO") in this section 10.6.1 et seq. refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

10.6.1.1 – Changes of Ownership (CHOWs) – Transitioned Certified Providers and Suppliers

(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

(Until further notice from CMS, the instructions in sections 10.6.1.1 through 10.6.1.1.4 apply only to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, Part A OPT/OSP, ASCs, and PXRSs. The contractor shall continue to use the existing CHOW instructions--now in section 10.6.22 of this chapter--for all non-transitioned certified provider/supplier types.

When executing the instructions in sections 10.6.1.1 through 10.6.1.1.4, the contractor can disregard directives that obviously do not apply to the provider/supplier type in question (e.g., references to home health agencies do not apply to SNFs).

Except as otherwise noted, the term "CHOW" as used in section 10.6.1.1 et seq. includes CHOWs, acquisitions/mergers, and consolidations. Though the Change of Ownership (CHOW) Information section of the Form CMS-855A separates the applicable transactions into CHOWs, acquisition/mergers, and consolidations for ease of disclosure and reporting, they fall within the general CHOW category under 42 CFR § 489.18 (e.g., an acquisition/merger is a type of CHOW under § 489.18).

Note that the CHOW instructions in 10.6.1.1 through 10.6.1.1.4 apply to HHA and hospice CHOWs taking place under 42 CFR § 489.18. For changes in majority ownership under 42 CFR § 424.550(b), see section 10.2.1.6.1 of this chapter.

10.6.1.1.1 – General Background on CHOWs

(Rev. 11125; Issued 11-18-21; Effective: 12-03-21; Implementation: 01-03-22)

A. Overall Process

CHOWs are officially defined in and governed by 42 CFR § 489.18 and CMS Publication (Pub.) 100-07, chapter 3, sections 3210 through 3210.5(C). In the past, the SOG Location had made the determination as to whether a CHOW had occurred (unless this function was delegated). The process now involves, in general (and with exceptions), the following:

- The contractor sends the application (and all supporting documentation) and its recommendation for approval (if applicable) to the state agency (hereafter simply "state") for review
- The state notifies the contractor of its recommendation

- The contractor notifies the CMS Provider Enrollment & Oversight Group (PEOG) of the recommendation. PEOG signs the provider agreement and performs other administrative functions pertaining to the CHOW application
- Once PEOG completes the required administrative actions, PEOG will notify the contractor thereof
- The contractor completes processing and notifies the provider of the approval of the transaction using the appropriate model letter (sending a copy thereof to the state and SOG Location (and, if applicable, accrediting organization)

(Thus, and except as otherwise stated in section 10.6.1.1 et seq., SOG Locations are no longer directly involved in the CHOW process for applications received on or after MMDDYY. SOG locations will, however, continue to provide policy-related assistance regarding CHOWs.)

Specific details on these steps are outlined in section 10.6.1.1 et seq.

Note that although certified suppliers are not explicitly referenced in § 489.18, the principles of this regulatory provision are generally applied to these suppliers.

B. Governing Regulations

Pursuant to § 489.18(a)(1) through (a)(4) (and as outlined in more detail below), the following situations generally constitute a CHOW:

(1) Partnership – The removal, addition, or substitution of a partner (unless the partners expressly agree otherwise), as permitted by applicable state law.

(2) Unincorporated sole proprietorship - Transfer of title and property to another party constitutes a CHOW.

(3) Corporation – (i) The merger of the provider corporation into another corporation; or (ii) the consolidation of two or more corporations that results in the creation of a new corporation.

(4) Leasing - The lease of all or part of a provider facility constitutes a change of ownership of the leased portion.

(See section 10.6.1.1.2 below for more detailed information on the types of transactions that can constitute a CHOW.)

Under § 489.18(c) and Pub. 100-07, chapter 3, section 3210, when there is a CHOW, the existing provider agreement is automatically assigned to the new owner unless the new owner rejects assignment of the provider agreement. If the new owner rejects this assignment, the provider cannot participate in Medicare without going through the same process as any new provider (e.g., initial enrollment, undergoing a state survey). Automatic assignment of the existing provider agreement to the new owner means the new owner is subject to all the terms and conditions under which the existing agreement was issued.

10.6.1.1.2 – Examples of CHOW and Non-CHOW Situations

(Rev. 11125; Issued 11-18-21; Effective: 12-03-21; Implementation: 01-03-22)

A. Introduction

Pub. 100-07, chapter 2, section 3210.1D outlines in detail certain types of transactions (based on business type) that involve (or do not involve) a CHOW. This list is not exhaustive, however, and CMS recognizes that scenarios may arise that do not fall within the normal/typical categories of CHOW transactions. Indeed, it is not possible for CMS to address in these instructions every conceivable case. Hence, if the contractor is uncertain as to how to handle a situation that could involve a CHOW under 42 CFR § 489.18, it may contact its PEOG BFL for assistance or the SOG location representative.

In reviewing this section 10.6.1.1.2, the contractor should keep in mind the following:

1. Other Business Types - Although § 489.18 addresses only sole proprietorships, partnerships, corporations, and lease arrangements, other types of business entities (such as limited liability companies (LLCs)) can have CHOWs. These entities will be identified within the category in section 10.6.1.1.2(B) to which they are most applicable.

2. Assignment – Any statement in section 10.6.1.1.2(B) that a particular business transaction constitutes a CHOW assumes that the new owner accepted assignment of the provider agreement. In cases where a § 489.18-type business transaction occurred but assignment was not accepted (as discussed in detail in section 10.6.1.1.3.2 below): (a) no CHOW has taken place; (b) the provider agreement does not transfer; and (c) the entity must enroll as a brand new provider. Moreover, the existing owner must voluntarily terminate the provider's enrollment and agreement consistent with existing regulations and the policies in this chapter.

3. CHOW Categories on the Form CMS-855A - For purposes of provider enrollment only, there are three main categories of CHOWs captured on the Form CMS-855A application:

a. "Standard" CHOW - This occurs when a provider's CMS Certification Number (CCN) and provider agreement are transferred to another entity as a result of the latter's purchase of the provider. To illustrate, suppose Entity A is enrolled in Medicare, but Entity B is not. B acquires A. Assuming all regulatory requirements are met, A's provider agreement and CCN will transfer to B.

This is the most frequently encountered change of ownership scenario. As explained in section 10.6.1.1 et seq., even though it is technically an acquisition (i.e., B bought/acquired A) under § 489.18, this situation falls under the "CHOW" category – as opposed to the "Acquisition/Merger" category – on the Form CMS-855A.

b. Acquisition/Merger - In general, this occurs when two or more Medicare-enrolled entities combine, leaving only one remaining CCN and provider agreement. For instance, suppose Entity A and Entity B are both enrolled in Medicare, each with its own CCN and provider agreement. The two entities decide to merge. Entity B's CCN and provider agreement will be eliminated (leaving only Entity A's CCN and provider agreement).

If the acquisition results in an existing provider having new owners but keeping its existing provider number, the applicant should check the CHOW box in the Basic Information section of the Form CMS-855A.

Unlike the new owner in a CHOW or consolidation, the new owner in an acquisition/merger need not complete the entire Form CMS-855A. This is because the new owner is already enrolled in Medicare. As such, the provider being acquired should be reported as a practice location in the Practice Location Information section of the new owner's Form CMS-855A.

c. Consolidations - This occurs when the merger of two or more Medicare-enrolled entities results in the creation of a brand new entity. To illustrate, if Entities A and B decide to combine and, in the process, create a new entity (Entity C), the CCNs and provider agreements of both A and B will be eliminated. Entity C will have its own CCN and provider agreement.

Note the difference between acquisitions/mergers and consolidations. In an acquisition/merger, when A and B combine there is one surviving entity. In a consolidation, when A and B combine there are no surviving entities. Rather, a new entity is created – Entity C.

Regardless of which of these three categories the particular transaction falls under on the Form CMS-855A, the central issue for the contractor is whether a CHOW has occurred pursuant to § 489.18. In other words, the question of how the transaction is reported on the application is less important than the determination as to whether the CHOW requirements have been met. Indeed, merely because the provider reports a transaction as a § 489.18 CHOW on the Form CMS-855 does not mean that one has legally occurred. The contractor will therefore (as discussed below) have to carefully analyze the scenario and legal documentation to ascertain whether a CHOW is involved.

4. Continued Responsibility – In ascertaining whether a CHOW has occurred, another important consideration for the contractor is whether the owning entity/individual is (or is no longer) responsible for the provider and its operations. If some form of ownership change has occurred but the same individual/entity (e.g., the same corporation) generally remains as the principal owner of the provider, no CHOW has occurred; except as otherwise stated in this chapter, therefore, the transaction should be treated as a change of information.

5. Change in Process – Notwithstanding the expanded CHOW instructions in this section 10.6.1.1 et seq., the contractor should remember that the only changes to the CHOW process are generally as follows:

- The SOG location no longer makes the formal determination as to whether a CHOW has occurred.
- If the contractor recommends approval of the CHOW, it forwards the application to the state only (not to the SOG Location)
- If the state recommends approval to the contractor, the contractor coordinates with PEOG (as described below)
- After PEOG responds to the contractor, the contractor finalizes the application

Except as otherwise stated in these instructions, therefore, the contractor shall continue to follow the procedures it has in the past.

B. CHOWs by Business Type

(See section 10.6.4 of this chapter for basic information on the forms of business structures frequently encountered in provider enrollment.)

The scenarios below are not an exhaustive list of all the types of CHOWs that may or may not occur. Furthermore, the following situations may have different, unique facts that could raise questions as to whether a CHOW has indeed taken place. The contractor will thus encounter CHOW cases not precisely addressed in these instructions and, if uncertain regarding how they should be handled, may contact its PEOG BFL for guidance.

1. Sole Proprietorship

If the provider is an entity owned by a single individual, a transfer of title to the enterprise to another person or firm (whether or not this includes transfer of title to the real estate) constitutes a CHOW. It is also a CHOW if the former owner becomes one of the members of a partnership or corporation succeeding him/her as the new owner (e.g., Mr. Jones is the sole proprietor of Provider X, and he sells the business to a corporation of which he will become a shareholder).

As discussed in section 10.6.4 of this chapter, a sole proprietorship is neither a solely-owned corporation nor a solely-owned LLC (e.g., an LLC with only one owner/member remains an LLC and is not a sole proprietorship simply because there is only a single owner/member).

2. Partnership

General partnership (i.e., a partnership with no limited partners) - In a general partnership, the removal, addition, or substitution of an individual/entity as a partner in the entity dissolves the partnership unless: (1) state law holds otherwise; or (2) the partnership agreement expressly states otherwise. If the partnership is indeed dissolved based on a partner's removal/addition/substitution, a new partnership is created and a CHOW has occurred.

Limited partnership – The departure/replacement of a general partner in a limited partnership will often result in the dissolution of the limited partnership, the creation of a new one, and the occurrence of a CHOW; these results typically do not stem from the departure or replacement of a limited partner. In either case, the contractor shall carefully examine the relevant documents (e.g., the Form CMS-855, limited partnership agreement) to see if the limited partnership has undergone a CHOW.

3 - Corporation

(For purposes of this section 10.6.1.1.2 only, and unless stated otherwise: (1) the term "corporation" includes LLCs; and (2) the term "stock" includes LLC ownership interests. Thus, a reference to the merger of two corporations could include, for instance, the merger of an LLC with a corporation to create a brand new LLC or corporation.)

A merger of one or more corporations into the surviving Medicare-participating provider corporation (i.e., a merger "into" the participating corporation) is not recognized as a CHOW of the surviving corporation. However:

- If the corporation that survives is not the former owner of the provider entity, there is a CHOW; and

- Consolidation or merger of two or more corporations that results in the creation of a new corporate entity having ownership/control over a provider organization constitutes a CHOW.

4 - Leasing

When all or part of a provider facility is leased, it constitutes a CHOW. If only part of the provider is leased, the original provider agreement remains in effect only with respect to the unleased portion. The lease of part of the facility constitutes a CHOW.

10.6.1.1.3 – Ascertaining Whether a CHOW Has Occurred
(Rev. 11125; Issued 11-18-21; Effective: 12-03-21; Implementation: 01-03-22)

Sections 10.6.1.1.3.1, 10.6.1.1.3.2, and 10.6.1.1.3.3 outline the general steps the contractor must undertake in a potential CHOW situation. The contractor should also review sections 10.6.1.1.3.1.1 and 10.6.1.1.4 below regarding special circumstances that might occur when performing these steps. In addition, nothing in this section 10.6.1.1.3 et seq. prohibits the contractor from returning or rejecting the application if grounds for doing so under this chapter 10 exist.

Except as otherwise stated, the instructions in this section 10.6.1.1.3 et seq. apply to both Form CMS-855A and Form CMS-855B applications from certified providers.

10.6.1.1.3.1 – Step 1 - Initial Review of the CHOW Application
(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Process

Upon receipt of a Form CMS-855 CHOW application, the contractor shall undertake the following (in whichever order the contractor prefers):

(i) Ensure that all data validations otherwise required per this chapter have been performed.

(ii) Ensure that the submitted application(s) is complete consistent with the instructions in this chapter.

(iii) Ensure that the provider has submitted all documentation otherwise required per this chapter. For CHOW purposes, this also includes the following:

(a) Legal Documentation of CHOW - The legal documents that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1 below for more information on such documents.)

(b) Form CMS-1561 (Health Insurance Benefit Agreement). (In lieu of the Form CMS-1561, rural health clinics (RHCs) must submit the Form CMS-1561A and ambulatory surgical centers (ASCs) must submit the Form CMS-370.) (See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List for more information.) These forms are generally known as "provider agreements" and "supplier agreements," as applicable.

(c) Evidence of state licensure, if applicable. (This can be furnished consistent with existing instructions in this chapter concerning submission of evidence of state licensure.)

(d) Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(e) Applicable CMS Form that requests certification in Medicare. (These include, for example, CMS-377 for ASCs, CMS-3427 for end-stage renal disease (ESRD) facilities, etc.) (See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List for more information.)

(f) Form CMS-1539 - Medicare/Medicaid Certification and Transmittal (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS011722).

(g) Form CMS-2567 – Statement of Deficiencies and Plan of Correction (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS008860).

(h) For skilled nursing facilities (SNFs), a signed patient transfer agreement. (See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Facility-Transfer-Agreement-Example.pdf for an example.)

(The provider must complete, sign, date, and include the applicable CMS forms described in this subsection (A)(iii); the provider need not, of course, complete those sections of the forms that are reserved for CMS. For organizational providers, an authorized official (as defined in § 424.502) must sign the forms; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if any document in subsection (A)(iii)(b), (d), (e), (f), (g), or (h) above is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its

recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

Note that if the application is rejected and this results in the expiration of the applicable time period for reporting the change (e.g., 30 days), the contractor shall e-mail its PEOG BFL notifying him/her of the rejection. PEOG will determine whether the provider's/supplier's billing privileges should be deactivated under § 424.540(a)(2) or § 424.550(b)(2) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.

(iv) Ascertaining whether a formal § 489.18 CHOW has occurred – This involves performing all necessary background research, which can include:

- Reviewing the sales or lease agreement
- Reviewing the ownership information in Sections 2, 5, and 6 of the Form CMS-855A (or Sections 5 and 6 of the Form CMS-855B)
- Reviewing whether the provider checked "Yes" or "No" to the question in Section 2 of the Form CMS-855A concerning the acceptance of assignment of the provider agreement.
- Contacting the provider(s) to request clarification of the sales agreement, etc. (Unless otherwise stated in this chapter, the provider must furnish any such clarification in writing; e-mail (including the PCV) is acceptable.)

(v) As applicable, take into account the supplemental instructions in sections 10.6.1.1.3.1(B), 10.6.1.1.3.1.1 and 10.6.1.1.4 of this chapter.

B. Additional Instructions

1. TIN Change - While a CHOW is typically accompanied by a TIN change, this is not always the case. On occasion, the TIN remains the same; conversely, sometimes the provider is changing its TIN but not its ownership. In short, while a change of TIN (or lack thereof) is evidence that a CHOW may or may not have occurred, it is not the most important factor; rather, the change in the provider's ownership arrangement is the central issue. Hence, the contractor shall review the sales/lease agreement closely, for this will help indicate whether a CHOW has occurred. Again, CMS stresses that the terms and conditions of the sales agreement are the primary indicator of the existence or non-existence of a CHOW.

2. Request for Information and/or Clarification – If, after its initial review under subsection (A), the contractor remains uncertain as to whether a CHOW has taken place, the contractor: (i) reserves the right to request any clarifying information from the provider (e.g., additional documentation concerning the sale); and/or (ii) may contact its PEOG BFL or the SOG Location for assistance. (This may include situations where, for instance, (i) the provider believes that the transaction is merely a stock transfer but the contractor disagrees, and (ii) the contractor is uncertain whether the provider is accepting assignment.)

3. Acceptance of Assignment – Regardless of the provider's response to the Form CMS-855 question concerning whether the provider accepts assignment, the contractor shall review the sales/transfer agreement and any other documentation to confirm whether the provider's

response is consistent with the agreement. (For example, if the provider responds "no" to the question, the contractor shall review the sales agreement to ensure consistency.) If an inconsistency is discovered, the contractor shall contact the provider for clarification.

4. Situations Requiring Referral to PEOG – The contractor shall refer the case and all supporting documentation (e.g., sales agreement) to its PEOG BFL in either of the following situations:

- The provider reports a CHOW based strictly on a relinquishment by the owner of all authority and responsibility for the provider organization without a § 489.18-level change of ownership. (For instance, the sales agreement indicates that the provider is selling only 10% of its ownership stake but the provider claims the transaction is a CHOW because it is relinquishing all control of the provider to the party to which its 10% ownership share is being sold.)
- It appears the owner of a provider is entering into a franchise agreement with a corporate chain (and thus uses the chain's name).

10.6.1.1.3.1.1 – Special Processing Instructions and Considerations for the Initial Review Process

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Form CMS-855A – Old and New Owner Applications

Unless stated otherwise in this chapter:

- The contractor shall ensure that all applicable sections of the Form CMS-855A for both the old and new owner are completed in accordance with the instructions on the Form CMS-855A.

- The instructions in this section 10.6.1.1.3.1.1(A) apply only to the Form CMS-855A.

1. Previous Owner(s)

The previous owner's Form CMS-855A CHOW application does not require a recommendation for approval. Any recommendations will be based on the CHOW application received from the new owner.

If the previous owner's Form CMS-855A is available at the time of review, the contractor shall examine the information therein against the new owner's Form CMS-855A to ensure consistency (e.g., same names). If the previous owner's Form CMS-855A has not been received, the contractor shall contact the previous owner and request it. However, the contractor may begin processing the new owner's application without waiting for the arrival of the previous owner's application. It may also make its CHOW recommendation to the state without having received the previous owner's Form CMS-855A.

If a certification statement is not on file for the individual signing the previous owner's application, the contractor shall request that the Individual Ownership and/or Managing Control section of the Form CMS-855A be completed for said person.

Note that the previous owner's Form CMS-855A CHOW application is essentially the equivalent of a Form CMS-855A voluntary termination submission; this is because the old owner is voluntarily leaving the Medicare program. As such, the contractor shall not require the old owner to submit a separate Form CMS-855A voluntary termination along with its Form CMS-855A CHOW application.

2. New Owner

If a Form CMS-855A is not received from the new owner within 14 calendar days of receipt of the old owner's Form CMS-855A, the contractor shall contact the new owner. If, within 30 calendar days after the contractor contacted it, the new owner fails to (1) submit a Form CMS-855A and (2) indicate that it accepts assignment of the provider agreement, the contractor shall send an e-mail to its PEOG BFL notifying him/her of the situation. PEOG will determine whether the provider's billing privileges should be deactivated under § 424.540(a)(2) or § 424.550(b) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.

In the situations described in the previous paragraph where the contractor is awaiting the new owner's application after received the old owner's, the contractor shall: (1) begin processing the old owner's application; and (2) if possible, ascertain whether a CHOW has taken place.

3. Order of Processing of Old/New Owner Applications

To the maximum extent practicable, Form CMS-855A applications from the previous and new owners in a CHOW should be processed as they arrive. However, unless the instructions in this chapter indicate otherwise, the contractor should attempt to send the previous and new owners' applications to the state simultaneously, rather than as soon as they are processed. For instance, suppose the previous owner submits an application on March 1. The contractor should begin processing the application immediately without waiting for the arrival of the new owner's application. Yet the contractor should avoid sending the previous owner's application to the state until the new owner's application is processed. (For acquisition/mergers and consolidations (as those terms are described on the Form CMS-855A), the contractor may send the applications to the state separately.)

4. Form CMS-855A: CHOWs Involving Subtypes

a. Separate Reporting

Any subunit that has a separate provider agreement must report its CHOW on a separate Form CMS-855A. It cannot report the CHOW via the main provider's Form CMS-855A. If the subunit does not have a separate provider agreement (e.g., hospital psychiatric unit), the CHOW can be disclosed on the main provider's Form CMS-855A; this is because the subunit is a practice location of the main provider and not a separately enrolled entity.

b. Change in Subtype

A CHOW may occur in union with a change in the facility's provider subtype. This can happen, for instance, when a hospital undergoes a CHOW and changes from a general hospital to another

type of hospital, such as a psychiatric hospital. Although a change in hospital type is considered a change of information (COI), the provider need not submit separate applications – one for the COI and one for the CHOW. Instead, all information (including the change in hospital type) should be reported on the CHOW application; the entire application should then be processed as a CHOW (assuming it indeed qualifies as such). However, if the facility is changing from one main provider type to another (e.g., hospital converting to a skilled nursing facility) and also undergoing a CHOW, the provider must submit its application as an initial enrollment. The contractor shall notify the provider of this and return the application.

(NOTE: For Medicare purposes, a critical access hospital (CAH) is a separately-recognized provider type. Thus, a general hospital undergoing a CHOW while converting to a CAH must submit its Form CMS-855A as an initial enrollment, not as a CHOW.)

5. Transitioning to Provider-Based Status (Form CMS-855A Submissions Only)

Consistent with existing CMS policy, a provider undergoing a CHOW pursuant to 42 CFR § 489.18 may be assigned to a new contractor jurisdiction only if the provider is transitioning from freestanding to provider-based status. In such cases, the contractor for the new jurisdiction (the "new contractor") shall process both the old and new owner's Form CMS-855A applications. Should the "old/previous" (or current) contractor receive the old and/or new owner's Form CMS-855A applications, it shall (a) forward the application to the new contractor within 5 business days of receipt and (b) notify the new contractor within that same timeframe that the application was sent.

B. Sales and Lease Agreements

Except as indicated otherwise, this subsection (B) applies to Form CMS-855A and Form CMS-855B applications.

1. Verification of Terms

The contractor shall ascertain whether: (1) the sales/lease agreement includes the signatures of the old and new owners, for the agreement must contain the signatures of both parties to the transaction (if it does not, the contractor shall develop for an agreement containing both signatures); (2) the information contained in the sales agreement is consistent with that reported on the new owner's Form CMS-855A or the submitted Form CMS-855B (e.g., same names, effective date); (3) the terms of the contract indicate that the new owner will accept assignment of the provider agreement; and (4) the transaction falls within the scope of organizational transactions covered under § 489.18 and this section 10.6.1.1 et seq.

(Note that a bill of sale/lease agreement/sales transfer agreement is a sales/lease business document and should not be confused with a patient transfer agreement.)

A sales/lease agreement often will not specifically refer to the Medicare provider agreement, assets, and liabilities. However, if (1) the box in the Change of Ownership (CHOW) Information section of the Form CMS-855A is checked "Yes" and (2) the sales/lease agreement either confirms that the new owner will accept assignment or is relatively silent on the matter, the

contractor can proceed as normal. If the agreement indicates that assignment will not be accepted, however, the contractor shall follow the instructions in section 10.6.1.1.3.2(A) below.

As previously mentioned, any clarifying data must be furnished in writing (e.g., additional legal documentation, letter, e-mail). If the clarification – for whatever reason - requires an update to the supplier's Form CMS-855 application, the contractor shall request the submission of said update. In addition, if the contractor discovers discrepancies between the data in the sales agreement and that on the Form CMS-855, the contractor shall seek clarifying information and, if necessary, obtain an updated Form CMS-855.

2. Form of Sales/Lease Agreement

There are instances where the parties in a CHOW did not sign a "sales" or "lease" agreement in the conventional sense of the term; the parties, for example, might have documented their agreement via a "bill of sale." The contractor can accept such documentation in lieu of a sales/lease agreement so long as (1) the document addresses the transaction's terms and (2) the information in the agreement is consistent with that on the Form CMS-855 (as discussed above).

3. Submission of Sales/Lease Agreement

a. General Requirements – Unless specified otherwise in this chapter: (i) both the previous and new owners in a Form CMS-855A CHOW situation must submit copies of the interim and final sales/lease agreements; and (ii) copies of the interim and final sales/lease agreement must be submitted in Form CMS-855B CHOW situations.

b. Forwarding to State - The contractor shall not forward a copy of the application to the state until it has received and reviewed the final sales/lease agreement. However, the contractor need not reverify the information on the Form CMS-855 while waiting for the final agreement, even if the data therein may be somewhat outdated by the time the final agreement is received.

c. Failure to Submit - If a final sales/lease agreement is not submitted within 30 days after the contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 30th day to reject the application, the contractor may proceed with rejection regardless of how many times it contacted the new owner or what types of responses (short of the actual receipt of the agreement) were received.

C. Relocation of Entity

A new owner may intend to relocate the provider concurrent with a CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the state via e-mail immediately. If the state believes that this situation has resulted in the effective creation of a new provider, the contractor shall return the application and notify the new owner that a new, initial enrollment application must be submitted. The provider must also notify the state or, if applicable, accreditation agency.

D. Intervening Change of Ownership

In situations where the provider (1) submits a Form CMS-855 initial application or CHOW application and (2) subsequently submits a Form CMS-855 CHOW application before the contractor has finalized the first application, the contractor shall adhere to the following:

Situation 1 – The provider submitted an initial application followed by a CHOW application, and a recommendation for approval to the state has not yet been made for the initial application: The contractor shall return both applications and require the provider to re-submit an initial application with the new owner's information.

Situation 2 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval to the state has not yet been made for the first CHOW application: The contractor shall process both applications – preferably in the order they were received – and shall, if recommendations for approval are warranted, refer both applications to the state in the same package. The accompanying notice/letter to the state shall explain the situation.

Situation 3 - The provider submitted an initial application followed by a CHOW application, and a recommendation for approval of the initial application has been made to the state – The contractor shall:

- Return the CHOW application.

- Notify the state via e-mail that a change of ownership has occurred (the new owner should be identified) and that the contractor will require the new provider to resubmit a new initial application containing the new owner's information.

- Request via letter that the provider submit a new initial Form CMS-855 application containing the new owner's information within 30 days of the date of the letter. If the provider fails to do so, the contractor shall return the originally submitted initial application and notify the provider and the state of this via letter. If the provider submits the requested application, the contractor shall process it as normal and, if a recommendation for approval is made, send the revised application package to the state with an explanation of the situation; the originally submitted initial application becomes moot. If the newly submitted/second initial application is denied, however, the first submitted application is denied as well; the contractor shall notify the provider and the state accordingly.

Situation 4 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval has been made for the first application - The contractor shall:

- Notify the state via e-mail that (1) a subsequent change of ownership has occurred (the new owner should be identified) and (2) the contractor will require the provider to resubmit a new CHOW application containing the subsequent/second new owner's information.

- Process the new/second CHOW application as normal. If a recommendation for approval is made, the contractor shall send the revised CHOW package to the state with an explanation of the situation; the first CHOW application becomes moot. If the newly submitted/second CHOW

application is returned per section 10.6.1.1.3.2 below, the first application should, too, be returned. The contractor shall notify the provider and the state accordingly.

E. Potential CHOW

On occasion, a provider or supplier submits a Form CMS-855 change of information to report a large-scale stock transfer or other significant ownership change that the provider does not believe is (or report as) a CHOW. If the contractor suspects that the transaction in question might indeed be a CHOW, it shall request clarifying information (e.g., copy of the stock transfer agreement).

F. Entry into PECOS - Paper Applications Only

If it appears that the new owner will be accepting assignment and that the transaction falls within the scope of § 489.18, the contractor shall enter the CHOW information into the new enrollment record that shall be created for the new owner. (If the state recommends approval of the CHOW (see section 10.6.1.1.3.3 below), the Part A provider's CCN will be maintained in the new owner's enrollment record once the record is switched to an approved status.)

A new enrollment record must be created if a new TIN is established pursuant to the CHOW.

(For PECOS applications, PECOS will automatically perform the enrollment record activities described in this subsection (F).)

10.6.1.1.3.2 – Step 2 – Post-Initial Review Actions and Scenarios
(Rev. 11125; Issued 11-18-21; Effective: 12-03-21; Implementation: 01-03-22)

After the contractor completes the tasks in section 10.6.1.1.3.1, several results are possible. These are discussed below. Should the contractor encounter a scenario not addressed herein, it may contact its PEOG BFL for guidance. As a reminder, nothing in section 10.6.1.1.3.2 prohibits the contractor from returning or rejecting the application if otherwise permitted to do so per this chapter.

A. Scenarios

1. <u>The contractor ascertains that the transaction falls within the scope of § 489.18 and that the new owner has accepted assignment</u> – If there are no apparent grounds for denying the application (e.g., the new owner has a felony conviction, false information was submitted, a newly reported chief executive officer is excluded), the contractor shall make a recommendation for approval to the state consistent with existing practice and via existing means. (This includes sending recommendations via hard copy mail if the state only accepts this method of transmission.) If a denial ground exists, however, the contractor shall refer the matter to its PEOG BFL for guidance before submission to the state, notwithstanding any other instruction in this chapter to the contrary. The contractor should include an explanation of the ground(s) it believes exists for the denial (including the regulatory citation).

(For Form CMS-855B CHOW applications: Note that an approval recommendation can be made (and must be treated as a CHOW) notwithstanding the general rule that a TIN change constitutes

an initial enrollment; in other words, the reporting rules regarding CHOWs/assignments in this particular situation take precedence over the "change of TIN" principle.)

2. The contractor ascertains that the transaction falls within the scope of § 489.18 but the new owner has not accepted assignment – The contractor shall:
(a) return the application; and (b) notify the new owner in the return letter that it must submit the following within 30 days from the date of the return letter: (i) an initial Form CMS-855 application to enroll as a new provider; and (ii) a voluntary termination application for the existing provider. If the new owner fails to do so within 30 days of the request, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter. PEOG will review the matter and respond to the contractor.

3. The contractor ascertains that the transaction does not fall within the scope of § 489.18 (e.g., stock transfer), regardless of whether the new owner accepted assignment - This qualifies as an ownership change under 42 CFR § 424.516 rather than a CHOW under § 489.18. The contractor shall: (a) return the application; and (b) notify the provider in the return letter that it must submit a Form CMS-855 application to report the ownership change within 30 days of the return letter. If the provider fails to do so, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

(The only exception to the policies in the previous paragraph is if (1) the submission is a Form CMS-855B and (2) the § 424.516 ownership change also involves a change of TIN. In this scenario, the contractor shall: (a) return the application; and (b) notify the supplier in the return letter that it must submit the following within 30 days from the date of the return letter: (i) an initial Form CMS-855B application to enroll as a new supplier; and (ii) a voluntary termination application. If the supplier fails to do so, the contractor shall contact its PEOG BFL the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

B. Referral to State

If the contractor believes that a recommendation for approval per section 10.6.1.1.3.2(A)(1) is warranted, it shall send a recommendation letter to the state (with a copy to the accreditation organization (AO), if applicable). The letter shall follow the format of existing model CHOW recommendation letters in section 10.7 et seq. of this chapter. (Neither the SOG Location nor PEOG need be copied on the letter.) The CHOW package shall: (1) be sent to the state in a manner consistent with existing and past practice; and (2) contain all the applicable documents described in section 10.6.1.1.3.1(A)(iii) above. (For instance, the package must include, among other things, the CMS-377 for ASC and the CMS-3427 for ESRD facilities.)

The state will: (1) review the package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the provider, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the

state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

10.6.1.1.3.3 – Step 3 – Post-State Review Actions and Scenarios
(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

The state will notify the contractor once it has completed the tasks identified in section 10.6.1.1.3.2(B) above (normally within 90 days of receiving the package from the contractor). In general, there are two potential outcomes:

A. Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. The contractor may accept the notification so long as it is in writing (e-mail is fine). No later than 5 business days after receiving this notification, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application or PECOS Application Data Report; (2) a copy of the final sales/transfer agreement; and (3) a copy of the Form CMS-1539 or similar documentation received from the state. PEOG will review the matter, perform any administrative functions, and respond to the contractor with applicable direction.

B. Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a tie-in or tie-out notice, neither of which are issued any longer for CHOWs.)

No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application (or PECOS Application Data Report) and all application attachments; (2) a copy of the final sales/transfer agreement; (3) a copy of the Form CMS-1539 or similar documentation received from the state; (4) a copy of the provider-signed Form CMS-1561/1561A/370 (as applicable); (5) a copy of the Form HHS-690; and (6) a copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. PEOG will countersign the provider agreement, assign an effective date of the CHOW based on the information received from the contractor, and approve the draft letter (with possible edits).

Within 5 business days of receiving from PEOG the signed provider agreement and effective date, the contractor shall: (1) send the CHOW approval letter and a copy of the CMS-countersigned provider agreement to the provider (with a copy to the AO, if applicable); and (2) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

10.6.1.1.4 – Additional CHOW Processing Policies
(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

Except as otherwise stated, the instructions in this section 10.6.1.1.4 apply to the Form CMS-855A and Form CMS-855B.

A. Payment Changes - In a CHOW, the contractor shall continue to pay the old owner until it receives from PEOG the e-mail, effective date, and signed provider agreement referenced in Section 10.6.1.1.3.3(B). Hence, any application from the old owner or new owner to change the EFT account or special payment address to that of the new owner shall be returned. It is ultimately the responsibility of the old and new owners to coordinate any payment arrangements between themselves while the contractor and the state are reviewing the CHOW. It is recommended that the contractor notify the new owner of this while processing the application.

B. National Provider Identifiers (NPI) - Depending on the sale's terms, the new owner may obtain a new NPI or maintain the existing NPI. Once CHOW processing is complete, the old owner is prohibited from billing for services (i.e., services furnished after CHOW processing is complete); only the new owner may submit claims using the existing CCN. As already stated, the old owner and new owner must arrange between themselves any payment matters regarding claims for services furnished during the CHOW processing period.

C. CHOW Pre-Approval Changes of Information

1. Old Owner

If – prior to receiving an approval recommendation from the state -– the contractor receives from the old owner a Form CMS-855 request to change any of the provider's enrollment data, the contractor shall return the change request if the information involves changing the provider's:

i. EFT or special payment address information to that of the new owner (as described in section 10.6.1.1.4(A) above);

ii. Practice location or base of operations to that of the new owner;

iii. Ownership or managing control to that of the new owner;

iv. Legal business name, TIN, or "doing business as" name to that of the new owner.

All other "pre-state recommendation" Form CMS-855 change requests from the old owner can be processed normally.

2. New Owner

If – prior to receiving an approval recommendation from the state - the contractor receives from the new owner a Form CMS-855 request to change any of the provider/supplier's existing enrollment information, the contractor shall return the change request. This is because the old owner remains the owner of record at this time; the new owner therefore has no standing to submit Form CMS-855 changes on behalf of the provider.

D. Change of Transaction Type in PECOS - There may be instances where the contractor enters a transaction into PECOS as a CHOW, but it turns out that the transaction was not a CHOW (e.g., was a stock transfer; was an initial enrollment because the new owner refused to accept assignment). If the contractor cannot change the transaction type in PECOS, it can leave the record in a CHOW status; however, it should note in PECOS that the transaction was not a CHOW.

E. Unreported CHOW - If the contractor learns via any means (including from the state or SOG Location) that an enrolled provider has been purchased by another entity or has purchased another Medicare-enrolled provider, the contractor shall immediately request Form CMS-855A CHOW applications from both the previous and new owners (or request a Form CMS-855B CHOW application from the ASC or PXRS). If the new owner fails to submit a Form CMS-855 within the latter of (1) the date of acquisition or (2) 30 days after the request, the contractor shall send an e-mail to its PEOG BFL notifying him/her of the situation. PEOG will determine whether the provider's billing privileges should be deactivated under § 424.540(a)(2) or § 424.550(b) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.

F. Precise Time of CHOW - In general, a Medicare CHOW is considered to have taken place at 12:01 a.m. on the date specified (i.e., in the first minute of the 24-hour day). Legal responsibility and the right to payment changes when the clock moves past midnight into the CHOW effective date.

G. Termination of CCN - If the new owner rejects assignment, the CCN associated with that agreement (the old owner's) also terminates on the date of the ownership transfer.

H. Clock Stoppages and Processing Alternatives - While awaiting PEOG's reply on any matter in this section 10.6.1.1 et seq. in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.1 et seq. negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.1 et seq.

10.6.1.1.5 – HHA and Hospice Ownership Changes

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

A. Background – 36-Month Rule

1. General Principles

In accordance with 42 CFR § 424.550(b)(1), if there is a change in majority ownership of an HHA or hospice by sale (including asset sales, stock transfers, mergers, and consolidations)

within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA or hospice must instead:

- Enroll in the Medicare program as a new (initial) HHA or hospice under the provisions of § 424.510, and

- Obtain a state survey or an accreditation from an approved accreditation organization.

For purposes of § 424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR § 424.502) occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA's or hospice's initial enrollment into the Medicare program or the 36 months following the HHA's or hospice's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA or hospice through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's or hospice's most recent change in majority ownership.

2. Exceptions

There are several exceptions to § 424.550(b)(1). Specifically, the requirements of § 424.550(b)(1) do not apply if:

- The HHA or hospice has submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)

- The HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The HHA or hospice is changing its existing business structure – such as from a corporation, a partnership (general or limited), or a limited liability company (LLC) to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- An individual owner of the HHA or hospice dies.

In addition, § 424.550(b)(1) does not apply to "indirect" ownership changes. For purposes of the 36-month rule's application, an indirect owner is a party that owns a direct or indirect owner of the provider. Consider the following illustrations:

EXAMPLE 1: Smith Hospice is established as a corporation. It is listed as the provider in Section 2 of the Form CMS-855A. The corporation has four shareholders (W, X, Y, and Z), each of which own 25% of Smith. Since Smith is the enrolling provider and W, X, Y, Z own Smith's stock, W, X, Y, and Z are considered direct owners of Smith. Thus, if W, X, and Y sell

their 25% shares to Jones, Jones now directly owns 75% of Smith. A change in majority enrollment under § 424.550(b)(1) has occurred.

EXAMPLE 2: Smith Hospice is established as an LLC. It is listed as the provider in Section 2 of the Form CMS-855A. The corporation has two owners, Company X and Company Y. X owns 80% of Smith, and Y owns 20%. X and Y are accordingly direct owners of Smith. Company Z owns 100% of X, making Z an indirect owner of Smith. Now suppose that Company V purchases Z in its entirety. Since the transaction involves a sale of one of Smith indirect owners, § 424.550(b)(1) is not invoked.

To the extent this previously occurred, hospices and HHAs should not assume that – using the above examples: (1) the corporation is the direct owner of Smith; (2) W, X, Y, and Z were therefore merely indirect owners of Smith; and (3) the sale of W/X/Y's shares to Jones is an indirect ownership change that does not trigger the 36-month rule. To the contrary, the corporation – as Smith Hospice – IS the provider, hence making W/X/Y/Z direct owners of Smith.

3. Timing of 36-Month Period for Hospices

The provisions of 42 CFR § 424.550(b)(1) and (2) with respect to hospices (as enacted in "CMS-1780-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2024") became effective January 1, 2024. This means these provisions impact only those hospice ownership transactions whose effective date is on or after January 1, 2024. However, the provisions can apply irrespective of when the hospice first enrolled in Medicare. Consider the following illustrations:

- Example 1 – Smith Hospice initially enrolled in Medicare effective February 1, 2022. Smith undergoes a change in majority ownership effective February 1, 2024. The provisions of § 424.550(b)(1) apply to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.

- Example 2 – Jones Hospice initially enrolled in Medicare effective February 1, 2016. Jones undergoes its first change in majority ownership effective February 1, 2024. Section 424.550(b)(1) does not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, that Jones undergoes another change in majority ownership effective February 1, 2025. Section 424.550(b)(1) applies to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2024).

- Example 3 – Davis HHA initially enrolled in Medicare effective February 1, 2012. It underwent its first change in majority ownership effective February 1, 2016. This change was not affected by § 424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis underwent another change in majority ownership effective February 1, 2023. This change, too, was unaffected by § 424.550(b)(1), for it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on February 1, 2016). Davis underwent another majority ownership change on February 1, 2025. This

change is impacted by § 424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on February 1, 2023).

B. Determining the 36-Month Rule's Applicability

If the contractor receives a Form CMS-855A application reporting an HHA or hospice ownership change (and unless a CMS instruction or directive states otherwise), it shall undertake the following steps:

Step 1 – Change in Majority Ownership

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and

- The change involves a party assuming a greater than 50 percent ownership interest in the HHA or hospice.

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of three ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA or hospice, this would constitute a change in majority ownership. This is consistent with the verbiage in the above-mentioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc. Another example of a change in majority ownership would be if a 50 percent owner obtains any additional amount of ownership (regardless of the percentage) and hence becomes a majority owner; thus, for instance, if a 50 percent owner were to acquire an additional .001 percent ownership stake, he or she becomes a majority owner and the transaction involves a change in majority ownership.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally (which will typically be as a change of information under 42 CFR § 424.516(e)). If it does qualify, the contractor shall proceed to Step 2:

Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's or hospice's (1) initial enrollment in Medicare or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA or hospice – regarding the effective date of the HHA's or hospice's most recent change in majority ownership, if applicable.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.

If the transfer's effective date falls within one of these 36-month timeframes, the contractor shall proceed to Step 3.

Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall determine whether any of the exceptions in § 424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

i. The HHA or hospice has submitted 2 consecutive years of full cost reports.

(A) For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. (See 42 CFR § 413.24(h) for a definition of low Medicare utilization.)

(B) The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer; and (2) accepted by the contractor.

ii. The HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

iii. The HHA or hospice is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

(A) If the HHA or hospice is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its PEOG Business Function Lead (BFL) for guidance.

(B) For the exemption to apply, the owners must remain the same.

iv. An individual owner of the HHA or hospice dies – regardless of the percentage of ownership the person had in the HHA or hospice.

Step 4 - Determination

If the contractor concludes that one of the aforementioned exceptions applies (and unless a CMS instruction or directive states otherwise), it may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) (via the instructions in section 10.6.1.2 of this chapter) or as a potential change of ownership under 42 CFR § 489.18 (via the instructions in section 10.6.1.1 of this chapter).

If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor apply the 36-month rule to the HHA or hospice and require an initial enrollment based thereon without the prior approval of PEOG. If PEOG agrees with the contractor's determination:

(1) PEOG will terminate the seller in ASPEN.

(2) The contractor shall identify the voluntary termination action in PECOS as a deactivation ---- and hence shall deactivate the HHA's or hospice's billing privileges pursuant to § 424.540(a)(8) --- with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per § 424.540(d)(1)(ii)(E), the effective date of the deactivation shall be the date of the sale.

(3) The contractor shall send to the HHA or hospice the "36-Month Rule Voluntary Termination Letter" in section 10.7.5.1. This letter will include, among other things, rebuttal rights regarding the deactivation as well as language stating that, as a result of § 424.550(b)(1), the HHA or hospice must:

- Enroll as an initial applicant; and

- Obtain a new state survey or accreditation survey after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the state.

(In preparing this letter, the contractor may, if applicable to the situation, change any reference therein to "HHA" or "home health agency" to "hospice.")

(4) The HHA or hospice need not submit a Form CMS-855A voluntary termination application.

Providers and/or their representatives (e.g., attorneys, consultants) shall contact their local MAC with any questions concerning (1) the 36-month rule in general and (2) whether the rule and/or its exceptions apply in a particular provider's case.

C. Additional Notes

The contractor is advised of the following:

1. If the contractor learns of an HHA or hospice ownership change by means other than the submission of a Form CMS-855A application, it shall notify its PEOG BFL immediately.

2. If the contractor determines, under Step 3 above, that one of the § 424.550(b)(2) exceptions is applicable, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It underwent a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from § 424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA underwent another change in majority ownership that did not qualify for an exception. The HHA thus had to enroll as a new HHA under § 424.550(b)(1) because the transaction occurred within 36

months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from § 424.550(b)(1).

10.6.1.2 – Changes of Information – Transitioned Certified Providers and Suppliers

(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

(Until further notice from CMS, the instructions in this section 10.6.1.2 apply only to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, FQHCs, Part A OPT/OSP providers, ASCs, PXRSs, hospitals, hospices, and ESRD facilities. The contractor shall continue to use the existing change of information instructions--now in section 10.6.22.1 of this chapter--for all non-transitioned certified provider/supplier types.

When executing the instructions in this section 10.6.1.2, the contractor can disregard directives that obviously do not apply to the transitioned provider/supplier type in question (e.g., references to hospitals).

All references to the SOG Location (formerly the "RO") in this section 10.6.1.2 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

The instructions in this section 10.6.1.2 address the handling of changes of information involving certified providers and certified suppliers. With the transition of certain functions from the SOG Locations to the contractors and the Provider Enrollment & Oversight Group (PEOG), the processing instructions for these changes of information are slightly different from previous guidance. In particular: (1) the SOG Locations will be much less involved in the process; (2) tie-in and tie-out notices will no longer be issued; (3) the contractor will be responsible for finalizing changes previously requiring SOG Location approval; and (4) recommendations of approval will be made to (and reviewed by) the state agency (hereafter occasionally referenced simply as "state") only and not the SOG Location.

Except as stated otherwise:

(1) Any provider-specific instructions in section 10.2.1 et seq. of this chapter pertaining to changes of information (e.g., relocation of a federally qualified health clinic site; addition or deletion of an OPT/OSP extension site) take precedence over those in this section 10.6.1.2.

(2) Any instructions pertaining to ownership changes in section 10.6.1.1 et seq. of this chapter take precedence over those in this section 10.6.1.2.

(3) Any instructions pertaining to voluntary terminations of entire enrollments and/or provider agreements in section 10.6.1.3 of this chapter take precedence over those in this section 10.6.1.2.

(4) Any instructions in this section 10.6.1.2 concerning the voluntary termination of a branch, sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.1.2 when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Changes of Information Requiring Recommendation to the State

1. Types

The following Form CMS-855 transactions require an approval recommendation to (and review by) the state prior to approval:

- Addition or relocation/change of outpatient physical therapy/outpatient speech pathology extension site
- Addition of HHA branch
- Addition or deletion of a prospective payment system (PPS)-excluded psychiatric unit, rehabilitation unit, or transplant program.
- Addition or deletion of swing-bed approval (see Section 2A2 of the Form CMS-855A)
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Addition, deletion, or relocation of a hospice practice location
- Addition, change, and/or relocation of a hospital practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)
- Addition of PXRS practice location

2. Initial Contractor Review and Recommendation

The contractor shall process the change request consistent with the instructions in this chapter (e.g., verification of data, developing for missing or conflicting data). If the contractor determines that the change/addition should be approved, it shall send the appropriate recommendation letter (see section 10.7 et seq.) to the state with all applicable documentation

that the contractor currently sends in such situations. The SOG Location need not be copied on the letter.

Nothing in this section 10.6.1.2(A)(2):

- Prohibits the contractor from returning or rejecting the application if grounds for doing so exist.
- Supersedes any applicable requirement for performing a site visit (including the timing of such visits).

3. State Review and Contractor Receipt of Recommendation

The state will review the recommendation of approval, the application, and any other pertinent information. If the state decides to perform a survey, it will do so and notify the contractor thereof.

a. State Recommends Approval

If the state concludes that the change/addition should be approved, it will make a recommendation to this effect to the contractor, typically via a Form CMS-1539 and/or similar confirming documentation. No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov containing general identifying data about the provider (including LBN, NPI, CCN, specialty, facility name and address), a copy of the Form CMS-1539 (or other similar documentation evidencing the state's approval recommendation, if available), the draft provider approval letter, and a description of the change to be made. If, to the contractor's knowledge, a new CCN is required, the name and address of the new entity requiring the CCN should be furnished along with the effective date. If a termination is involved (e.g., HHA branch), the contractor shall include the old CCN and the termination date in the e-mail.

Once PEOG responds to the contractor, the latter may finalize its processing of the application (e.g., sending copies of the provider notification of approval to the state and, if applicable, accrediting organization; switching the PECOS record from "approval recommended" to "approved").

b. State Does Not Recommend Approval

If the state does not recommend approval, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov for guidance. The e-mail to him/her shall contain (1) the identifying data described in (3)(a) above; (2) a copy of the notification from the state declining to recommend approval; and (3) any other information the contractor deems pertinent. PEOG will review the matter and furnish the contractor additional instructions, which the contractor shall follow.

4. Additional Policies

a. Post-Recommendation Inquiries - Once the contractor has made its recommendation for approval to the state, any inquiry the contractor receives from the provider regarding the status of its change request shall be referred to the state.

b. Pending State Recommendation - So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive the state's recommendation after 120 days, it may contact the state to see if its recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to ascertain the recommendation's status.

c. State Practice - The PECOS record should not be switched to "Approved" until the contractor receives the state's approval recommendation. However, if the contractor knows that the state in question generally does not review this type of transaction, the contractor need not send the transaction to the state and shall instead follow the instructions in section 10.6.1.2(B) below.

B. Post-Approval State Notification Required

Form CMS-855 changes that do not mandate a recommendation to the state but do require post-approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) include:

- Except as described in section 10.6.1.2(A), deletions/voluntary terminations of practice locations or hospital subunits. (Note that this scenario is different from cases where the provider is voluntary terminating its enrollment as a whole (per section 10.6.1.3 of this chapter) rather than simply terminating a single location or subunit within its enrollment.)

- LBN, TIN, or "doing business as name" changes that do not involve a CHOW.

- Except as described in section 10.6.1.2(A), address changes that generally do not require a survey of the new location.

- Addition, change, and/or relocation of a hospital practice location (including physician/practitioner group practice locations) for which a survey is not required.

- Deletion of an OPT/OSP extension site or practice location.

- Ownership changes that involve neither a 42 CFR § 489.18 CHOW nor a § 424.550(b) exempt or non-exempt change in HHA majority ownership (e.g., a 15 percent owner of a hospice sells her ownership stake).

The contractor shall:

(1) Inform PEOG, the state, and the AO (if appropriate) of the changed information (via any mechanism it chooses, including copying PEOG/state/AO on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction. Such notice to the PEOG/state/AO shall specify the type of information that is changing. (Prior

PEOG approval of the change is not required, though PEOG will update applicable national database as needed.)

(2) Switch the PECOS record to "Approved."

C. All Other Changes of Information

1. General Principle

For all Form CMS-855 change requests not identified in section 10.6.1.2(A)(1) and (B) above (and except as stated in subsection (C)(2) below), the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made; and (2) switch the PECOS record to "Approved." The contractor need not notify the state, SOG Location, or PEOG of the change.

2. FQHCs

If an FQHC is adding, deleting, or changing a Section 13 contact person , the contractor shall send an approval letter via e-mail and copy the MedicareProviderEnrollment@cms.hhs.gov mailbox (with "FQHC COI" in the subject line) thereon. (Aside from this exception, all other instructions in subsection (C)(1) apply to this scenario.) See section 10.2.1.4(D) of this chapter for more information on FQHC changes of information.

D. Revalidations, Reactivations, and Complete Form CMS-855 Applications

1. When Referral Required - In situations where the provider submits a (1) Form CMS-855 reactivation, (2) Form CMS-855 revalidation, or (3) full Form CMS-855 as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in section 10.6.1.2(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855, the contractor shall make a recommendation to the state and await the state's approval recommendation before switching the record to "Approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state needs to consider is the new hospital unit.

2. No Referral Required - If the application contains new/changed data falling within one of the categories in section 10.6.1.2(B), the contractor can switch the PECOS record to "Approved." It shall also inform the state of the changed information (via any mechanism it chooses, including copying the state on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction.

E. Unsolicited Notifications from State

If the contractor receives notice of a provider's change of information from the state but the provider never submitted the required Form CMS-855 change request to the contractor, the contractor shall: (1) alert the state of the situation; and (2) contact the provider and have it

complete and submit the change request. However, if the data in question is not collected on the Form CMS-855, the contractor need not make this request.

F. Special ESRD Instructions

Notwithstanding any other contrary instruction in this chapter, if an ESRD change of information application results in the issuance of a new or additional CCN, the contractor shall copy the ESRD Network on the approval letter it sends to the provider. The contact information for the ESRD Network can be found at https://esrdnetworks.org/membership/esrd-networks-contact-information/.

G. Clock Stoppages and Processing Alternatives

While awaiting PEOG's reply on any matter in this section 10.6.1.2 in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.2 negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.2.

10.6.1.3 – Voluntary Terminations

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

The CMS Provider Enrollment & Oversight Group (PEOG) and Medicare Administrative Contractors have assumed a number of enrollment-related functions previously handled by state agencies (hereafter occasionally referenced as "state") and CMS Survey & Operations Group Locations (SOG Locations) concerning certified provider and certified supplier voluntary terminations. This section 10.6.1.3 instructs the contractor on how to process such transactions. Unless stated otherwise, these instructions take precedence over those in section 10.4.3 of this chapter.

Except as stated otherwise in this chapter, this section does not apply to voluntary terminations pursuant to an HHA change in majority ownership under § 424.550(b)(1). Instructions concerning the handling of these transactions are in section 10.2.1.6.1 of this chapter.

A. Background

Consistent with the principles of 42 CFR § 489.52(a) (and except as otherwise required), a certified provider/supplier that wishes to terminate its agreement with Medicare must send written notice of its intention to the SOG Location, the state agency, or the contractor within the timeframes addressed in § 489.52. Under CMS Publication (Pub.) 100-07, chapter 2, section 2005F, the notice is a letter on letterhead with an authorized signature.

Submission of a Form CMS-855 voluntary termination application is not mandatory but is highly preferred. Providers and suppliers are encouraged to continue to submit this form.

Section 10.6.1.3(B) below discusses various scenarios that the contractor may encounter in processing certified provider/supplier voluntary terminations. These should be reviewed and considered in conjunction with the policies in section 10.6.1.3(C) below, particularly those in subsections (C)(2), (C)(3), (C)(6), and (C)(7).

B. Situations and Scenarios

1. Termination Reported to Contractor Via Form CMS-855 or Letter with No Prior Notice from State Agency or SOG Location

If the contractor receives a Form CMS-855 voluntary termination application or a voluntary termination letter (but not both) directly from a certified provider/supplier without having received any termination notification from the state/SOG Location, the following apply:

(i) The contractor shall: (a) process the application/letter consistent with the timeframes for voluntary terminations in section 10.4.3 of this chapter; and (b) as applicable, follow the instructions in section 10.6.1.3(C) below.

(NOTE: If the application/letter is from a skilled nursing facility (SNF), the contractor shall contact the state agency to determine whether the SNF complies with the requirements of 42 CFR §§ 483.15(c)(8) and 483.70(l). These two provisions address the SNF's required notice to the state of an impending closure and patient safety. If the state indicates that the SNF is not compliant, the contractor shall contact its PEOG Business Function Lead (BFL) for guidance; if compliance is confirmed, the contractor can proceed as normal.)

(ii) Prior to finalizing its processing of the Form CMS-855 or letter submission, the contractor shall e-mail a copy of the draft approval letter (see the applicable model letter in section 10.7.5.1) containing the appropriate termination effective date, reason for termination, and source of the termination notice (i.e., Form CMS-855 or letter) to PEOG at MedicareProviderEnrollment@cms.hhs.gov, with "S&C Voluntary Termination" in the e-mail's subject line.

(iii) PEOG will update the Automated Survey Process Environment (ASPEN) system, notify the contractor thereof, and, if the provider/supplier is deemed, provide the contractor the name and e-mail address of the applicable accreditation organization (AO).

(iv) Within 3 business days of receiving of the aforementioned notice from PEOG, the contractor shall: (1) e-mail a copy of the final signed approval letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed); and (2) deactivate the provider/supplier in the Provider Enrollment, Chain and Ownership System (PECOS) pursuant to the instructions/guidance in section 10.6.1.3(C)(9) below.

2. Termination Reported to Contractor Via Form CMS-855 and Letter with No Prior Notice from State Agency or SOG Location

If the contractor receives a Form CMS-855 voluntary termination application and a voluntary termination letter directly from a certified provider/supplier without having received any termination notification from the state/SOG Location, the following apply:

(i) If the Form CMS-855 and letter arrive either simultaneously or before the contractor begins processing one of them, the contractor has the discretion to determine which submission to process unless a Form CMS-855 was submitted via PECOS; in this latter case, the contractor shall process the Form CMS-855 rather than the letter. It need not process both of them; the submission that the contractor does not process may be returned (consistent with the instructions in this chapter) or placed in the provider/supplier file, and the contractor need take no further action thereon.

(ii) If the contractor receives both submissions and it has begun processing one of them, the contractor shall continue processing that document. The contractor can return the other submission (consistent with the instructions in this chapter) or place it in the provider/supplier file; no further action thereon is required.

(iii) Regardless of whether (2)(i) or (ii) applies, the contractor shall process the submission consistent with the instructions in section 10.6.1.3(B)(1) above.

3. Notice of Voluntary Termination Received from State Agency and/or SOG Location without the Contractor Having Received a Form CMS-855 or Letter Directly From the Provider/Supplier

Although many voluntary termination submissions from certified providers/suppliers are via the Form CMS-855, there are occasions where the provider/supplier will only notify the state agency and/or SOG Location. The contractor will typically learn of this when it receives a Form CMS-1539 ("Medicare/Medicaid Certification and Transmittal") and/or other written notification from the state/SOG Location. (The state uses the Form CMS-1539 to communicate findings to the SOG Location with respect to a facility's compliance with health and safety requirements.) In such situations, the following apply:

(i) The contractor may accept from the state/SOG Location written documentation other than the Form CMS-1539. This includes, for example, a Form CMS-2007 or even a voluntary termination letter of the type described in sections 10.6.1.3(B)(1) and (B)(2) above; indeed, the provider/supplier sometimes sends its termination letter directly to the state/SOG Location and the latter simply forwards it to the contractor.

If the contractor has questions concerning said documentation, it shall contact the state/SOG Location for clarification. (This could include situations when it is unclear: (1) whether a termination is involved; (2) which provider/supplier is to be terminated; or (3) if the state forwards to the contractor a termination request that the state received from the provider, whether the state considers it to be a valid termination request.).

(ii) Upon receipt of the Form CMS-1539 (or other/additional state/SOG Location document), the contractor need not develop with the provider/supplier for a Form CMS-855A/B voluntary termination application or a letter. Instead:

(A) The contractor shall abide by the applicable instructions in section 10.6.1.3(C) below (e.g., section (C)(6) regarding effective dates; section (C)(7) concerning cessations of business). If the notice from the state was a voluntary termination letter from the provider/supplier (as described in section 10.6.1.3(B)(3)(i) above), the contractor shall pay particular attention to the instructions in section 10.6.1.3(C)(3) below.

(B) The contractor shall e-mail a copy of the draft approval letter (see section 10.7.5.1 of this chapter) containing the appropriate termination effective date, reason for termination, and source of the termination notice to MedicareProviderEnrollment@cms.hhs.gov, with "S&C Voluntary Termination" in the subject line.

(C) PEOG will update ASPEN, notify the contractor thereof, and, if the provider/supplier is deemed, provide the contractor the name and e-mail address of the applicable AO.

(D) Within 3 business days of receiving of the aforementioned notice from PEOG, the contractor shall: (1) e-mail a copy of the final signed letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed); and (2) deactivate the provider/supplier in PECOS pursuant to the instructions/guidance in section 10.6.1.3(C)(9)) below.

4. Notification of Termination Received from the State Agency and/or SOG Location and Directly from the Provider/Supplier Via the Form CMS-855 and/or Letter

The contractor shall adhere to the instructions in this section (B)(4) in the following situations:

(i) **The contractor receives notification of termination (i.e., via Form CMS-1539 or other documentation) from the state/SOG Location after the provider/supplier has been deactivated in PECOS pursuant to the latter's Form CMS-855/letter voluntary termination submission** - Within 10 calendar days of receiving the state/SOG Location notification, the contractor shall inform the state/SOG Location via e-mail that the provider/supplier has already been deactivated in PECOS and terminated in ASPEN. No further action by the contractor is necessary.

(ii) **The contractor receives notification of termination from the state/SOG Location while the contractor is processing a Form CMS-855/letter voluntary termination submission but before the provider/supplier has been deactivated in PECOS** – The contractor shall: (i) continue processing the application/letter normally and to completion, consistent with the instructions in this section 10.6.1.3; and (ii) e-mail a copy of the final signed letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed) after the provider/supplier has been deactivated in PECOS.

(iii) **The contractor receives notification of termination (i.e., via Form CMS-1539 or other documentation) from the state/SOG Location before the contractor received or began processing the provider's/supplier's Form CMS-855/letter voluntary termination submission** – The contractor:

(A) Shall follow the instructions in section 10.6.1.3(B)(3) above

(B) Need not contact the provider/supplier about its Form CMS-855/letter submission prior to the completion of all of the steps in section 10.6.1.3(B)(3)(ii) above

(C) Either in the termination approval letter (which the contractor may modify for the purpose) sent to the provider/supplier or via a simultaneous or separate e-mail to the provider/supplier, the contractor shall notify the provider/supplier that its submission to the contractor was not processed due to the provider/supplier's prior notification to the state/SOG Location. (If this communication is sent separately from the approval letter or the e-mail containing the letter, the contractor shall send the separate e-mail no later than 10 calendar days after sending the letter.)

(iv) The contractor receives notification of termination from the state/SOG Location and a separate voluntary termination Form CMS-855/letter from the provider/supplier without having begun the processing of either – The contractor has the discretion to determine which submission to process unless a Form CMS-855 was submitted via PECOS; in this latter case, the contractor shall process the Form CMS-855. It need not process both of them; the submission that the contractor does not process may be returned (consistent with the instructions in this chapter) or placed in the provider/supplier file, and the contractor need take no further action thereon.

C. Additional Certified Provider/Supplier Voluntary Termination Policies

1. Completion of Form CMS-1539 – The state completes the Form CMS-1539. In Part II thereof, the following fields contain: (i) 26-Termination Action "00"; Code for a voluntary termination; and (ii) 28 –Termination Date; this is the effective date of the voluntary termination.

2. Required Contents of Voluntary Termination Letter Received Directly from Provider/Supplier – If the contractor is processing a voluntary termination letter it received directly from the provider/supplier (as opposed to receiving it from the state/SOG Location), the contractor shall ensure that the letter:

- Is on the provider/supplier's letterhead
- Contains the provider/supplier's legal business name, NPI, and CMS Certification Number (CCN)
- States with sufficient clarity (in the contractor's judgment) that the provider/supplier wishes to terminate its Medicare provider/supplier agreement and/or enrollment. (No exact, uniform, standard language from the provider/supplier is necessary; the letter must merely furnish adequate notice of the provider/supplier's intentions).
- Is signed and dated by an authorized representative of the provider/supplier. This person need not be on file as an authorized or delegated official of the provider/supplier. The contractor shall accept the person's signature if it has no reason to suspect that he/she lacks the authority to act on the provider/supplier's behalf. If it has doubts, however, it may contact its PEOG for guidance.

(The applicable regulations do not require that the letter contain the termination effective date or the reason for the termination. For purposes of ascertaining the effective date and reason, the contractor shall follow the instructions in section 10.1.3(C)(6).)

If the letter does not meet all of the above requirements, the contractor shall develop with the provider/supplier for the missing or deficient information. Development shall be consistent with the general developmental instructions in this chapter (e.g., 30 days for provider/supplier to respond) except as follows:

- The contractor may develop for the missing or clarifying information via any means, even by telephone. No application development letter is required.
- Except as stated in sections 10.6.1.3(C)(3) and (C)(6) below, all missing or clarifying data must be furnished via a new letter signed by an authorized representative (who need not be the same person who signed the original letter).

If the provider/supplier fails to respond fully and completely to the aforementioned request within the required timeframe, the contractor shall contact its PEOG BFL for guidance and include a copy of the initial provider/supplier letter in the e-mail to PEOG.

(See section 10.6.1.3(C)(3) below for instances where the guidance in this section 10.6.1.3(C)(2) may apply to voluntary termination letters submitted to the state/SOG Location rather than to the contractor.)

1. Provider/Supplier's Voluntary Termination Letter Received Directly from the state/SOG Location Without the Contractor Having Received a Termination Notification from the Provider/Supplier – As explained in section 10.6.1.3(B)(3) above, the contractor may receive a provider/supplier's voluntary termination letter directly from the state/SOG Location without having received any termination notification (i.e., letter or Form CMS-855) from the provider/supplier. If the contractor encounters this situation, the contractor shall adhere to the following:

(i) Provider/Supplier Voluntary Termination Letter Received from State/SOG Location Without Other Confirming Documentation - If the letter is unaccompanied by a Form CMS-1539 or other documentation signifying that the state/SOG Location (1) considers the termination letter as valid or (2) otherwise accepts the termination request, the contractor shall contact the state via e-mail for clarification on these issues. If the state indicates that it considers the provider/supplier as having terminated its provider/supplier agreement, the contractor shall process the termination consistent with the instructions in section 10.6.1.3(B)(3); any missing or unclear information (e.g., reason for the termination, effective date, CCN) shall be obtained from the state and/or SOG Location. If the state is merely forwarding the provider/supplier letter to the contractor for processing without making any determination as to whether the termination is valid, the contractor shall process the letter consistent with the instructions in section 10.6.1.3(B)(1) and (C)(2).

(ii) Provider/Supplier Voluntary Termination Letter Received from State/SOG Location With Additional Documentation Confirming that the State Considers the Provider/Supplier As Having Terminated Its Agreement - The contractor shall process the termination consistent with the instructions in section 10.6.1.3(B)(3).

4. Tie-Out Notices – SOG Locations no longer issue tie-out notices (Form CMS-2007) for voluntary terminations.

5. Special Payments - Upon receipt of a Form CMS-855 voluntary termination application or a voluntary termination letter directly from the provider/supplier per the instructions in this section 10.6.1.3, the contractor may (but is not required to) ask the provider/supplier to complete or update the "Special Payments" portion of Section 4 of the Form CMS-855 so that future payments can be sent thereto. If the provider/supplier is adding a special payment address, it should be included in the same transaction as the voluntary termination action (i.e., one transaction incorporating both items). If the provider/supplier is changing its existing special payments address, the transaction constitutes a separate change request (i.e., one termination and one change request). The provider/supplier is not required to submit a Form CMS-588 in conjunction with a termination.

6. Termination Effective Dates and Termination Reasons – As noted previously, § 489.52(b) outlines the applicable effective dates for voluntary terminations. The contractor shall adhere to the following instructions regarding these dates as well as certain situations pertaining to termination reasons:

(i) The contractor receives a Form CMS-855 or voluntary termination letter per section 10.6.1.3(B)(1) or (B)(2) (i.e., the contractor receives a termination submission from the provider/supplier before receiving notification from the state/SOG Location):

(A) If the provider/supplier's submission is missing either the effective date of termination or the reason for the termination (or if either data element is not sufficiently clear to the contractor), the contractor shall develop with the provider/supplier for the missing/unclear data. The contractor may develop for the information via any means, even by telephone; no development letter is required. The provider/supplier must furnish the data via e-mail or other written format, but a new letter is not required. If the provider/supplier fails to submit the requested data within 30 days, the contractor shall contact its PEOG BFL for guidance. If the provider/supplier submits the data, the following effective dates apply:

(1) The termination reason is that the provider/supplier has ceased business (which includes non-operational status) – The termination effective date in ASPEN is that on which the provider/supplier stopped providing services to the community. (See section 10.6.1.3(C)(6)(i)(C) below for additional instructions concerning cessations of business.)

(2) The termination reason does not involve a cessation of business or non-operational status (e.g., the provider simply wishes to depart Medicare without closing its business; the provider elects not to renew its state license) – The contractor shall include on the draft approval letter the termination effective date the provider/supplier furnished. However, the contractor shall include in its e-mail to PEOG (see section 10.6.1.3(B)(1)(ii) above) notification as to whether this effective date is less than 6 months from the date on which the contractor first received the provider/supplier's Form CMS-855/letter. If it is less than 6 months, PEOG will determine whether this termination effective date is acceptable.

(B) If the provider/supplier's initial submission contains the termination effective date and reason, and no development on these issues is needed, the contractor shall proceed as instructed per, as applicable, sections 10.6.1.3(B)(1), (B)(2), and (C)(6)(i)(A) above.

(C) In cases where a cessation of business (including non-operational status) is involved, a retroactive termination effective date is permissible if there were no Medicare beneficiaries receiving services from the facility on or after the requested termination date. The contractor shall confirm this via a claims review prior to forwarding the e-mail and approval letter to PEOG per section 10.6.1.3(B)(1)(ii). If claims were submitted, the contractor shall contact the provider/supplier via e-mail to confirm that services were indeed rendered and adjust the termination date with the provider/supplier; if no adjustment is made or contact cannot be made, an overpayment request must be issued.

(ii) The contractor is processing a Form CMS-1539 or other documentation received from the state/SOG Location other than the provider/supplier's voluntary termination letter – The contractor shall use the termination date listed on the Form CMS-1539 or other documentation as the termination effective date, even if a subsequent submission from the provider/supplier (e.g., Form CMS-855) uses a different date. If no termination date is listed on the submission from the state/SOG Location, the contractor shall contact the state agency for guidance.

Except as otherwise stated in this section 10.6.1.3 or unless directed otherwise by PEOG, the contractor: (1) shall use/apply the termination effective date listed on whichever submission it is processing (e.g., the contractor is processing the provider's Form CMS-855 voluntary termination application before receiving any documentation from the state); and (2) need not alter this termination effective date based on a subsequent submission from provider/supplier or the state/SOG Location.

7. State Agency Performs Survey Based on Cessation of Business

(i) Solicitation of Information

Situations may arise where the state (i) performs a survey of a certified provider/supplier based on a compliant or a cessation of business and (ii) finds that the provider/supplier is no longer operational and/or has vacated the practice location. The state will notify the contractor of its findings via the Form CMS-1539 or other documentation. Upon receipt of this documentation, the contractor shall send to the provider/supplier the applicable notice in section 10.7.2 of this chapter requesting that the provider/supplier: (1) provide evidence to the contractor (with a copy to the state) that it is still operational; (2) submit a request to the contractor (either via letter or a Form CMS-855) to voluntarily terminate its enrollment; or (3) submit a Form CMS-855 change of information application to report a changed practice location address (and any other changed data). The contractor shall copy the state and SOG Location on the notice and give the provider/supplier 10 calendar days from the date the notice is sent to respond to the request.

(ii) Potential Outcomes

(A) The provider/supplier timely furnishes evidence to the contractor and the state that it is still operational at the same location – The contractor need take no additional action on the matter until it receives confirmation from the state concerning the latter's review. (If the contractor receives evidence from the provider/supplier more than 10 days after the request was made, it shall contact the state for guidance.)

While the contractor may forward the provider/supplier's evidence to the state to ensure that the latter received it, the contractor is not required to do so. It is ultimately (1) the provider/supplier's responsibility to copy the state on its submission to the contractor and (2) up to the state to determine whether the evidence of operational status the provider/supplier submitted is sufficient.

Upon receiving notice from the state as to the review's results, the contractor shall follow the applicable instructions in this section 10.6.1.3 if the provider/supplier is to be terminated (e.g., the state sends a Form CMS-1539 to the contractor). If the provider/supplier was indeed found operational, the contractor need take no further action.

(B) The provider/supplier submits a Form CMS-855 voluntary termination and/or a voluntary termination letter in response to the contractor's aforementioned solicitation - The contractor shall process the submission consistent with the instructions in section 10.6.1.3(B)(1) and/or (B)(2), as applicable. Notwithstanding any instruction to the contrary in this section 10.6.1.3, the contractor shall use the termination effective date listed on the Form CMS-1539 or other documentation from the state (rather than the date on the Form CMS-855/letter) as the termination effective date.

(C) The provider/supplier timely submits a Form CMS-855 to change its address – The contractor shall process the change request to completion, notify the provider/supplier thereof via the applicable instructions in this chapter 10, and forward a copy of the change request via e-mail to the state and SOG Location via e-mail. In this e-mail, the contractor shall: (1) notify the state/SOG Location of the new address; (2) reference the Form CMS-1539 (or other documentation) that the state had sent to the contractor; and (3) notify the state if PECOS indicated any addresses other than the "old" or "new" address at which the provider/supplier might be located.

(D) The provider/supplier fails to respond to the contractor's solicitation - The contractor shall process the voluntary termination consistent with the instructions in section 10.6.1.3(B)(3) above.

8. Clock Stoppages – In any circumstance where the contractor is required under section 10.6.1.3 to contact PEOG (including sending a termination to PEOG for approval) or the state/SOG Location for a determination, approval, or guidance of some type, the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG/state/SOG Location's decision, resolution, determination, or final guidance, as applicable. Interim communication between the contractor and PEOG/state/SOG Location during such "waiting periods" (e.g., PEOG request for additional information from the contractor) does not restart the clock. Optional communications---that is, communications with PEOG/state/SOG Location that are not specifically directed under this section 10.6.1.3---do not stop the processing clock.

9. PECOS Deactivation Date

a. Matching Dates - As indicated previously, the termination effective date will be entered into ASPEN. The date of deactivation in PECOS (and except if PEOG instructs otherwise) should

match the termination effective date with the exception of certified suppliers paid via MCS, in which case the PECOS deactivation date shall be the day after the termination date.

b. Already Deactivated – If the provider/supplier is already deactivated in PECOS pursuant to 42 CFR § 424.540(a)(1) through (a)(6) (i.e., the provider/supplier's billing privileges are merely stopped) and the provider/supplier is now voluntarily terminating their enrollment, no change in the deactivation effective date in PECOS is needed (notwithstanding any contrary instruction in this chapter).

c. Seller CHOW - Notwithstanding paragraph (9)(b) above, the deactivation effective date in PECOS---as well as the voluntary termination date---is the day before the date of the sale. For certified suppliers paid via MCS, however, the deactivation effective date shall be the date of the sale. (Note that this paragraph (9)(c) does not apply to HHA changes in majority ownership for which no exception applies; see section 10.2.1.6.1(B) of this chapter for more information.)

10.6.2 – Establishing Effective Dates

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

In reviewing this section 10.6.2, it is important that the contractor keep in mind the distinctions between: (1) the date of enrollment/approval; (2) the effective date of billing privileges under 42 CFR § 424.520(d); and (3) the date from which the supplier may retrospectively bill for services under § 424.521(a).

(Note that the date of receipt of a PECOS application is the date on which the contractor received it, not the date on which the application required the contractor's manual intervention per section 10.3.)

A. Date of Enrollment/Approval

This section 10.6.2(A) does not apply to the application of § 424.535(g)(3). See section 10.4.7.2(A)(3) for more information.

For suppliers other than ambulatory surgical centers and portable x-ray suppliers, the date of enrollment is the date the contractor approved the application. The enrollment date cannot be made retroactive. To illustrate, suppose a practitioner met all the requirements needed to enroll in Medicare (other than the submission of a Form CMS-855I) on January 1. He submits his Form CMS-855I to the contractor on May 1, and the contractor approves the application on June 1. The date of enrollment is June 1, not January 1.

B. Establishing Effective Dates of Billing Privileges for Certain Suppliers Under 42 CFR § 424.520(d)

1. Applicability

This section 10.6.2(B) applies to the following individuals and organizations:

a. Physicians; physician assistants; nurse practitioners; audiologists; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; certified nurse- midwives; clinical social workers; clinical psychologists; independently billing psychologists, registered dietitians or nutrition professionals; physical therapists; occupational therapists; speech-language pathologists; mental health counselors; marriage and family therapists; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified above.

b. Ambulance suppliers

c. Part B hospital departments

d. CLIA labs

e. Opioid treatment programs.

f. Mammography centers

g. Mass immunizers/pharmacies

h. Radiation therapy centers

i. Home infusion therapy suppliers

(See 42 CFR §§ 424.520(d)(2) and 424.521(a)(2) for the regulatory listing of these providers/suppliers.)

2. Background

In accordance with 42 CFR § 424.520(d)(1), the effective date of billing privileges for the individuals and organizations identified in § 424.520(d)(2) (and section 10.6.2(B)(1) above) is the later of:

(i) The date the supplier filed an enrollment application that was subsequently approved, or

(ii) The date the supplier first began furnishing services at a new practice location.

NOTE: The date of filing for Form CMS-855 applications is the date on which the contractor received the application, regardless of whether the application was submitted via paper or Internet-based PECOS.

3. Retrospective Billing Under 42 CFR § 424.521(a)

Consistent with 42 CFR § 424.521(a)(1), the individuals and organizations identified in § 424.521(a)(2) (and section 10.6.2(B)(1) above) may retrospectively bill for services when:

(i) The supplier has met all program requirements, including state licensure requirements; and

(ii) The services were provided at the enrolled practice location for up to—

(A) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

(B) 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

The contractor shall interpret the above-mentioned phase "circumstances precluded enrollment" to mean that the supplier meets all program requirements (including state licensure) during the 30-day period before an application was submitted and no final adverse action (as that term is defined in § 424.502) precluded enrollment. If a final adverse action precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved--so long as it is not more than 30 days prior to the date on which the application was submitted.

If the contractor believes that the aforementioned Presidentially-declared disaster exception may apply in a particular case, it shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead for a determination on this issue.

4. Summarizing the Distinction Between Effective Date of Billing Privileges and Retrospective Billing Date

As already discussed, the effective date of billing privileges is "the later of the date of filing or the date (the supplier) first began furnishing services at a new practice location." The retrospective billing date, however, is "up to…30 days prior to (the supplier's) effective date (of enrollment)." To illustrate, suppose that a non-Medicare enrolled physician begins furnishing services at an office on March 1. She submits a Form CMS-855I initial enrollment application on May 1. The application is approved on June 1 (which, as discussed in section 10.6.2(A) above, is the date of enrollment). The physician's effective date of billing privileges is May 1, which is the later of: (1) the date of filing, and (2) the date she began furnishing services. The retrospective billing date is April 1 (or 30 days prior to the effective date of billing privileges), assuming the requirements of 42 CFR § 424.521(a) are met. The effective date entered in PECOS and the Multi-Carrier System will be April 1; claims submitted for services provided before April 1 will not be paid.

C. Effective Date of Reassignment

Consistent with 42 CFR § 424.522(a), the effective date of the reassignment is 30 days before the reassignment application is submitted if all applicable requirements during that period were otherwise met. However, and except as otherwise stated in this section 10.6.2(C), an additional retroactive reassignment period of:

- 30 days shall be applied per § 424.521(a)(1)(i); or
- 90 days shall be applied if a Presidentially declared disaster applies per § 424.521(a)(1)(ii)

(For purposes of this section 10.6.2(C), the dates described in the previous paragraph and bullets will be collectively referenced as the "§ 424.522(a) date.")

Under this, therefore, the retroactive billing period would be 60 days (or 30 days under § 424.522(a) + 30 days per § 424.521(a)(1)(i)) or 120 days (30 days under § 424.522(a) + 90 days if § 424.521(a)(1)(ii) applies). This applies to initial reassignments as part of an initial enrollment or involving an enrolled supplier that is adding a new reassignment.

As noted elsewhere in this chapter, individual physicians and practitioners who wish to reassign their benefits must now complete Section 4(F) of the Form CMS-855I rather than the discontinued Form CMS-855R. With this, the following scenario occasionally arises:

(1) The physician or practitioner submits a Form CMS-855I to reassign his or her benefits;
(2) Section 4(F) is either blank or incomplete;
(3) The contractor develops for a completed Section 4(F); and
(4) The physician or practitioner submits Section 4(F).

The reassignment effective date in this situation -- assuming the application and Section 4(F) are ultimately approved and all applicable requirements were met during this timeframe -- should be based on the date on which the Form CMS-855I was initially submitted and not the date on which the physician or practitioner finally submitted Section 4(F). For instance, suppose a reassigning physician submits her Form CMS-855I on March 1 with Section 4(F) incomplete. She later submits Section 4(F) on March 14. The reassignment effective date is predicated on the March 1 date and not March 14. This means that the extra 30-day or 90-day period goes back from March 1.

The policies in this section 10.6.2(C) apply to: (1) initial reassignments as part of an initial enrollment; and (2) enrolled suppliers that are adding a new reassignment.

D. Effective Date for Certified Providers and Certified Suppliers

Note that 42 CFR § 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Section 489.13 has been revised to state that: (1) the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met; and (2) such requirements include the contractor's review and verification of an application to enroll in Medicare.

E. Effective Date for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Per § 424.57(b), DMEPOS suppliers must meet, among other requirements, the following conditions to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations

it uses to furnish Medicare-covered DMEPOS excluding locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

The contractor shall indicate the supplier's status as approved in PECOS upon the contractor making the determination the supplier meets all of the supplier standards found at § 424.57(c). The date the supplier was approved in PECOS shall be the supplier's effective date.

F. Form CMS-855O Effective Dates

Notwithstanding any other instruction in the chapter to the contrary, the effective date of a Form CMS-855O enrollment per 42 CFR § 424.522 is the date on which the Medicare contractor received the Form CMS-855O application if all other requirements are met --- meaning the Form CMS-855O was processed to approval.

G. Effective Date for Medicare Diabetes Prevention Program (MDPP) Suppliers

In accordance with 42 CFR § 424.205(f), the effective date of billing privileges for MDPP suppliers is the later of:

- The date the supplier filed an enrollment application that was subsequently approved,

- The date the supplier filed a corrective action plan that was subsequently approved by a Medicare contractor, or

- The date the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number. (For PECOS applications, see section 10.3 of this chapter for information about what constitutes an enrollment record in PECOS.)

Under no circumstances should an effective date for billing privileges be prior to April 1, 2018. For any Form CMS-20134 submitted prior to April 1, 2018, and subsequently approved, the contractor shall note April 1, 2018, as the MDPP supplier's effective date, even if this date is in the future.

NOTE: The date of filing for paper Form CMS-20134 applications is the date on which the contractor received the application. For Internet-based PECOS applications, the date of filing is the date that the contractor received an electronic version of the enrollment application and a signed certification statement submitted via paper or electronically.

H. Future Effective Dates

If the contractor cannot enter an effective date into PECOS because the provider/supplier, its practice location, etc., is not yet established, the contractor may use the authorized official's date

of signature as the temporary effective date. Once the provider/supplier and the effective date are established (e.g., notification from the state is received), the contractor shall change the effective date in PECOS.

10.6.3 – Legal Business Name

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

A. Legal Business Name

There must be exact match between:

- *The LBN in NPPES and that in PECOS in all circumstances.*
- *The LBN on the IRS CP-575 and that in NPPES/PECOS except as described in this section 10.6.3.*

1. Punctuation and Special Characters

PECOS and NPPES allow for the entry of punctuation and certain special characters in the provider's *l*egal *b*usiness *n*ame (LBN). Examples of acceptable punctuation and special characters are ampersands, apostrophes, commas, hyphens, left and right parentheses, periods, pound signs, and quotation marks.

When punctuation or special characters are part of a provider's LBN as shown on the IRS CP-575, the punctuation or special characters should also appear in the LBN in NPPES and the LBN in PECOS. However, the contractor *shall accept an LBN* match between *the CP-575 and NPPES/PECOS (hereafter respectively the "CP-575 LBN" and the "System LBN") -- without requiring the provider to revise the LBN in NPPES and PECOS -- if:*

- *There is no more than one punctuation/character discrepancy between the CP-575 LBN and the System LBN; and*
- *The contractor believes – based on the data and documentation furnished on and with the application, including the CP-575 – that the CP-575 and System LBNs are of the same provider.*

2. Common Words

There are also instances where certain common words may be present on the CP-575 but not in PECOS/NPPES or vice versa. These words include "the", "a", "to", "of", "and", "in", "for", "as", "you", and "at". The contractor shall accept an LBN match between the CP-575 and System LBNs – without requiring the provider to revise the LBN in PECOS and NPPES – if:

- *There is no more than one discrepancy between the two LBNs involving any of these 10 words; and*
- *The contractor believes – based on the data and documentation furnished on and with the application -- that the two LBNs are of the same provider.*

3. Additional Guidance

a. It is acceptable to have one discrepancy in (A)(1) and in (A)(2), but no more than one in either.

b. Subsection (A)(2) only applies to the 10 listed words. However, the discrepancy can be between one of the common words and a non-common word (e.g., between "of" and "with" in the James Doctors example in (c) below).

c. If the contractor has questions regarding how to handle a particular discrepancy, it may contact its PEOG BFL for guidance.

CMS reiterates that in all cases, the LBNs in NPPES and PECOS must be an exact match. The discrepancies addressed in this section 10.6.3 ONLY pertain to those between the CP-575 and Systems LBNs. If a discrepancy between them is not acceptable per section 10.6.3, the provider must correct the LBN in NPPES and PECOS.

B. Subparts

Many enrolled providers may be subparts of other enrolled providers, and some of those subparts entered their "doing business as name" as their LBN when applying for their NPIs. Once a contractor determines for certain that this situation exists, the contractor shall ask the provider to correct its NPPES information. The provider can (1) change its LBN in NPPES to read in accordance with the IRS CP-575, and (2) report its "doing business as" name in NPPES as an "Other Name" and indicate the type of other name as a "doing business as" name.

C. Examples of LBN Matches and Non-Matches and Actions to Be Taken

CP-575 **LBN**	*SYSTEMS* **LBN**	**Exact Match**
Quality Care, Incorporated	Quality Care, Inc.	No, this is not an exact match (because of the abbreviation 'Inc.' in the PECOS LBN). *However,* the contractor *shall* accept the match since both versions are an accurate match (e.g., Incorporated or Inc; Limited Liability Company or LLC; etc.)
Health & Rehabilitation Inc.	Health and Rehabilitation Inc.	No, this is not an exact match (because the ampersand and 'and' do not match). *However, the contractor shall accept the match because "&" and "and" have the same meaning.*
Allergy & Asthma, Inc.	Allergy & Asthma, INC.	Yes, this is an exact match. Upper and lower cases do not affect a match.
Foot Ankle, LLC	Foot Ankle LLC	No, this is not an exact match (because the *comma* is in one LBN but not in the other). *However, the contractor shall accept the discrepancy per subsection (A)(1) if the test in that subsection is met.*

CP-575 LBN	*SYSTEMS* LBN	Exact Match
Rehab and Health, Inc.	Rehabilitation and Health, Inc.	No, this is not an exact match because 'Rehab' and 'Rehabilitation are different words. *T*he contractor *shall* ask the provider to correct its NPPES *and PECOS* information. The provider must change its LBN in NPPES *and PECOS* to read in accordance with the IRS CP-575.
Health Systems, Inc.	HEALTH SYSTEMS, INC.	Yes, this is an exact match.
The Jones Hospital, Inc.	*Jones Hospital, Inc.*	*Though this is not an exact match, the contractor shall accept the discrepancy if the test in subsection (A)(2) above is met.*
Smith Home Health at Town X, LP	*Smith Home Health Town X, LP*	*Though this is not an exact match, the contractor shall accept the discrepancy if the test in subsection (A)(2) above is met.*
The Johnson Clinic of Town Y, Inc.	*Johnson Clinic for Town Y, Inc.*	*This is not an exact match and cannot be accepted because there are two common word discrepancies – "The" and "of"/"for".*
James Doctors With Jones Hospital, Inc.	*James Doctors of Jones Hospital, Inc.*	*Though this is not an exact match, the contractor shall accept the discrepancy if the test in subsection (A)(1) above is met. (See (A)(3)(b) above).*

10.6.4 – Provider and Supplier Business Structures

(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

This section explains the legalities of various types of business organizations that may enroll, including sole proprietorships. Note that the provider's or supplier's (hereafter occasionally referred to collectively as "provider") organizational structure can have a significant impact on the type of information it must furnish on the Form CMS-855 or CMS-20134.

Business organizations are generally governed by state law. Thus, State X may have slightly different rules than State Y regarding certain entities. (In fact, X may permit the creation of certain types of legal entities that Y does not.) The discussion below gives only a broad overview of the principal types of business entities and does not take into account different state nuances.

Since CMS issues a 1099 based on an enrolled entity's business structure, providers should consult their accountant or legal advisor to ensure that they are establishing the correct business structure.

A. Sole Proprietorships

A business is a sole proprietorship if it meets all of the following criteria:

- It files a Schedule C (1040) with the Internal Revenue Service (this form reports the business's profits/losses);
- One person owns all of the business's assets; and
- It is not incorporated.

A sole proprietorship is not a corporation. Suppose a physician operates his/her business as a home health agency. If he/she incorporates his/her business, the business becomes a corporation (even though the physician is the only stockholder). The frequently used term "unincorporated sole proprietorship" is therefore a misnomer because sole proprietorships by definition are unincorporated. In addition, merely because the sole proprietor hires employees does not mean the business is no longer a sole proprietorship. Assume that W is a sole proprietor and he hires X, Y, and Z as employees. W's business is still a sole proprietorship because he remains the 100% owner of the business. If, however, W had sold parts of his sole proprietorship to X, Y, and Z, the business would no longer be a sole proprietorship because there is now more than one owner.

Note that professional associations (PAs) are generally not considered to be sole proprietorships; the PA designation is typically used in states that do not allow individuals to incorporate and form professional corporations. The PA will have its own employer identification number and is considered (like a professional corporation) to be a legal entity that is separate and distinct from the individual.

B. Processing Enrollments for Sole Proprietorships

1. Application Form Sections

If the provider indicates in the Identifying Information/Business Information section of the Form CMS-855A, CMS-855B, CMS-855I, CMS-855S or CMS-20134 that he/she is a sole proprietor, the contractor shall adhere to the following:

- The legal business name (LBN) in the Business Information section should list the person's (the sole proprietor's) legal name.
- The tax identification number (TIN) in the Business Information section should list the person's social security number.
- The Final Adverse Legal Actions/Convictions section of the Form CMS-855A, CMS-855B, CMS-855I, CMS-855S or CMS-20134 must be completed with information about the individual's final adverse action history.
- The Organizational Ownership and/or Managing Control section of the Form CMS-855A, CMS-855B, CMS-855I, CMS-855S or CMS-20134 will not apply unless the person has hired an entity to exercise operational or managerial control over the

business (i.e., no owners will be listed in the section, for the sole owner has already reported his/her personal information in the Identifying Information and Adverse Legal Actions sections).

- No owners, partners, or directors/officers need to be reported in the Individual Ownership and/or Managing Control section. However, all managing employees (whether W-2 or not) must be listed.

- If the sole proprietor is not enrolling as a physician or non-physician practitioner via the Form CMS-855I, he/she may have authorized and delegated officials.

Since most sole proprietorships that complete the Form CMS-855A, CMS-855B, CMS-855I, CMS-855S or CMS-20134 will also have an EIN, the contractor shall request from the provider a copy of its CP-575, any federal tax department tickets, or any other preprinted information from the IRS containing the provider's EIN.

2. Reassignments of Benefits

If a physician or non-physician practitioner who is currently reassigning all of his/her benefits attempts to enroll as a sole proprietorship or the sole owner of his/her professional corporation, professional association, or limited liability company, the contractor shall call or e-mail the old practice location to determine if the physician or non-physician practitioner is still employed there; if he or she is not, the contractor shall contact the practitioner to verify that he or she is indeed attempting to enroll as a sole proprietorship or sole owner.

C. Partnerships

A partnership is an association of two or more persons/entities who carry on a business for profit. Each partner in a partnership is an owner. If A and B form the "Y Partnership" and each contributes $50,000 to start the business, each partner owns one-half of Y.

In several respects, a partnership is the opposite of a corporation:

- Each partner is liable for all the debts of the partnership. Using the example above, suppose the Y Partnership breached a contract it had with X, who now sues for $10,000. Since each partner is liable for all debts, X can collect the entire $10,000 from A, or from B, or $5,000 from each, etc. This is because, unlike a corporation, a partnership is not really a separate and distinct entity from its partners/owners; the partners are the partnership. If Y had been a corporation, the owners (A and B) would likely have been shielded from liability.

- There is no "double taxation" with partnerships. The partnership itself does not pay taxes, although each partner pays taxes on any income he/she earns from the business.

- Unlike a corporation, a partnership generally does not file with the state upon its creation documents similar to articles of incorporation. Instead, a partnership has a

"partnership agreement," which amounts to a contract between the partners outlining duties, responsibilities, powers, etc.

- Each partner has the right to participate in running the business's day-to-day operations, unless the partnership agreement dictates otherwise.

An alternative type of partnership is a limited partnership (as opposed to a "general partnership," described above). While possessing many of the characteristics of a general partnership, there are some key differences. First, a limited partnership (LP) must file formal documents with the state. Second, a LP has two types of partners – general and limited. The general partner(s) runs the business yet is personally responsible for all of the LP's debts; the limited partner(s) has limited liability yet cannot participate in the management of the business.

D. Limited Liability Companies

A limited liability company (LLC) is a legal entity that is neither a partnership nor a corporation but has characteristics of both. Its owners have limited liability (as with stockholders in a corporation). Also, the LLC does not pay federal taxes (similar to a partnership), although its owners – usually labeled "members" - must pay taxes on any dividends they earn.

An LLC should not be confused with a limited liability corporation, which is a type of corporation in some states. A limited liability company is not a corporation or partnership but a distinct legal entity created and regulated by special state statutes.

Note that certain Form CMS-855 or Form CMS-20134 information is required of different entities. The primary example of this is in the Individual Ownership and/or Managing Control section. If the provider is a corporation, it must list its officers and directors on the form. Partnerships and LLCs, on the other hand, do not have officers or directors and therefore need not list them.

E. Joint Ventures

A joint venture is when two or more persons/entities combine efforts in a business enterprise and agree to share profits and losses. It is similar to a partnership and is treated as a partnership for tax purposes. The core difference is that while a partnership is an ongoing business, a joint venture is a temporary, one-time business undertaking. A joint venture, therefore, is to some extent a "temporary partnership."

F. Corporations

A corporation is an entity that is separate and distinct from its owners (called stockholders, or shareholders). To form a corporation, various documents – such as articles of incorporation – must be filed with the state in which the business will incorporate. The principal elements of a corporation are:

- Limited Liability – This is the main reason for a business's decision to operate as a corporation. Suppose Corporation X has ten stockholders, each owning 10% of the business. X breached a contract it had with Company Y, which now wants to sue X's owners. Unfortunately for Y, it can generally only sue X itself; it cannot sue X's shareholders. The corporation's owners are essentially shielded from liability for the corporation' actions because, as stated above, a corporation is separate and distinct from its owners.

  Despite the concept of limited liability, there may be isolated instances where a corporation's owners/stockholders can be held personally liable for the corporation's debts. This is known as "piercing the corporate veil."

- "Double" Taxation – This is the principal reason for a business's decision not to be a corporation. "Double" taxation means that: (1) the corporation itself must pay taxes; and (2) each shareholder must pay taxes on any dividends he/she receives from the business.

- Board of Directors – Most corporations are run by a governing body, typically called a board of directors.

  (As discussed in section 10.6.7.2 of this chapter, there is an important difference between the term "director" in the context of board members and someone who has "director" in his/her job title (e.g., "Director of Finance"). Simply because an individual works for a corporation as a director of a department, unit, etc., does not automatically mean he/she is a member of the board of directors. If the entity is a corporation, and for purposes for the Individual Ownership and/or Managing Control section of the Form CMS-855 and Form CMS-855, the term "director" means board members.

Two special types of corporations that contractors may encounter are:

- "Professional Corporation" (PC) - In general, a PC (1) is organized for the sole purpose of rendering professional services (such as medical or legal), and (2) all stockholders in a PC must be licensed to render such services. Thus, if A, B, and C want to form a physician practice (each is a 1/3 stockholder) and only A is a medical professional, a PC probably cannot be formed (depending, though, on what the applicable state PC statute says). A PC's title will usually end in "PC," "PA" (Professional Association), or "Chartered."

- "Close" Corporation (CC) (or "closely-held" corporation) – This type of corporation has a very limited number of stockholders. Unlike most corporations, a CC's board of directors generally does not run the business; rather, the shareholders do. The stock is typically not sold to outsiders.

Although PCs and CCs are considered "corporations" for enrollment purposes, state laws governing these entities are often different from those that govern "regular" corporations

(i.e., states have separate statutes for "regular" corporations and for PCs/CCs.) In many cases, an entity must specifically elect to be a PC or CC when filing its paperwork with the state.

G. Non-Profit Organizations

The term "non-profit organization" (NPO) can be misleading. It does not signify an organization that is prohibited from making a profit. Rather, it means that all of the organization's profits are put back into the entity to promote its goals, which are usually political, social, religious, or charitable in nature; an NPO is not organized primarily for profit but instead to further some other goal. An entity can acquire NPO status by obtaining an IRS 501(c)(3) certification from the IRS (meaning it is tax-exempt) or by acquiring such status from the state in which it is located.

NPOs are typically operated and/or managed by a board of trustees or other governing body. NPO status is important for enrollment purposes because NPOs generally do not have owners. (See section 10.6.4(D)(3) of this chapter for more information on NPO reporting requirements.)

H. Government-Owned Entities

For purposes of enrollment, a government-owned entity (GOE) exists when a particular government body (e.g., federal, state, city or county agency) will be legally and financially responsible for Medicare payments received. For example, suppose Smith County operates Hospital X. Medicare overpaid X $100,000 last year. If Smith County is the party responsible for reimbursing Medicare this amount, X is considered a government-owned entity.

Note that--

- GOEs do not have "owners." Thus, the Organizational Ownership and/or Managing Control sections of the Form CMS-855 or CMS-20134 need only contain the name of the government body in question. Using our example above, this would be Smith County.

- For the Individual Ownership and/or Managing Control section of the Form CMS-855 or CMS-20134, the only people that must be listed are "managing employees." This is because GOEs do not have corporate officers or directors.

The provider must submit a letter from the government body certifying that the government entity will be responsible for any Medicare payments.

10.6.5 – National Provider Identifier (NPI)

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Submission of NPI

Every provider or supplier that submits an enrollment application must furnish its NPI(s) in the applicable section(s) of the Form CMS-855 or CMS-20134. The provider need not submit a copy of the NPI notification it received from the National Plan and Provider Enumeration System (NPPES) because PECOS will verify the NPIs of the provider/supplier and all other NPIs listed on the application.

B. Additional NPI Information

The contractor shall only enter NPI data into PECOS that is submitted in conjunction with a Form CMS-855 or CMS-20134 (e.g., initial, change request). Thus, if a provider submits a Form CMS-855 or CMS-20134 change of information that only reports the provider's newly assigned NPI, or reports multiple NPIs that need to be associated with a single Medicare identification number, the contractor may treat this as a change request and enter the data into PECOS.

C. Subparts - General

The contractor shall review and become familiar with the principles outlined in the "Medicare Expectations Subpart Paper," the text of which follows below. It was originally issued in January 2006 and has since been slightly updated to reflect certain changes in Medicare terminology.

CMS encourages all providers to obtain NPIs in a manner similar to how they receive CMS Certification Numbers (CCNs) (i.e., a "one-to-one relationship"). For instance, suppose a home health agency is enrolling in Medicare. It has a branch as a practice location. The main provider and the branch will typically receive separate (albeit very similar) CCNs. It would be advisable for the provider to obtain an NPI for the main provider and another one for the branch – that is, one NPI for each CCN.

D. Medicare Subparts Paper - Text

MEDICARE EXPECTATIONS ON DETERMINATION OF SUBPARTS BY MEDICARE ORGANIZATION HEALTH CARE PROVIDERS WHO ARE COVERED ENTITIES UNDER HIPAA

Purpose of this Paper

Medicare assigns unique identification numbers to its enrolled health care providers. They are used to identify the enrolled health care providers in the HIPAA standard transactions that they conduct with Medicare (such as electronic claims, remittance advices, eligibility inquiries/responses, claim status inquiries/responses, and coordination of benefits) and in cost reports and other non-standard transactions.

This paper is a reference for Medicare contractors. It reflects the Medicare program's expectations on how its enrolled organization health care providers that are covered entities

under HIPAA[1] will determine subparts and obtain NPIs for themselves and any subparts. These expectations may change over time to correspond with any changes in Medicare statutes, regulations, or policies that affect Medicare provider enrollment.

These expectations are based on the NPI Final Rule, on statutory and regulatory requirements with which Medicare must comply, and on policies that are documented in Medicare operating manuals and other directives. These Medicare statutes, regulations and policies pertain to conditions for provider participation in Medicare, enrollment of health care providers in Medicare and assignment of identification numbers for billing and other purposes, submission of cost reports, calculation of payment amounts, and the reimbursement of enrolled providers for services furnished to Medicare beneficiaries.

This paper categorizes Medicare's enrolled organization health care providers as follows:

- Certified providers and certified suppliers
- Supplier groups and supplier organizations
- Suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS)

This paper is not intended to serve as official HHS guidance to the industry in determining subparts for any covered health care providers other than those that are organizations and are enrolled in the Medicare program. This paper does not address health care providers who are enrolled in Medicare as individual practitioners. These practitioners are Individuals (such as physicians, physician assistants, nurse practitioners, and others, including health care providers who are sole proprietors). In terms of NPI assignment, an Individual is an Entity Type 1 (Individual) and is eligible for a single NPI. As Individuals, these health care providers cannot be subparts and cannot designate subparts. A sole proprietorship is a form of business in which one person owns all of the assets of the business and the sole proprietor is solely liable for all of the debts of the business. There is no difference between a sole proprietor and a sole proprietorship. In terms of NPI assignment, a sole proprietor/sole proprietorship is an Entity Type 1 (Individual) and is eligible for a single NPI. As an Individual, a sole proprietor/sole proprietorship cannot have subparts and cannot designate subparts.

Discussion of Subparts in the NPI Final Rule and its Applicability to Enrolled Medicare Organization Health Care Providers

The NPI Final Rule adopted the National Provider Identifier (NPI) as the standard unique health identifier for health care providers for use in HIPAA standard transactions. On or before May 23, 2007, all HIPAA covered entities (except small health plans), to include enrolled Medicare providers and suppliers that are covered entities, were required to obtain NPIs and to use their NPIs to identify themselves as "health care providers" in the HIPAA standard transactions that they conduct with Medicare and other covered entities. Covered organization health care providers are responsible for determining if they have "subparts" that need to have NPIs. If such

[1] Covered entities under HIPAA are health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a health transaction for which the Secretary of HHS has adopted a standard (referred to in this paper as HIPAA standard transactions). Most Medicare Organization health care providers send electronic claims to Medicare (they are HIPAA standard transactions), making them covered health care providers (covered entities).

subparts exist, the covered organization health care provider must ensure that the subparts obtain their own unique NPIs, or they must obtain them for them.

The NPI Final Rule contains guidance for covered organization health care providers in determining subparts. Subpart determination is necessary to ensure that entities within a covered organization health care provider that need to be uniquely identified in HIPAA standard transactions obtain NPIs for that purpose.

The following statements apply to **all** entities that could be considered subparts:

- A subpart is not itself a separate legal entity, but is a part of a covered organization health care provider that is a legal entity. (All covered entities under HIPAA are legal entities.)

- A subpart furnishes health care as defined at 45 CFR § 160.103.

The following statements may relate to some or all of the entities that a Medicare covered organization health care provider could consider as subparts:

- A subpart may or may not be located at the same location as the covered organization health care provider of which it is a part.

- A subpart may or may not have a Taxonomy (Medicare specialty) that is the same as the covered organization health care provider of which it is a part.

- Federal statutes or regulations pertaining to requirements for the unique identification of enrolled Medicare providers may relate to entities that could be considered subparts according to the discussion in the NPI Final Rule. Medicare covered organization health care providers must take any such statutes or regulations into account to ensure that, if Medicare providers are uniquely identified now by using Medicare identifiers in HIPAA standard transactions, they obtain NPIs in order to ensure they can continue to be uniquely identified. Medicare is transitioning from the provider identifiers it currently uses in HIPAA standard transactions (for organizations, these could be CCNs, Provider Transaction Access Numbers (PTANs)—known as legacy identifiers or legacy numbers) to NPIs. This makes it necessary that Medicare organization health care providers obtain NPIs because the NPIs have replaced the identifiers currently in use in standard transactions with Medicare and with all other health plans. In addition, Medicare organization health care providers must determine if they have subparts that need to be uniquely identified for Medicare purposes (for example, in HIPAA standard transactions conducted with Medicare). If that is the case, the subparts will need to have their own unique NPIs so that they can continue to be uniquely identified in those transactions.

- A subpart that conducts any of the HIPAA standard transactions separately from the covered organization health care provider of which it is a part must have its own unique NPI.

Enrolled Medicare organization health care providers that are covered entities under HIPAA must apply for NPIs as Organizations (Entity Type 2). Organization health care providers as

discussed in this paper are corporations or partnerships or other types of businesses that are considered separate from an individual by the State in which they exist. Subparts of such organization health care providers who apply for NPIs are also Organizations (Entity Type 2).

Medicare Statutes, Regulations, Manuals

The Social Security Act (sections 1814, 1815, 1819, 1834, 1861, 1865, 1866, and 1891) and Federal regulations (including those at 42 CFR 400.202, 400.203, 403.720, 405.2100, 409.100, 410.2, 412.20, 416.1, 418.1, 424, 482.1, 482.60, 482.66, 483, 484, 485, 486, 489, 491, and 493.12) establish, among other things, the Conditions for Participation for Medicare providers and set requirements by which Medicare enrolls providers, requires cost reports, calculates reimbursement, and makes payments to its providers. These Medicare statutory and regulatory requirements are further clarified in various Medicare operating manuals, such as the State Operations Manual and the Program Integrity Manual, in which requirements and policies concerning the assignment of unique identification numbers, for billing and other purposes, are stated.

Medicare Organization Providers and Subparts: Certified Providers and Certified Suppliers

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to Medicare certified providers and certified suppliers for billing purposes.

Certified Providers that bill Medicare Part A (hereinafter referred to as "providers"):

- Providers apply for Medicare enrollment by completing a Form CMS-855A.
- Most providers are surveyed and certified by the States[3] prior to being approved as Medicare providers.[2]
- Providers have in effect an agreement to participate in Medicare.
- Providers include, but are not limited to: skilled nursing facilities, hospitals[4,] critical access hospitals, home health agencies, rehabilitation agencies (outpatient physical therapy, speech therapy), comprehensive outpatient rehabilitation facilities, hospices, community mental health centers, religious non-medical health care institutions.
- Providers are assigned CCNs to identify themselves in Medicare claims and other transactions, including cost reports for those providers that are required to file Medicare cost reports.

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[2] Religious non-medical health care institutions are handled differently.
[3] Hospitals bill Medicare Part B for certain types of services. [4] The check-digit algorithm will determine the validity of an NPI. This is not the same as knowing the health care provider being identified by a particular NPI.

- In general, each entity that is surveyed and certified by a State is separately enrolled in Medicare and is considered a Medicare provider. (One exception involves home health agency branches. The branches are not separately enrolled Medicare providers.) In many cases, the enrolled provider is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

Certified Suppliers, which bill Medicare Part B:

- Certified suppliers apply for Medicare enrollment by completing a Form CMS-855A or CMS-855B, depending on the supplier type.[3]

- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health centers.

- Certified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)

- Certified suppliers may have in effect an agreement to participate in Medicare.

- Certified suppliers are assigned CCNs for purposes of identification within Medicare processes. However, the contractors assign unique identification numbers to certain certified suppliers for billing purposes. (For CLIA labs, a CLIA number is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA number may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA number has no relation to the Medicare PTAN.)

- In many cases, the enrolled certified supplier is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider or certified supplier that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

In general, Medicare bases its enrollment of providers and certified suppliers on two main factors: (1) whether a separate State certification or survey is required, and (2) whether a separate provider or certified supplier agreement is needed. (The Taxpayer Identification Number, or TIN, is a consideration as well, though not to the degree of the two main factors.) The CMS Survey & Operations Group (SOG) Location generally make the final determinations on both of these factors; hence, Medicare provider and certified supplier enrollment policy is dictated to a significant degree by the CMS regional offices' decisions in particular cases.

Medicare Expectations for NPI Assignments for Providers and Certified Suppliers: To help ensure that Medicare providers and certified suppliers do not experience denials of claims or delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled providers and certified suppliers to obtain its own unique NPI. These NPIs have replaced the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror Medicare

enrollment, each enrolled provider and certified supplier that is a covered organization health care provider should:

- Obtain its own unique NPI.

- Determine if it has any subparts that are themselves enrolled Medicare providers. If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them. Example: An enrolled provider (a hospital) owns 10 home health agencies, all operating under the TIN of the hospital. Because the hospital and each of the 10 home health agencies is separately surveyed and enters into its own provider agreement with Medicare, a total of 11 unique NPIs should be obtained: one for the hospital, and one for each of the 10 home health agencies.

Regardless of how an enrolled provider or certified supplier that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if they exist), Medicare payments, by law, may be made only to an enrolled provider or certified supplier.

Medicare Organization Providers and Subparts:
Supplier Groups and Supplier Organizations

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to supplier groups and supplier organizations for billing purposes.

- Supplier groups and supplier organizations apply for Medicare enrollment by completing a Form CMS-855B or CMS-20134.

- Supplier groups and supplier organizations bill Medicare Part B.

- Certain supplier organizations are certified by the States, certified by the Food and Drug Administration (FDA), or must undergo an on-site inspection by the contractor. These requirements vary by type of supplier organization.

    - Supplier groups are primarily group practices, such as a group of physicians or other practitioners.

    - Supplier organizations include ambulance companies, mammography facilities, independent diagnostic testing facilities (IDTFs) and MDPP Suppliers.

Medicare enrolls supplier groups/supplier organizations based on TINs. A supplier group or supplier organization may have multiple locations; however, if each location operates under the same single TIN, Medicare does not separately enroll each location. There are exceptions:

1. When there is more than one Medicare specialty code associated with a single TIN. For instance, if a physician group practice is also an IDTF, it has two different Medicare specialties. The supplier group (the physician group practice) must enroll as a group and the supplier

organization (the IDTF) must enroll as a supplier organization. The group practice would complete a Form CMS-855B and the IDTF would complete a Form CMS-855B. Each one would receive its own unique Medicare identification number.

2. If a separate site visit, state certification, or on-site inspection by the contractor or if FDA certification is required for each practice location of that supplier group/supplier organization.

In these above exceptions, Medicare separately enrolls each different Medicare specialty and each separately visited, certified or contractor-inspected practice location.

Medicare Expectations for NPI Assignments for Supplier Groups and Supplier Organizations: To help ensure that Medicare supplier groups and supplier organizations do not experience delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled supplier groups and supplier organizations to obtain its own unique NPI. These NPIs have replaced the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror Medicare enrollment, each enrolled supplier group and supplier organization that is a covered organization health care provider should ensure the following:

- Obtain its own unique NPI.

- Determine if it has any subparts that are themselves enrolled Medicare providers. If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them.

EXAMPLE: An enrolled IDTF has four different locations, and each one must be separately inspected by the contractor. All four locations operate under a single TIN. Because each location is separately inspected in order to enroll in Medicare, a total of four unique NPIs should be obtained: one for each location.

Regardless of how an enrolled supplier group or supplier organization that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if they exist), Medicare payments, by law, may be made only to an enrolled supplier group or supplier organization.

Medicare Organization Providers and Subparts: DMEPOS Suppliers

Medicare regulations require that each practice location of a supplier of DMEPOS (if it has more than one) must, by law, be separately enrolled in Medicare and have its own unique Medicare identification number.

- A supplier of DMEPOS enrolls in Medicare by completing a Form CMS-855S.

- Suppliers of DMEPOS bill Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

- Suppliers of DMEPOS include but are not limited to pharmacies, oxygen suppliers, and outpatient physical therapy agencies. (Any organization that sells equipment or supplies that are billed to Medicare through the DME MAC must be enrolled as a supplier of DMEPOS via the appropriate NPE contractor. Sometimes, these are organizations that also furnish services that are covered by Medicare, such as ambulatory surgical centers. In order to be reimbursed for the DME supplies that they sell, they must separately enroll in Medicare as a supplier of DME.)

Medicare Expectations for NPI Assignments for Suppliers of DMEPOS: Each enrolled supplier of DMEPOS that is a covered entity under HIPAA must designate each practice location (if it has more than one) as a subpart and ensure that each subpart obtains its own unique NPI.

Final Notes About NPIs

Enrolled organization health care providers or subparts that bill more than one Medicare contractor: An enrolled organization health care provider or subpart is expected to use a single (the same) NPI when billing more than one Medicare contractor. For example, a physician group practice billing Contractor X and also billing Contractor Y would use a single (the same) NPI to bill both contractors.

Enrolled organization health care providers or subparts that bill more than one type of Medicare contractor: Generally, the type of service being reported on a Medicare claim determines the type of Medicare contractor that processes the claim. Medicare will expect an enrolled organization health care provider or subpart to use a single (the same) NPI when billing more than one type of Medicare contractor. However, in certain situations, Medicare requires that the organization health care provider (or possibly even a subpart) enroll in Medicare as more than one type of provider. For example, an ambulatory surgical center enrolls in Medicare as a certified supplier and bills a Part A/B MAC. If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a supplier of DME and bill a DME MAC. This ambulatory surgical center would obtain a single NPI and use it to bill the A/B MAC and the DME MAC. Medicare expects that this ambulatory surgical center would report two different Taxonomies when it applies for its NPI: (1) that of ambulatory health care facility—clinic/center--ambulatory surgical (261QA1903X) and (2) that of suppliers—durable medical equipment & medical supplies (332B00000X) **or** the appropriate sub-specialization under the 332B00000X specialization.

Enrolled organization health care providers that determine subparts for reasons unrelated to Medicare statutes, regulations or policies:

Consistent with the NPI Final Rule, covered organization health care providers designate subparts for reasons that are not necessarily related to Medicare statutes or regulations. If a Medicare organization health care provider designates as subparts entities other than those that are enrolled Medicare providers, and those subparts obtain their own NPIs and use those NPIs to identify themselves in HIPAA standard transactions with Medicare, those NPIs will not identify enrolled Medicare providers. Medicare is not required to enroll them. (NPI Final Rule, page 3441: "If an organization health care provider consists of subparts that are identified with their

own unique NPIs, a health plan may decide to enroll none, one, or a limited number of them (and to use only the NPIs of the one(s) it enrolls."))

Medicare uses NPIs to identify health care providers and subparts in HIPAA standard transactions. (NPI Final Rule, page 3469: section 162.412(a): "A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.") Medicare ensures that the NPIs it receives in HIPAA standard transactions are valid[5]. Medicare rejects HIPAA standard transactions that contain invalid NPIs. Valid NPIs, however, like the provider identifiers used today, must be "known" to Medicare. Medicare is not permitted to make payments for services rendered by non-Medicare providers, nor is it permitted to reimburse providers that are not enrolled in the Medicare program. Medicare returns, with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.[4]

10.6.6 – Final Adverse Actions

(Rev. 12550; Issued: 03-21-24; Effective: 04-21-24; Implementation: 04-21-24)

Unless stated otherwise, the instructions in this section 10.6.6 apply to the following sections of the Form CMS-855 and Form CMS-20134:

- Final Adverse Actions/Convictions (Section 3 of the Form CMS-855A, Form CMS-855B, Form CMS-855I, Form CMS-855O, and Form CMS-20134, and Section 7 of the Form CMS-855S)

- Business Information section/Private Practice Business Information section of the Form CMS-855I

- Organizational Ownership and/or Managing Control Final Adverse Legal Action History Section (Section 5 of the Form CMS-855A, Form CMS-855B, and Form CMS-20134, and Section 8 of the Form CMS-855S)

- Individual Ownership and/or Managing Control Final Adverse Legal Action History Section (Section 6 of the Form CMS-855A, Form CMS-855B, Form CMS-855I, and Form CMS-20134, and Section 9 of the Form CMS-855S)

For purposes of this section 10.6.6, the terms "final adverse action" and "adverse legal action" (as those terms are explained in section 10.6.6(F) of this chapter) will be collectively referred to as "ALA(s)", unless otherwise noted.

A. Prior Approval

The contractor shall send the application (if applicable) and ALA information to CMS (in accordance with section 10.6.6(I) below) for review for potential administrative action if:

[4] The check-digit algorithm will determine the validity of an NPI. This is not the same as knowing the health care provider being identified by a particular NPI.

- If the provider/supplier discloses its ALA on the Form CMS-855 or Form CMS-20134;

- If the provider/supplier discloses the ALA of an associated individual/entity on the Form CMS-855 or Form CMS-20134; or

- The contractor discovers---on its own volition and regardless of whether the provider/supplier is submitting a Form CMS-855 or Form CMS-20134---a provider's/supplier's ALA or that of an associated individual or entity of the provider/supplier.

In this chapter, and unless otherwise noted, "associated" individuals/entities refer to parties listed under the "Ownership Interest and/or Managing Control Information" sections of the Form CMS-855 or Form CMS-20134.

B. Review of the Provider Enrollment, Chain and Ownership System (PECOS)

If the contractor is reviewing a provider's/supplier's Form CMS-855 or Form CMS-20134 application for potential denial or revocation based on an ALA, the contractor shall search PECOS to determine whether the individual/entity with the ALA has any other associations (e.g., is listed in PECOS as an owner or managing employee of three Medicare-enrolled providers). This review requires searching the tax identification number (TIN) of the individual/entity and clicking "Associates w/ Connections" in PECOS. The TIN is the social security number or employer identification number (EIN).

If the contractor finds such an association and there are grounds to revoke the associated enrollment(s) of other provider(s)/supplier(s), the contractor shall submit the revocation referral(s) to CMS at ProviderEnrollmentRevocations@cms.hhs.gov.

C. Chain Home Offices, Billing Agencies, and Home Health Agency Nursing Registries

If the contractor discovers that an entity listed in Section 7 of the Form CMS-855A, Section 8 of the Forms CMS-855A/B/I/20134, or Section 12 of the Form CMS-855A has had an ALA imposed against it, the contractor shall contact its Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance if needed. For any ALA against individuals listed in Section 7 of the Form CMS-20134, the contractor shall refer to section 10.3.2.7 of this chapter, where this process is outlined in detail.

D. Review of the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Online Searchable Database and the System for Award Management (SAM)

(NOTE: The required reviews described in this subsection (D) do not apply to (a) voluntary termination submissions and (b) associated individuals/entities being deleted/removed on the Form CMS-855 or Form CMS-20134. Moreover, the review requirement only applies to data that is reported via an **actual submission**. Data that has previously been reported (and thus is not part of the submission in question) need not be reviewed. To illustrate, suppose a provider has 20 managing employees on file in PECOS. It submits a change request to add two more

managing officials. The contractor need only review the two officials. It need not check the other 20.)

Except as otherwise stated in this section 10.6.6, the contractor shall review each submission of a Form CMS-855 or Form CMS-20134 for (1) any exclusion(s) by HHS OIG of the provider/supplier and (2) exclusion(s) of any associated individuals/entities listed in the "Ownership Interest and/or Managing Control Information" Sections (e.g., an owner, managing employee, or authorized official), regardless of whether the provider/supplier reported the exclusion on the application (as applicable).

The OIG Online Searchable Database is located at exclusions.oig.hhs.gov; it includes all active exclusions for an individual or entity. The contractor shall verify the exclusion by entering the TIN of the excluded individual/entity and shall save that screenshot of the exclusion. (No screenshot is needed if no exclusion is involved.) The contractor shall also search for (1) any waivers to the HHS OIG exclusion and (2) any conviction(s) that may be tied to an exclusion (see section 10.6.6(G) and the applicable Decision Tree tables in section 10.6.6(I) for more details. In addition, if PECOS shows any associated enrollments (by TIN) of the excluded individual/entity that are not voluntarily withdrawn from Medicare, the contractor shall include this information in the ALA referral to CMS (as well as indicate whether CMS can take administrative action on the associated enrollment(s)).

In addition---and except as otherwise stated in this section 10.6.6---the contractor shall review each submission of a Form CMS-855 or Form CMS-20134 and search the SAM (i.e., at SAM.gov; formerly, the General Services Administration Excluded Parties List System) for exclusions/debarments if there is no HHS OIG exclusion—as identified on the OIG Online Searchable Database—for the provider/supplier and for any associated individuals/entities listed under the "Ownership Interest and/or Managing Control Information" Sections (e.g., an owner, managing employee, or authorized official). Only if SAM populates an exclusion/debarment—that the OIG Online Searchable Database does not populate—shall the contractor save that SAM screenshot when sending the ALA referral to CMS (even if the contractor learns from OIG that the exclusion is not active).

When an entity or individual is listed as debarred in the SAM (i.e., at SAM.gov), the SAM record may identify associated entities and persons that are also debarred. To illustrate, suppose John Smith is identified as debarred. The SAM record may also list individuals and entities associated with John Smith that are debarred as well, such as "John Smith Company," "Smith Consulting," "Jane Smith," and "Joe Smith."

If the contractor learns via the Form CMS-855 or Form CMS-20134 verification process, a Unified Program Integrity Contractor (UPIC) referral, or other similar means that a particular individual/entity is debarred or excluded, the contractor shall search the individual/entity in the SAM to see if the SAM record discloses any associated parties that are debarred or excluded. If associated parties are listed, the contractor – after verifying, via the instructions in this chapter, that the associated party is indeed debarred – shall check PECOS to determine whether the party is listed in any capacity. If the party is listed, the contractor shall take all applicable steps outlined in this chapter with respect to revocation proceedings against the party and against any persons/entities with whom the party is associated. For instance, using our example above, if the contractor confirms that Jane Smith is debarred and PECOS shows Jane Smith as an owner of

Entity X, the contractor shall, as applicable, send an ALA referral to CMS for review for potential administrative action against X as outlined in this section 10.6.6.

In instances where an HHS OIG exclusion populates SAM but not the OIG Online Searchable Database, this could mean that the provider/supplier (or associated individual/entity) has been reinstated but the SAM has not been accordingly updated. In such cases, the contractor shall contact the appropriate OIG official to (1) verify whether the exclusion is still active, (2) determine the date of reinstatement (if applicable), and (3) request the reinstatement letter from HHS OIG (if applicable). The contractor can find the appropriate OIG official on the Exclusion Record of an individual/entity on SAM by clicking on the respective Excluding Agency (as the respective contact information would populate there). The contractor shall, as applicable, include this information and the reinstatement letter (if available) when sending the ALA referral to CMS.

E. Disclosure of ALA

This section 10.6.6(E) discusses the disclosure and non-disclosure of ALAs on the Form CMS-855 and Form CMS-20134 as well as required documentation.

1. ALA Disclosed

a. Non-Felonies

If the provider/supplier discloses a non-felony ALA on the Form CMS-855/20134, the provider/supplier must furnish documentation concerning (i) the type of reported non-felony ALA, (ii) the date the non-felony ALA occurred, and (iii) what court or governing/administrative body imposed the action. (This documentation is referenced in Section 3 of the Form CMS-855/20134.) The provider/supplier must furnish the documentation regardless of whether the non-felony ALA occurred in a state different from that in which the provider/supplier seeks enrollment or is enrolled. The contractor shall develop for any such documentation that the provider/supplier fails to submit using the general developmental procedures outlined in this chapter.

b. Felony Convictions

(As a reminder, this subsection (E)(1)(b) applies only if the felony was disclosed.)

(i) Acquisition

For felony conviction documentation (and except as stated in subsection (E)(1)(b)(ii) below), the contractor shall:

- Develop for any required documentation (as described in subsection (E)(1)(a)(i) through (iii) above and on Section 3 of the Form CMS-855) that the provider/supplier fails to submit using the general developmental procedures outlined in this chapter; and

- Follow the instructions in subsection (E)(3) regarding the acquisition of the felony-specific documentation discussed therein.

(ii) Potential Overlap

In all instances discussed in this subsection (E)(1)(b), the contractor shall secure the mandatory documentation subsection (E)(3)(b) below. If the mandatory documentation captures the same information described in subsection (E)(1)(a)(i) through (iii) above, however, the contractor need not obtain the separate/additional (E)(1)(a)(i) through (iii) documentation. For instance, suppose the mandatory documentation identifies the court that imposed the action. The contractor need not obtain additional documentation verifying this data (as stated in subsection (E)(1)(a)(i) through (iii) above and Section 3 of the Form CMS-855). If, however, the mandatory documentation does not contain the data in subsection (E)(1)(a)(i) through (iii), the contractor shall develop for this information if the felony was reported.

2. ALA Is Not Disclosed

This section (E)(2) applies to situations where the contractor discovers an ALA that was not reported on the Form CMS-855/20134.

a. Non-Felonies

For ALAs other than felony convictions, the contractor need not develop for ALA documentation unless CMS instructs otherwise.

b. Felony Conviction

For felony conviction documentation, the contractor shall follow the instructions in section 10.6.6(E)(3).

3. Special Requirements Concerning Felony Documentation

a. Introduction

(This subsection (E)(3) applies (i) only to felony convictions and (ii) regardless of whether the felony conviction was reported on the Form CMS-855/20134.)

If, in felony conviction situations, the provider/supplier does not submit the mandatory documentation described in section 10.6.6(E)(3)(b) below (and, as applicable, the documentation in subsection (E)(1)(a)(i) through (iii) above), the contractor shall directly develop for the documentation with the provider/supplier using the existing development procedures outlined in this chapter; prior approval or instruction from CMS to develop in this scenario is not needed. After obtaining the documents (or after an unsuccessful attempt), the contractor shall submit the felony referral, application, and any supporting document(s) to CMS for review. The provider/supplier must fully submit all of the requested documentation within 30 calendar days of the date of the development request. If the provider/supplier fails to do so, the contractor shall

reject the application, upon PEOG approval; PEOG will then determine, if applicable, whether a revocation is warranted.

b. Documentation to Be Submitted

Mandatory – When sending the felony referral for review (and except as otherwise stated in this chapter), the contractor shall obtain from the provider/supplier and submit to CMS the following documentation:

- Judgment and/or sentencing order (as applicable);
- Any amended judgment and/or amended sentencing order (if applicable); and
- Jury verdict form or guilty plea acceptance document (as applicable; availability may vary from court to court). Note that some courts may incorporate the jury verdict or guilty plea entry/acceptance directly into the judgment and/or sentencing order. Also, some courts may not have a separate jury verdict form or guilty plea entry/acceptance, in which case the judgment and/or sentencing order suffices.

Not Required but Encouraged – The following documentation is optional, though the contractor is encouraged to, if possible, secure and submit this material to CMS; the data below could help furnish valuable background and context to CMS regarding the case.

- Any document showing the court's dismissal of charges (if applicable)
- Plea agreement (if applicable)
- Docket report/case summary
- Information or indictment
- Any amended information document(s) or superseding indictment(s)
- Police criminal complaint and/or affidavit of probable cause

4. Additional Policies

a. Reinstatements - If the individual or entity in question was excluded or debarred but has since been reinstated, the contractor shall confirm the reinstatement through HHS OIG or, in the case of debarment, through the federal agency that took the action. The appropriate OIG contact for such reinstatement verification requests is sanction@oig.hhs.gov. SAM.gov provides the appropriate contact for the federal agency that took debarment action on the screenshot page of that action (when searching the individual/entity).

b. Scope of Disclosure – All ALAs that occurred under the legal business name (LBN) and TIN of the disclosing entity (e.g., applicant, Section 5 owner) must be reported.

Example (A) - Smith Pharmacy, Inc. had 22 separately enrolled locations in 2017. Each location was under Smith's LBN and TIN. In 2018, two locations were excluded by the OIG and then subsequently revoked by CMS. Smith submits a Form CMS-855S application for a new location on Jones Street. Suppose, however, that each of Smith's locations had its own LBN and TIN. The Jones Street application need not disclose the two revocations from 2018.

Example (B) – A home health agency (HHA), hospice, and hospital are enrolling under Corporation X's LBN and TIN. X is listed as the provider in Section 2 of each applicant's Form CMS-855A. All three successfully enroll. Six months later, Company X's enrollment for the HHA is revoked due to an OIG exclusion. Both the hospice and the hospital must report that X was excluded on a Form CMS-855A change request because X is under the provider's LBN and TIN. Assume now that X seeks to enroll an ambulatory surgical center (ASC) under X's LBN and TIN. The exclusion would have to be reported in Section 3 of the ASC's initial Form CMS-855B.

Example (C) – Company Y is listed as the provider/supplier for two HHAs and two suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). These four providers/suppliers are under Y's LBN and TIN. Each provider/supplier is located in a different state. All are enrolled. Y's enrollment for one of the DMEPOS suppliers is revoked due to a felony conviction. Y now seeks to enroll an ASC in a fifth state. Y must disclose its felony conviction even though the felony conviction occurred in a state different from that in which the ASC is located.

c. Timeframe – With the exception of felony and misdemeanor convictions (and unless stated otherwise in this chapter), all ALAs must be reported in the final adverse legal action section of the Form CMS-855 or Form CMS-20134 regardless of when the final adverse legal action occurred.

d. Evidence to Indicate ALA – There may be instances where the provider or supplier states on the Form CMS-855 or Form CMS-20134 that the person or entity has never had an ALA imposed against him/her/it, but the contractor finds evidence to indicate otherwise. In such cases, the contractor shall follow the decision tree in section 10.6.6(I) below.

e. MDPP Coaches - MDPP suppliers enrolling via the Form CMS-20134 are not required to report any ALA as it relates to MDPP coaches submitted on Section 7 of that form.

F. Scope of a Reportable ALA

Providers and suppliers shall disclose all reportable ALAs on their enrollment applications. To satisfy the reporting requirement, the provider/supplier shall complete the Final Adverse Legal Action section(s) (Form CMS-855 or Form CMS-20134) in its entirety and attach all applicable documentation concerning the ALA to the application. All ALAs must be reported, regardless of whether any records have been expunged or sealed or any appeals are pending.

ALAs that must be disclosed on the Form CMS-855 or Form CMS-20134 include:

1. Felony conviction(s) within 10 years

a. Reporting – Providers/suppliers are required to report a felony (federal or state) when: (1) a conviction has occurred; and (2) the felony conviction date (e.g., the date of a court's acceptance of a guilty plea or the date of a jury verdict) is within 10 years from the submission date of a Form CMS-855 or Form CMS-20134 application.

b. When a Conviction Occurs - A conviction (as the term 'convicted' is defined in 42 CFR 1001.2) has occurred when:

(A) A judgment of conviction has been entered against an individual or entity by a federal, state, or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(B) A federal, state, or local court has made a finding of guilt against an individual or entity;

(C) A federal, state, or local court has accepted a plea of guilty or nolo contendere by an individual or entity; or

(D) An individual or entity has entered into participation in a first offender, deferred adjudication, or other program or arrangement where judgment of conviction has been withheld.

A felony conviction shall be reported by the provider/supplier even if the conviction has been sealed or expunged or there is an appeal or post-trial motion pending. Furthermore, in instances where the defendant pleads guilty to a felony and a court orders deferred adjudication/adjudication withheld/treatment in lieu of conviction/probation with a suspended imposition of sentence/pre-trial diversion, these dispositions generally fall under 42 CFR 1001.2's definition of 'convicted.' Consequently, the provider/supplier shall report these types of convictions on the Form CMS-855 or Form CMS-20134.

c. Additional Information

For any submission of a Form CMS-855 or Form CMS-20134 for initial enrollment, reactivation, change of information, or revalidation---and except as stated in the following paragraph---the contractor shall review and use APS as a resource to determine if there are any felony convictions on which CMS can take administrative action. The contractor shall include any felony conviction(s) and/or ongoing criminal case(s) listed on APS in its referral email to CMS.

(NOTE: The aforementioned APS review is not required for (a) voluntary termination submissions, (b) associated individuals/entities being deleted/removed on the Form CMS-855, and (c) any individuals and entities listed on the application who have previously been reviewed against APS as part of any prior application submission. Moreover, the APS review requirement only applies to data that is reported via an actual submission. Data that has previously been reported (and thus is not part of the submission in question) need not be reviewed.)

The aforementioned APS review would be to determine whether (a) the provider/supplier submitting the Form CMS-855 or Form CMS-20134 or (b) any associated individual/entity (e.g., owner or managing employee) listed in the "Ownership Interest and/or Managing Control Information" sections of the provider/supplier's Form CMS-855 or Form CMS-20134 has a felony conviction.

2. Misdemeanor conviction within 10 years

- Report a misdemeanor conviction (federal or state) when—
    - A conviction has occurred;
    - The misdemeanor conviction date (e.g., the date of a court's acceptance of a guilty plea, or the date of a jury verdict) is within 10 years from the submission date of a Form CMS-855 or Form CMS-20134 application; and
    - The misdemeanor is related to any of the following:
        - The delivery of an item/service under Medicare or a state health care program;
        - The abuse or neglect of a patient in connection with the delivery of a health care item or service;
        - Theft, fraud, embezzlement, breach of fiduciary duty or other financial misconduct in connection with the delivery of a health care item/service;
            - The interference with or obstruction of any investigation into any criminal offense described under 42 CFR 1001.101 or 1001.201; or
        - The unlawful manufacture, distribution, prescription or dispensing of a controlled substance.

- A conviction has occurred when any of the criteria in 42 CFR 1001.2 (and as described in the second in bullet in (F)(1)(b) above) are met.

- A misdemeanor conviction shall be reported even if the conviction has been sealed, expunged, or there is an appeal or post-trial motion pending.

3. Current or past suspension(s)/revocations(s)/voluntary surrender(s) in lieu of further disciplinary action of a medical license(s)

- A medical license board suspends or revokes a medical license for any period of time; or the provider voluntarily surrenders her/his medical license in lieu of further disciplinary action.

4. Current or past suspensions(s)/revocation(s) of an accreditation -- An accrediting body suspends or revokes an accreditation for any period of time.

5. Current or past exclusion(s) imposed by HHS OIG -- Items/services furnished, ordered, or prescribed by a specified individual/entity are not reimbursed under Medicare, Medicaid, and/or all other federal health care programs until the individual or entity is reinstated by the HHS OIG.

6. Current or past debarment(s) from participation in any federal executive branch procurement or non-procurement program -- An individual or entity is suspended throughout

the executive branch of the federal government, as it applies to procurement and non-procurement programs. An individual or entity will not be solicited from, contracts will not be awarded to, or existing contracts will not be renewed or otherwise extended to those individuals or entities with a debarment (e.g., GSA debarment).

7. Medicaid exclusion(s), revocation(s) or termination(s) of any billing number -- A state terminates an active provider agreement or prohibits a provider from enrolling in the Medicaid program. Any Medicaid terminations shall be forwarded to ProviderEnrollmentRevocations@cms.hhs.gov for review by PEOG.

G. Reviewing for ALAs

The contractor shall address the reporting of ALA in its review of initial enrollment, revalidation, reactivation, or change of information applications submitted by a provider or supplier. The contractor may receive information of ALAs not yet reported by the provider or supplier from CMS or other contractors via the application screening process. The contractor shall consider this information and take action as described in (but not limited to) this section 10.6.6 and other applicable sections of this chapter.

Providers and suppliers shall include all reportable ALAs on their enrollment applications. This information must be reported by the provider/supplier on the initial/revalidation application and pursuant to the reporting requirements specified in 42 CFR § 424.516 and section 10.4(J) of this chapter. Reportable ALAs are listed in section 10.6.6(F) above. All applicable ALAs shall be reported, regardless of whether any (1) records were expunged or sealed, (2) appeals are pending, or (3) waivers were granted.

Notwithstanding any other instruction to the contrary in this chapter, the contractor need not send an ALA referral to CMS/PEOG for review if:

- The provider/supplier previously disclosed that same reportable ALA on a Form CMS-855 or Form CMS-20134 application and CMS/PEOG had already reviewed it; or
- The provider/supplier discloses a non-reportable ALA along with a reportable one. In this case, the non-reportable ALA need not be referred to CMS/PEOG in conjunction with the reportable ALA.

H. Non-Reportable ALAs

Non-reportable ALAs include but are not limited to: license probations in which the state board does not prohibit the practice of medicine; malpractice suits; false claims act civil judgments; and felony or misdemeanor convictions that are not within the previous 10 years from the submission date of a Form CMS-855 or Form CMS-20134 application.

The contractor need not send an ALA referral to CMS for review if the provider/supplier previously reported that same non-reportable ALA on a Form CMS-855 or Form CMS-20134 application that CMS had already reviewed.

I. ALA Decision Tree

To assist the contractor in determining what actions to take when an ALA is involved, CMS has produced an ALA Decision Tree (see below) for the contractor to use as a guide. Except as otherwise stated in this section 10.6.6, chapter 10 itself, or another CMS directive, the contractor: (1) shall follow the ALA Decision Tree when it receives ALA information regarding a provider or supplier (or discovers an ALA through independent research or other means); and (2) shall not develop with the provider or supplier for reported or unreported ALA(s). Note that the term "provider" in the Decision Tree includes "supplier" unless noted otherwise.

The instructions in the Decision Tree take precedence over all others in this chapter.

TABLE 1 -- INITIAL/REACTIVATION APPLICATIONS – LICENSE OR ACCREDITATION CURRENTLY SUSPENDED / REVOKED / VOLUNTARILY SURRENDERED IN SAME STATE – REPORTED			
Licensure Scenario	**Did the provider report the ALA taken on their license / accreditation?**	**MAC Action**	**Notes**
Provider's accreditation/medical license is currently suspended / revoked / voluntarily surrendered in lieu of further disciplinary action by a state licensing authority, where the licensure action is in the same state in which the provider is enrolling.	Yes	The contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(1) and any other applicable denial reasons. Refer to Tables 3 – 13.	The contractor shall read board orders thoroughly to determine if there is any other ALA associated with the license suspension, revocation, or voluntary surrender in lieu of further disciplinary action (e.g., a felony conviction). If the board order mentions another license suspension / revocation / voluntary surrender from another state, the contractor shall include this information in its referral to CMS and note whether

TABLE 1 -- INITIAL/REACTIVATION APPLICATIONS – LICENSE OR ACCREDITATION CURRENTLY SUSPENDED / REVOKED / VOLUNTARILY SURRENDERED IN SAME STATE – REPORTED			
Licensure Scenario	**Did the provider report the ALA taken on their license / accreditation?**	**MAC Action**	**Notes**
			revocation action is appropriate for any other enrollment. The contractor shall not refer to CMS/PEOG under 42 CFR § 424.530(a)(1) if the licensure action is any of the following: (i) a suspension is "stayed" in its entirety; (ii) the license is placed on probation but is otherwise still active for the practice of medicine; (iii) advertising/ administrative penalties; or (iv) fines, violations, stipulations, reprimands.

TABLE 2 -- INITIAL/REACTIVATION APPLICATIONS – LICENSE OR ACCREDITATION CURRENTLY OR PREVIOUSLY SUSPENDED/REVOKED/VOLUNTARILY SURRENDERED IN SAME STATE – NOT REPORTED			
Licensure Scenario	**Did the provider report the ALA taken on their license or accreditation?**	**MAC Action**	**Notes**
Provider's accreditation /medical license is currently or was previously suspended / revoked / voluntarily surrendered in lieu of further disciplinary action by a state licensing authority, where the licensure action is in the same state in which the provider is enrolling.	No	The contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(1), § 424.530(a)(4) and/or any other applicable denial reasons. Refer to Tables 1 and 3 – 14.	424.530 (a)(4) shall ONLY be included as a denial reason if the provider has never reported this ALA. The contractor shall read board orders thoroughly to determine if there is any other ALA associated with the license suspension / revocation / voluntarily surrendered in lieu of further disciplinary action. If the board order mentions another license suspension / revocation / voluntary surrendered in lieu of further disciplinary action. from another state, the contractor shall include this information in its referral to CMS under § 424.530(a)(4) and any other applicable denial reasons; the contractor shall note whether revocation action is appropriate for any other enrollment. There is no reporting requirement for/if: (i) a suspension is "stayed" in its entirety; (ii) the license is on probation but otherwise is still active for the practice of medicine; (iii) advertising / administrative penalties; or (iv) fines, violations, stipulations, reprimands.

TABLE 3 -- INITIAL/REACTIVATION APPLICATIONS – LICENSE CURRENTLY SUSPENDED OR REVOKED IN DIFFERENT STATE – REPORTED			
Licensure Scenario	**Did the provider report the ALA taken on their license?**	**MAC Action**	**Notes**
Provider's medical license currently suspended / revoked / in a state different from that in which the provider is enrolling.	Yes or No	The contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(14) and any other applicable denial reasons. Refer to Tables 1-2 and 4-14.	Denial under 42 CFR § 424.530(a)(14) is appropriate only if the license suspension/revocation action in the different state (i.e., the state other than that in which the provider is enrolling) occurred on or after March 17, 2020. The contractor shall read board orders thoroughly to determine if there is any other ALA associated with the license suspension or revocation (e.g., a felony conviction). The contractor shall note whether revocation action is appropriate for any other enrollment. Note that voluntary surrenders in lieu of further disciplinary action do not give rise to denial under 42 CFR § 424.530(a)(14).

TABLE 4 -- INITIAL/REACTIVATION APPLICATIONS – FELONIES			
Felony	**Did the provider report the felony conviction?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, or managing organization has been adjudged guilty of a felony.	Yes or No	The contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(3) and any other applicable denial reasons. Refer to Tables 1-3 and 5-14.	A felony is defined as a crime that has a maximum penalty—as specified in the criminal statute—by imprisonment for a period of more than one year. All felony convictions within the preceding 10 years of the submission date of a Form CMS-855 or Form CMS-20134 application shall be forwarded to CMS for review and decision unless CMS instructs otherwise.

TABLE 5 -- INITIAL/REACTIVATION APPLICATIONS – MISDEMEANORS			
Misdemeanor	**Did the provider report the misdemeanor conviction?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, or managing organization has been adjudged guilty of a misdemeanor related to health care abuse or neglect of a patient; financial misconduct; interference with a criminal investigation; or unlawful manufacture, distribution, or dispensing of a controlled substance.	Yes or No	Process application unless another reported or unreported ALA precludes processing. Refer to Tables 1 – 4 and 6 – 14.	A misdemeanor is defined as a crime that has a maximum penalty—as specified in the criminal statute—by imprisonment for a period of not more than a year (i.e., one year or less).

TABLE 6 -- INITIAL/REACTIVATION APPLICATIONS – ACTIVE EXCLUSION/DEBARMENT - REPORTED			
Current Exclusion or Debarment	**Did the provider report the exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel has an active OIG exclusion or SAM debarment.	Yes	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(2) and any other applicable denial reasons. Refer to Tables 1 – 5 and 7-14.	A waiver does not guarantee automatic enrollment into the Medicare program. All waivers shall be sent to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision, along with the corresponding ALA information and application.

TABLE 7 -- INITIAL/REACTIVATION APPLICATIONS – ACTIVE EXCLUSION/DEBARMENT – NOT REPORTED			
Current Exclusion or Debarment	**Did the provider report the exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel has an active OIG exclusion or SAM debarment.	No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(2), § 424.530(a)(4), and/or any other applicable denial reasons. Refer to Tables 1 – 6 and 8 – 14.	Note that (a)(4) shall ONLY be included as a denial reason if the provider has never reported this ALA. A waiver does not guarantee automatic enrollment into the Medicare program. All waivers shall be sent to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision, along with the corresponding ALA information and application.

TABLE 8 -- INITIAL/REACTIVATION APPLICATIONS – EXPIRED EXCLUSION/DEBARMENT - REPORTED			
Exclusion Period/Debarment Period Has Expired	**Did the provider report the past exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel had an OIG exclusion or a federal/SAM debarment (or an exclusion by a federal agency other than OIG) and has been reinstated by HHS and/or OIG and/or the federal agency in question.	Yes	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 1 – 7 and 10 – 14.	

TABLE 9 -- INITIAL/REACTIVATION APPLICATIONS – EXPIRED EXCLUSION/DEBARMENT – NOT REPORTED			
Exclusion Period/Debarment Period Has Expired	**Did the provider report the past exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel had an OIG exclusion or a federal/SAM debarment (or an exclusion by a federal agency other than OIG) and has been reinstated by HHS and/or OIG and/or the federal agency in question.	No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(4) and any other applicable denial reasons. Refer to Tables 1 – 7 and 10-14.	Note that (a)(4) shall ONLY be included as a denial reason if the provider has never reported this ALA. A waiver does not guarantee automatic enrollment into the Medicare program. All waivers shall be sent to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision, along with the corresponding ALA information and application. If CMS previously revoked this provider due to that prior OIG exclusion, debarment, or other federal action--and the provider or associated individual/entity has been reinstated by OIG/HHS/federal agency--the contractor shall process the application unless there is another reported or unreported ALA that precludes processing the application.

TABLE 10 -- INITIAL/REACTIVATION APPLICATIONS – MEDICARE PAYMENT SUSPENSION – CURRENT OR PAST			
Medicare Payment Suspension Status	**Did the provider report the Medicare payment suspension?**	**MAC Action**	**Notes**
Current Medicare payment suspension	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 1 – 9 and 11 – 14.	Providers are NOT required to report current Medicare payment suspensions to CMS. The contractor shall consider whether other denial reasons exist. Refer to Tables 1 – 9 and 11 – 14.
Past Medicare payment suspension	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 1 – 9 and 11 – 14.	Providers are NOT required to report past Medicare payment suspensions to CMS. The contractor shall consider whether other denial reasons exist. Refer to Tables 1 – 9 and 11 – 14.

TABLE 11 -- INITIAL/REACTIVATION APPLICATIONS – MEDICARE REVOCATION – ALL PRIOR ENROLLMENT BAR(S) EXPIRED			
Medicare Revocation	**Did the provider report the Medicare revocation?**	**MAC Action**	**Notes**
All prior enrollment bar(s) have expired.	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 1 – 10 and 12-14.	Providers are NOT required to report current or past Medicare revocations to CMS. The contractor shall consider whether other denial reasons exist. Refer to Tables 1 – 10 and 12-14. Under 42 CFR § 424.530(a)(3), CMS can still deny an application if there is a felony conviction within the preceding 10 years by a provider/supplier or by an individual/entity listed on the application as a 5 percent or greater owner, managing employee, partner, corporate director, corporate officer, or managing organization. This denial authority is still applicable and should be considered by the contractor even if the previous Medicare revocation had a 3-year re-enrollment bar and the bar has expired. In such instances, the contractor shall send the ALA information and application to CMS for review and decision at ProviderEnrollmentRevocaions@cms.hhs.gov.

TABLE 12 -- INITIAL/REACTIVATION APPLICATIONS – MEDICARE REVOCATION – ACTIVE REENROLLMENT BAR			
Medicare Revocation	**Did the provider report the Medicare revocation?**	**MAC Action**	**Notes**
Enrollment bar is active (in the state in which the provider is enrolling or in another state)	Yes or No	If the application is for an enrollment that has an active reenrollment bar on the enrollment itself, the application should be returned.	

TABLE 13 -- INITIAL/REACTIVATION APPLICATIONS - OTHER PROGRAM TERMINATION – CURRENT			
Other Program Termination	**Did the provider report the other program termination?**	**MAC Action**	**Notes**
The provider is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program.	Yes	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(14) and any other applicable denial reasons. Refer to Tables 1 – 12 and 14.	Denial may be appropriate under 42 CFR § 424.530(a)(14) if the provider is currently terminated/suspended/barred from participation in a state Medicaid program or any other federal health care program (e.g., TRICARE). The termination or suspension must occur by letter dated on or after March 17, 2020.

TABLE 14- INITIAL/REACTIVATION APPLICATIONS – FALSE CLAIMS ACT (FCA) CIVIL JUDGMENTS			
False Claims Act (FCA) Civil Judgments	**Did the provider report the False Claims Act (FCA) Civil Judgment?**	**MAC Action**	**Notes**
Provider or any individual/entity listed as a 5 percent or greater owner, partner managing employee or organization, corporate officer, or corporate director thereof has had a civil judgment under the FCA imposed against them within the previous 10 years.	Yes or No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.530(a)(17) and any other applicable denial reasons. Refer to Tables 1 – 13.	The FCA (31 U.S.C. 3729–3733) is the federal government's principal civil remedy for addressing false or fraudulent claims for federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant. Denial may be appropriate under 42 CFR § 424.530(a)(17) if the FCA civil judgment is within the preceding 10 years of the submission date of a Form CMS-855 or Form CMS-20134. FCA civil judgments must occur on or after January 1, 2024. Note that the term ''civil judgment'' is not inclusive of FCA settlement agreements and should not be referred to CMS for review. Providers are NOT required to report FCA civil judgments to CMS.

TABLE 15 – REVALIDATIONS/CHANGE OF INFORMATION APPLICATIONS – PREVIOUS LICENSURE OR ACCREDITATION – SAME STATE – REPORTED

If the contractor discovers an ALA that has not been reported by a provider, the contractor shall, upon CMS' approval, record the ALA in the PECOS Final Adverse Legal Actions Section ~~and/~~or PECOS profile for the associated individual/entity (as appropriate).

- If the contractor is inputting the ALA which has not been reported by the provider—and if CMS does not take administrative action due to that ALA—the contractor shall select "No" for the "Display in PI" field, thereby making this ALA not visible in the provider interface (as applicable).

- If the contractor is inputting the ALA which has not been reported by the provider—and if CMS does take administrative action due to that ALA—the contractor shall select "Yes" for the "Display in PI" field, thereby making the ALA visible in the provider interface.

Unless otherwise stated, the foregoing statements apply to Tables 15 through 26.

Provider holds a valid accreditation / medical license in the state in which it is revalidating or changing information	**Did the provider report the ALA taken on their license/ accreditation?**	**MAC Action**	**Notes**
Provider's accreditation/ medical license was previously suspended/revoked / voluntarily surrendered in lieu of further disciplinary action by a state licensing authority but is currently active for the practice of medicine AND where the licensure action is in the same state in which the provider is currently enrolled.	Yes	The contractor shall check whether the provider billed for dates of service during the period of license susp/rev/vol surrender in lieu of further disciplinary action. If the provider billed for dates of service during this period, the contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision for potential revocation action under 42 CFR § 424.535(a)(8). The contractor shall note this information when sending a referral to CMS for review. If the provider did not bill during the period of license susp/rev/vol surrender in lieu of further disciplinary action, the application shall	The contractor shall read board orders thoroughly to determine if there is any other ALA (e.g., a felony conviction) associated with the license susp/rev/vol surrender in lieu of further disciplinary action. If the board order mentions another license susp/rev/vol surrender in lieu of further disciplinary action from another state, the contractor shall include this information in its referral to CMS and note whether revocation action is appropriate for any other enrollment.

		be processed unless there is another reported or unreported ALA that precludes processing. Refer to Tables 17 – 27.	The contractor shall not refer to CMS/PEOG for revocation under 42 CFR § 424.535(a)(1) if the licensure action is any of the following: (i) a suspension is "stayed" in its entirety; (ii) the license is placed on probation but otherwise is active for the practice of medicine; (iii) advertising / administrative penalties; or (iv) fines, violations, stipulations, reprimands.

TABLE 16 – REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – LICENSE PREVIOUSLY SUSPENDED/REVOKED/VOLUNTARY SURRENDERED - SAME STATE – NOT REPORTED			
Provider holds a valid accreditation/ medical license in the state in which it is revalidating or changing information	**Did the provider report the ALA taken on its license or accreditation?**	**MAC Action**	**Notes**
Provider's accreditation/ medical license was previously suspended / revoked / voluntarily surrendered in lieu of further disciplinary action by a state licensing authority but is now active AND the licensure action is in the same state in which the provider is enrolling.	No	The contractor shall send the application and ALA information to ProviderEnrollment Revocations@cms.h hs.gov for review and decision under § 424.535(a)(4) and any other applicable revocation reasons. Refer to Tables 17 – 27. Note that § 424.535 (a)(4) shall ONLY be included as a revocation reason if the provider has never reported this ALA and CMS did not previously revoke the provider for that ALA.	The contractor shall check whether the provider billed for dates of service during the period of license susp/rev/vol surrender in lieu of further disciplinary action. If the provider billed for dates of service during this period, there may be potential revocation action under 42 CFR § 424.535(a)(8). The contractor shall note this information when sending a referral to CMS for review. The contractor shall read board orders thoroughly to determine if there is any other ALA associated with the license susp/rev/vol surrender in lieu of further disciplinary action. If the board order mentions another license susp/rev/vol surrender in lieu of further disciplinary action from another state, the contractor shall include this information in its referral to CMS and note whether revocation action is appropriate for any other enrollment. There is no reporting requirement for/if: (i) a suspension is "stayed" in its entirety; (ii) if license is on probation but otherwise is active for the practice of medicine; (iii) advertising / administrative penalties; or (iv) fines, violations, stipulations, reprimands.

TABLE 17 – REVALIDATIONS/CHANGE OF INFORMATION APPLICATIONS – CURRENT LICENSURE OR ACCREDITATION – SAME STATE – REPORTED			
Provider holds a valid accreditation / medical license in the state in which it is revalidating or changing information	**Did the provider report the ALA taken on their license/ accreditation?**	**MAC Action**	**Notes**
Provider's accreditation/ medical license is currently suspended/revoked/ voluntarily surrendered in lieu of further disciplinary action by a state licensing authority where the licensure action is in the same state in which the provider is currently enrolled.	Yes	The contractor shall send the application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.535(a)(1) and any other applicable revocation reasons. Refer to Tables 15-16 and 18- 27.	The contractor shall check whether the provider billed for dates of service during the period of license susp/rev/vol surrender in lieu of further disciplinary action. If the provider billed for dates of service during this period, there may be potential revocation action under 42 CFR § 424.535(a)(8). The contractor shall note this information when sending a referral to CMS for review. The contractor shall read board orders thoroughly to determine if there is any other ALA associated with the license susp/rev/vol surrender in lieu of further disciplinary action. If the board order mentions another license susp/rev/vol surrender in lieu of further disciplinary action from another state, the contractor shall include this information in its referral to CMS and note whether revocation action is appropriate for any other enrollment. There is no reporting requirement for/if: (i) a suspension is "stayed" in its entirety; (ii) if license is on

			probation but is otherwise active for the practice of medicine; (iii) advertising / administrative penalties; or (iv) fines, violations, stipulations, reprimands.

TABLE 18 -- REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – FELONIES			
Felony	**Did the provider report the felony conviction?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, or managing organization has been adjudged guilty of a felony.	Yes or No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under § 424.535(a)(3) and any other applicable revocation reasons. Refer to Tables 15-17 and 19 – 27.	A felony is defined as a crime that has a maximum penalty—as specified in the criminal statute—by imprisonment for a period of more than one year. All felony convictions within the preceding 10 years of the submission date of a Form CMS-855 or Form CMS-20134 application shall be forwarded to CMS for review and decision unless CMS instructs otherwise.

TABLE 19 – REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – MISDEMEANORS			
Misdemeanor	**Did the provider report the misdemeanor conviction?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, or managing organization has been adjudged guilty of a misdemeanor that is related to health care abuse or neglect of a patient; financial misconduct; interference with a criminal investigation; or unlawful manufacture, distribution, or dispensing of a controlled substance.	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 15 – 18 and 20 – 27.	A misdemeanor is defined as a crime that has a maximum penalty—as specified in the criminal statute—by imprisonment for a period of not more than a year (i.e., one year or less).

TABLE 20 – REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – ACTIVE OIG EXCLUSION OR SAM DEBARMENT - REPORTED			
Current Exclusion or Debarment	**Did the provider report the exclusion?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel has an active OIG exclusion or SAM debarment.	Yes	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under § 424.535(a)(2) and any other applicable revocation reasons. Refer to Tables 15-19 and 21 – 27.	A waiver does not guarantee automatic enrollment into the Medicare program. All waivers shall be sent to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision, along with the corresponding ALA information and application.

TABLE 21 -- REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – ACTIVE OIG EXCLUSION OR SAM DEBARMENT – NOT REPORTED			
Current Exclusion or Debarment	**Did the provider report the exclusion?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel has an active OIG exclusion or SAM debarment.	No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.535(a)(2), 42 CFR § 424.535(a)(4) and/or any other applicable revocation reasons. Refer to Tables 15 – 20 and 22 – 27.	Note (a)(4) shall ONLY be included as a revocation reason if the provider has never reported this ALA. A waiver does not guarantee automatic enrollment into the Medicare program. All waivers shall be sent to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision, along with the corresponding ALA information and application.

TABLE 22 – REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – EXCLUSION/DEBARMENT – EXPIRED - REPORTED			
Exclusion or Debarment Status	**Did the provider report the exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel had an OIG exclusion or a federal/SAM debarment (or an exclusion by a federal agency other than OIG) and has been reinstated by OIG and/or HHS and/or the other federal agency.	Yes	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 15 – 20 and 23 – 27.	

TABLE 23 – REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – EXCLUSION/DEBARMENT – EXPIRED – NOT REPORTED			
Exclusion or Debarment Status	**Did the provider report the exclusion or debarment?**	**MAC Action**	**Notes**
Provider or an individual/entity listed on the application as a 5 percent or greater owner, partner, managing employee, corporate director, corporate officer, managing organization, authorized official, delegated official, medical director, supervising physician, or other health care or administrative or management services personnel had an OIG exclusion or a federal/SAM debarment (or an exclusion by a federal agency other than OIG) and has been reinstated by OIG and/or HHS and/or other federal agency.	No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.535(a)(4) and any other applicable revocation reasons. Refer to Tables 15 – 21 and 24 – 27.	Note that (a)(4) shall ONLY be included as a revocation reason if the provider has never reported this ALA. If CMS previously revoked this provider due to the prior OIG exclusion and the provider or associated individual/entity has been reinstated by OIG, the contractor shall process the application unless there is another reported or unreported ALA that precludes processing.

TABLE 24 - REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – MEDICARE PAYMENT SUSPENSION – CURRENT OR PAST			
Medicare Payment Suspension Status	**Did the provider report the Medicare payment suspension?**	**MAC Action**	**Notes**
Current Medicare payment suspension	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 15 – 22 and 25 – 27.	Providers are NOT required to report current or past Medicare payment suspensions to CMS.
Past Medicare payment suspension	Yes or No	Process application unless there is another reported or unreported ALA that precludes processing the application. Refer to Tables 15 – 22 and 25 – 27.	Providers are NOT required to report current or past Medicare payment suspensions to CMS.

TABLE 25 -- REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – MEDICARE REVOCATION – ACTIVE ENROLLMENT BAR			
Status	**Did the provider report the Medicare revocation?**	**MAC Action**	**Notes**
Enrollment bar is active in the state in which the provider is submitting this application, or the enrollment bar is active in another state.	Yes or No	If the application is for an enrollment that has an active reenrollment bar on the enrollment itself, the application should be returned.	.

TABLE 26 -- REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – OTHER PROGRAM TERMINATION (CURRENT)			
Other Program Termination	**Did the provider report the other program termination?**	**MAC Action**	**Notes**
The provider/supplier is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program.	Yes	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.535(a)(12) and any other applicable revocation reasons. Refer to Tables 15-25 and 27.	Revocation may be appropriate under 42 CFR § 424.535(a)(12) if the provider/supplier is currently terminated/suspended/barred from participation in a state Medicaid program or any other federal health care program (e.g., TRICARE). The state Medicaid program termination or suspension must occur by letter dated on or after January 1, 2011. Any other federal health care program (e.g., TRICARE) termination or suspension must occur by letter dated on or after March 17, 2020.

TABLE 27- REVALIDATION/CHANGE OF INFORMATION APPLICATIONS – FALSE CLAIMS ACT (FCA) CIVIL JUDGMENTS			
FCA Civil Judgments	**Did the provider report the FCA Civil Judgment?**	**MAC Action**	**Notes**
Provider, or any individual/entity listed as a 5 percent or greater owner, partner managing employee or organization, corporate officer, or corporate director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years.	Yes or No	Send application and ALA information to ProviderEnrollmentRevocations@cms.hhs.gov for review and decision under 42 CFR § 424.535(a)(15) and any other applicable revocation reasons. Refer to Tables 15 – 26.	The FCA (31 U.S.C. 3729–3733) is the federal government's principal civil remedy for addressing false or fraudulent claims for federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant. Revocation may be appropriate under 42 CFR § 424.535(a)(15) if the FCA civil judgment is within the preceding 10 years of the submission date of a Form CMS-855 or Form CMS-20134. FCA civil judgments must occur on or after January 1, 2024. Note the term ''civil judgment'' is not inclusive of FCA settlement agreements and should not be referred to CMS for review. Providers are NOT required to report FCA civil judgments to CMS.

10.6.7 – Owning and Managing Information
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

All references to "provider(s)" in sections 10.6.7.1 through 10.6.7.3 include "supplier(s)" (unless noted otherwise).

10.6.7.1 – Organizational Owning and Managing Information
(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

Except as stated otherwise, this section 10.6.7.1 only applies to the Organizational Ownership and/or Managing Control Section of the Forms CMS-855A, CMS-855B, CMS-855S and CMS-20134; it is inapplicable to the Form CMS-855I.

A. Ownership Information Required in Forms CMS-855A, CMS-855B, CMS-855S and CMS-20134

All organizations that have any of the following (referenced in (A)(1) through (A)(4) must be listed in the Organizational Ownership and/or Managing Control section of the Form CMS-855 and CMS-20134 (hereafter collectively the Form CMS-855).

1. <u>5 percent or greater direct or indirect ownership interest in the provider</u>

(i) Direct Ownership

Examples of direct ownership are as follows:

- As listed in Section 2 of the Form CMS-855, the enrolling SNF is Smith, Inc. All the stock in Smith is owned by Company A.
- Jones Hospice, LLC (which owns four other enrolled hospices) wants to enroll a fifth hospice in Medicare. Company X owns 100% of Jones Hospice, LLC.

In the first example, Company A is considered the direct owner of the SNF/Smith, Inc. Likewise, Company X is the direct owner of Jones Hospice, LLC.

The two crucial factors in ascertaining direct ownership are:

- Which entity/LBN is listed in Section 2 of the Form CMS-855?
- Who are the first-level owners of the entity listed in Section 2?

Using our above examples, Smith, Inc. and Jones, LLC are listed in Section 2. For purposes of reporting ownership, they are considered the enrolling providers. As Companies A and X are the first-level owners of Smith and Jones, respectively, they are considered direct owners.

(ii) Indirect Ownership

Many organizations that directly own a provider are themselves wholly or partly owned by other organizations (or even individuals). This often results from the use of holding companies and parent/subsidiary relationships. Such organizations and individuals are considered "indirect" owners of the provider. The term "indirect ownership interest" generally means any ownership interest in an entity that has an ownership interest in the provider/supplier; this also includes an ownership interest in any entity that has an indirect ownership interest in the provider/supplier. Using the first example in the "Direct Ownership" subsection above, if Company B owned 100% of Company A, Company B is considered an indirect owner of Smith, Inc.; in sum, a direct owner has an actual ownership interest in the provider (e.g., owns stock in the business, etc.), whereas an indirect owner has an ownership interest in an organization that owns the provider.

(iii) Examples of Direct vs. Indirect Ownership

The following scenario further illustrates the difference between direct and indirect ownership:

> **<u>EXAMPLE 1</u>:** The supplier listed in Section 2(A) of the Form CMS-855B is XYZ Ambulance Company, Inc. XYZ is wholly (100 percent) owned by Company A. Company A is considered a direct owner of XYZ, which is considered the enrolling supplier. Now

assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of XYZ/the supplier.

In terms of the calculation and reporting of indirect ownership interests, consider this modified example from the Form CMS-855A (though note that individuals would need to be reported in the Individual Ownership and/or Managing Control section of the Form CMS-855A and Form CMS-20134, discussed further below):

EXAMPLE 2

LEVEL 3 (Third-Level)	**Individual X**	**Individual Y**
	5%	30%
LEVEL 2 (Second-Level)	**Company C**	**Company B**
	60%	40%
LEVEL 1 (First-Level)	**Company A**	
	100%	
Enrolling Provider Listed in Section 2 – Z Hospital System, LLC (ZHS)		

- Company A owns 100% of the Enrolling Provider/ZHS, LLC
- Company B owns 40% of Company A
- Company C owns 60% of Company A
- Individual X owns 5% of Company C
- Individual Y owns 30% of Company B

In Example 2, Company A (Level 1) is the direct owner of the provider identified in Section 2 of the application (ZHS). Companies B and C, as well as Individuals X and Y, are indirect owners of the provider/ZHS. The calculation of ownership shares would be as follows:

LEVEL 1

Company A owns 100% of the Enrolling Provider. Company A must be reported.

LEVEL 2

To calculate the percentage of ownership held by Company C of the Enrolling Provider, multiply the percentage of ownership the LEVEL 1 owner has in the Enrolling Provider by the percentage of ownership the LEVEL 2 owner has in that LEVEL 1 owner.

• Company A, the LEVEL 1 (or direct) owner, owns 100% of the Enrolling Provider. Company C, a LEVEL 2 owner, owns 60% of Company A. Accordingly, multiply 100% (or 1.0) by 60% (.60). The result is .60. Company C indirectly owns 60% of the Enrolling Provider and must be reported.

- Repeat the same procedure for Company B, the other LEVEL 2 owner. Since Company B owns 40% of Company A, multiply this figure by 100% (again, the ownership stake Company A has in the Enrolling Provider). Company B thus owns 40% of the Enrolling Provider and must be reported.

This process is continued until all LEVEL 2 owners have been accounted for.

LEVEL 3

To calculate the percentage of ownership that Individual X has in the Enrolling Provider, multiply the percentage of ownership the LEVEL 2 owner has in the Enrolling Provider by the percentage of ownership the LEVEL 3 owner has in that LEVEL 2 owner. Per Example 2:

- Company C owns 60% of the Enrolling Provider, and Individual X (Level 3) owns 5% of Company C. Multiplying 60% (.60) by 5% (.05) results in .03. This means that Individual X owns 3% of the Enrolling Provider and need not be reported as an owner.
- Repeat this process for Company B, which owns 40% of the Enrolling Provider. Individual Y (Level 3) owns 30% of Company B. Multiplying 40% (.40) by 30% (.30) results in .12, or 12%. Since Individual Y owns 12% of the Enrolling Provider, Individual Y must be reported (in Section 6: Individuals).

This process is continued until all owners in LEVEL 3 have been accounted for. This process must be repeated for Levels 4 and beyond.

2. <u>5 percent or greater mortgage or security interest</u>

For purposes of enrollment, ownership also includes "financial control." Financial control exists when:

(a) An organization or individual is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the Enrolling Provider or any of the property or assets of the Enrolling Provider, and

(b) The interest is equal to or exceeds 5 percent of the total property and assets of the Enrolling Provider.

All entities with at least a 5 percent mortgage, deed of trust, or other security interest in the Enrolling Provider must be reported in the Organizational Ownership and/or Managing Control section. This frequently will include banks, other financial institutions, and investment firms. To calculate whether this interest meets the 5% threshold, divide the dollar amount of the mortgage/deed of trust/other obligation secured by the Enrolling Provider or any of the property or assets of the Enrolling Provider <u>by</u> the dollar amount of the total property and assets of the Enrolling Provider.

EXAMPLE: Two years ago, an Enrolling Provider obtained a $20 million loan from Entity X to add a third floor to its facility. Various assets of the provider secure the mortgage. The total value of the provider's property and assets is $100 million.

Using the above formula, divide $20 million (the dollar amount of the secured mortgage) by $100 million (the total property and assets of the Enrolling Provider). This results in .20, or 20%. Because Entity X's interest represents at least 5% of the total property and assets of the Enrolling Provider, Entity X must be reported in this section.

3. Partnerships

(a) General partnerships - Any general partnership interest in the Enrolling Provider, regardless of the percentage.

(b) For limited partnerships: All general partnership and limited partnership interests, regardless of the percentage.

Only partnership interests in the Enrolling Provider need be disclosed in the Organizational Ownership and/or Managing Control section. Partnership interests in the Enrolling Provider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the Enrolling Provider, this indirect ownership interest would have to be disclosed in this section.

See section 10.6.4(C) of this chapter for more information on the differences between general and limited partnerships.

4. Managing control of the provider

A managing organization is one that exercises operational or managerial control over the provider or conducts the day-to-day operations of the Enrolling Provider. The organization need not have an ownership interest in the Enrolling Provider to qualify as a managing organization; for instance, the entity could be a management services organization under contract with the Enrolling Provider to furnish management services for one of the provider's practice locations.

The organizations referred to above generally fall into one or more of the following categories:

- Corporations
- Partnerships and limited partnerships
- Limited liability companies
- Charitable and religious organizations
- Governmental/tribal organizations
- Banks and financial institutions
- Investment firms
- Holding companies
- Trusts and trustees
- Medical providers/suppliers
- Consulting firms

- Management services companies
- Medical staffing companies
- Non-profit entities
- Private equity companies
- Real estate investment trusts

In the Organizational Ownership and/or Managing Control section of the Form CMS-855 and CMS-20134, the provider must indicate the type(s) of organizational categories the reported entity falls into.

B. Special Requirements for Governmental and Tribal Entities

If a federal, state, county, city or other level of government, or an Indian tribe, will be legally and financially responsible for Medicare payments received (including any potential overpayments), the name of that government or Indian tribe should be reported as an owner. The provider must submit a letter on the letterhead of the responsible government (e.g., government agency) or tribal organization attesting that the government or tribal organization will be legally and financially responsible for any outstanding debt owed to CMS. This letter must be signed by an appointed or elected official of the government or tribal organization who has the authority to legally and financially bind the government or tribal organization to the laws, regulations, and program instructions of the Medicare program. This governmental or tribal official, however, need not be an authorized or delegated official, or vice versa; that is, the person need not be one of the provider's authorized or delegated officials listed in the Certification Statement Section of the Form CMS-855 or Form CMS-20134. The only requirement is that the individual have the binding authority described above, and the contractor shall assume such authority exists unless there is evidence to indicate otherwise.

In addition, governmental and tribal entities:

- Must be identified in the Organizational Ownership and/or Managing Control section even if they are already listed in the Identifying Information section.

- Governmental and tribal entities need not submit a copy of an IRS 501(c)(3) form if it is otherwise obvious to the contractor that the entity is a governmental or tribal entity. The contractor can assume that the governmental or tribal entity is non-profit. (See section 10.6.7(D)(3) below and section 10.6.4(G) of this chapter for more information on non-profit entities.)

C. Submission of Diagram

In addition to completing the Organizational Ownership and/or Managing Control section, the provider must submit an organizational structure diagram/flowchart identifying (1) all the entities listed in this section; and (2) the relationships they have with the provider and each other. (This applies to the Form CMS-855A, CMS-855B, CMS-855S and CMS-20134.) If the provider is a skilled nursing facility or opioid treatment program, it must also include in the diagram/flowchart all entities and individuals that have less than a 5 percent direct or indirect

ownership interest (and were thus not required to otherwise be listed in the Organizational or Individual Ownership and/or Managing Control sections).

The above-mentioned diagram/flowchart must be submitted for Form CMS-855 and CMS-20134: (1) initial enrollments; (2) revalidations; (3) reactivations; (4) certified provider and certified supplier changes of ownership based on the principles of 42 § CFR 489.18; and (5) upon any contractor request. Upon receiving the chart, the contractor shall review the data thereon to ensure it matches what the provider/supplier is reporting on the Form CMS-855/20134. If the data is inconsistent, the contractor shall develop for revised Form CMS-855/20134 data and/or a revised chart, as applicable. If the data remains inconsistent after development, the contractor may reject the application.

D. Supporting Data/Contractor Request and Additional Information

1. IRS CP-575

Owning/managing organizations need not furnish an IRS CP-575 document unless requested by the contractor (e.g., the contractor discovers a potential discrepancy between the organization's reported legal business name and tax identification number).

2. Proof of Owning/Managing Control and Percentages

Proof of ownership interest, partnership interest, managerial control, security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

In addition, the percentage of managing control need not be reported.

3. Non-Profit, Charitable and Religious Organizations

As mentioned in section 10.6.4(G) of this chapter, many non-profit organizations are charitable or religious in nature and are generally typically operated and/or managed by a board of trustees or other governing body. The actual name of the board of trustees or other governing body must be reported in the Organizational Ownership and/or Managing Control. (Individual board members should be listed in the Individual Ownership and/or Managing Control section.)

Non-profit organizations typically do not have owners, and thus the latter would not need to be listed as such on the application. To confirm its non-profit status, the provider must submit an IRS 501(c)(3) document. If the non-profit entity does have owners, however, they would need to be disclosed in the Ownership and/or Managing Control section consistent with the instructions in section 10.6.7 et seq.

4. Duplicate Listing

Any entity listed as the provider in the Identifying Information section of the Form CMS-855A, CMS-855B and CMS-20134 need not be reported in the Organizational Ownership and/or Managing Control section. The only exception involves governmental entities, which must be

identified in the Organizational Ownership and/or Managing Control section even if they are already listed in the Identifying Information section.

5. Disregarded Entities

In general, a "disregarded entity" is a term the IRS uses for an LLC that – for federal tax purposes only – is effectively indistinguishable from its single owner/member. The LLC's income and expenses are shown on the owner's personal tax return. The LLC itself does not pay taxes.

If an enrolling provider claims that it is a disregarded entity, the contractor need not obtain written confirmation of this from the provider notwithstanding the instruction in the Supporting Documents section of the Form CMS-855 or CMS-20134 that such confirmation is required. As a disregarded entity does not receive a CP-575 form from the IRS confirming its legal business name (LBN) and tax identification number (TIN), the contractor may accept from the enrolling provider any government form (such as a W-9) that lists its LBN and TIN. The disregarded entity's LBN and TIN shall be listed in the Identifying Information/Business Information section of the Form CMS-855.

6. Ownership Disclosures

Consistent with the foregoing policies in this section 10.6.7.1, CMS re-emphasizes the following:

(i) The provider/supplier must disclose ALL persons and entities that meet the definition of "owner" in section 10.1.1 of this chapter
(ii) The applicable ownership percentage must be disclosed for each owner listed
(iii) There cannot be indirect owners without direct owners (i.e., the provider/supplier cannot list only indirect owners and no direct owners)
(iv) The combined disclosed ownership percentages for the provider/supplier's organizational and individual direct owners cannot be greater than 100 percent

(Requirements (ii) and (iv) are inapplicable to applications that do not capture percentages of ownership.)

If the provider/supplier's ownership data does not meet the above-mentioned requirements, the contractor shall develop for the correct/complete data (e.g., the direct ownership total is greater than 100 percent) consistent with the instructions in this chapter.

7. PECOS Entry

The new and revised data elements on the 09/23 version of the Form CMS-855A will be included in PECOS 2.0. Most of them, however, will not be incorporated into the current version of PECOS. Accordingly, and until PECOS 2.0 is operational, the contractor need only enter the following new or revised 09/23 data elements into existing PECOS when processing a paper version of the 09/23 application:

- Private equity company (PEC) checkbox responses
- Real estate investment trust (REIT) checkbox responses

- Responses to the following question: "Is this organization itself owned by any other organization or by any individual?" (See subsection (D)(8) below for more information on this data element.)

The provider **must** respond to all three of these data requests on its application. The contractors shall develop for this information if the provider fails to do so.
(PECs and REITs are defined in 42 CFR § 424.502.)

8. Indirect Owner Checkbox

For each entity listed in Section 5(A) of the Form CMS-855A, the provider must indicate whether the organization is itself owned by another organization or individual. A "Yes" or "No" checkbox response is required for each entity, regardless of whether the submitted organizational chart (or any other previously or presently submitted data) already indicates the response (e.g., the chart shows that Indirect Owner A is Owned by Indirect Owner B).

9. Type of Entity

For each entity listed in Section 5(A), the provider must indicate in Section 5(B) the type of organization involved. A "Yes" or "No" checkbox response is required for each listed entity type, regardless of whether the submitted organizational chart (or any other previously or presently submitted data) already indicates the response.

10.6.7.2 – Individual Owning and Managing Information

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

(See section 10.6.7.1 for more detailed information on ownership/managerial disclosures.)

A. Owning and Managing Individuals Who Must Be Listed in this Section

All individuals who have any of the following must be listed in this section:

(i) Ownership - A 5 percent or greater direct or indirect ownership interest in the provider.

(ii) Mortgage/Security Interest - A 5 percent or greater mortgage or security interest in the provider.

(iii) Partnership Interests

(a) General partnerships - Any general partnership interest in the provider, regardless of the percentage.

(b) For limited partnerships: All general partnership and limited partnership interests, regardless of the percentage.

(iv) Managing Control of the Provider - For purposes of enrollment, such a person is considered a "managing employee." A managing employee is any individual, including a

general manager, business manager, office manager or administrator, who exercises operational or managerial control over the provider's business, or who conducts the day-to-day operations of the business. A managing employee also includes any individual who is not an actual W-2 employee but who, either under contract or through some other arrangement, manages the day-to-day operations of the business.

Hospice and SNF medical directors and administrators are considered managing employees under § 424.502. If a hospice or SNF fails to list its medical director and administrator on an initial, revalidation, reactivation, or CHOW Form CMS-855A application, the contractor shall develop for this information. This includes listing "medical director" or "administrator" in the "Title" box.

(v) Corporate Officers and Directors/Board Members

Officers and directors/board members must be listed in the Individual Ownership and/or Managing Control section if – and only if - the applicant is a corporation. (For-profit and non-profit corporations must list all their officers and directors. If a non-profit corporation has "trustees" instead of officers or directors, these trustees must be listed in this section of the Form CMS-855A, CMS-855B, CMS-855S and CMS-20134.)

Only the enrolling provider's officers and directors must be reported. Board members of the provider's indirect owners need not be disclosed to the extent they are not otherwise required to be reported (e.g., as an owner or managing employee) in this section. However, there may be situations where the officers and directors/board members of the enrolling provider's corporate owner/parent also serve as the enrolling provider's officers and directors/board members. In such cases – and again assuming that the provider is a corporation – the indirect owner's officers and directors/board members would have to be disclosed as the provider's officers and directors/board members in this section.

With respect to corporations, the term "director" refers to members of the board of directors. If a corporation has, for instance, a Director of Finance who nonetheless is not a member of the board of directors, he/she would not need to be listed as a director/board member in this section. However, he/she may need to be listed as a managing employee in this section.

(See sections 10.6.7.1(A) of this chapter for more information on direct and indirect ownership, mortgage and security interests, and partnerships.)

Officers and directors can also include persons who serve in a voluntary or ceremonial capacity. CMS re-emphasizes, however, that officers and directors apply only to corporations.

B. Specific Reporting Policies

1. Proof of Owning/Managing Control and Percentages –- Proof of ownership interest, partnership interest, managerial control (including W-2s and other proof of employment), security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

2. Government Entities – Government entities need only report their managing employees, for they do not have owners, partners, corporate officers, or corporate directors.

3. Minimum Number of Managing Employees - The provider must report all managing employees but must have at least one if it is completing the Form CMS-855A, CMS-855B, CMS-855S, or CMS-20134. An individual completing the Form CMS-855I need not list a managing employee if he/she does not have one.

4. Practice Locations on the Form CMS-855I - All managing employees at all practice locations listed in the Business Information/Practice Location Information section of the Form CMS-855I must be reported in the Managing Employee Information section. The only exceptions to this are individuals who are (a) employed by hospitals, health care facilities, or other organizations shown in the Business Information/Practice Location Information section (e.g., the chief executive officer of a hospital listed in this section) or (ii) managing employees of any group/organization to which the practitioner will be reassigning his/her benefits; these persons need not be reported.

5. Partnership Interests Involving Indirect Owners - Only partnership interests in the enrolling provider need be disclosed. Partnership interests in the provider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the enrolling provider, this indirect ownership interest would have to be reported.

6. Ownership Disclosures – Concerning ownership disclosures, the contractor shall adhere to the instructions in section 10.6.7.1(D)(6).

10.6.7.3 – Owning and Managing Information – Tax Identification Numbers (TINs)

(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A. General Disclosure Requirement

Consistent with sections 1124 and 1124A of the Social Security Act, the provider must report the TINs (employer identification numbers (EIN) or social security numbers (SSN)) of all entities and individuals listed in the Organizational and Individual Ownership and/or Managing Control sections of the Form CMS-855 and Form CMS-20134. If the provider fails to do so, the contractor shall follow normal development procedures for requesting the TIN.

When documentation of the provider's TIN and/or legal business name (LBN) is required, the contractor may accept a CP-575, a federal tax department ticket, or any other pre-printed document from the IRS that identifies the TIN and/or LBN.

Except as otherwise stated in this chapter, if a provider is changing its TIN the transaction shall be treated as a brand new enrollment as opposed to a change of information; the provider must complete a full Form CMS-855 or CMS-20134 and a new enrollment record must be created in PECOS.

B. TIN Disclosure Requirements for Individuals Who Do Not Have (and Are Ineligible to Obtain) an Employer Identification Number or an SSN from the Social Security Administration (SSA)

In following the normal development procedures for requesting an unreported but required TIN, the contractor shall undertake the applicable steps described in section 10.6.7.3(B)(1) and (2) below if it determines that the TIN was not furnished because the entity or person in question is not eligible to obtain a SSN from the SSA.

1. Contacting Provider

The contractor shall ask the provider (via any means) whether the person or entity can obtain a TIN or, in the case of individuals, an individual taxpayer identification number (ITIN). (Only one inquiry is needed.)

a. If the provider fails to respond to the contractor's inquiry within 30 days, the contractor shall follow the instructions in section 10.6.7.3(B)(2) below.

b. If the provider states that the person or entity is able to obtain a TIN or ITIN, the contractor shall send an e-mail, fax, or letter to the provider stating that: (i) the person or entity must obtain a TIN/ITIN; and (ii) the provider must furnish the TIN/ITIN on the Form CMS-855/20134 with a newly-signed certification statement within 90 days of the contractor's request.

c. If the provider states that the person or entity cannot obtain a TIN or ITIN, the contractor shall send an e-mail, fax, or letter to the provider stating that: (i) the provider must submit written documentation to the contractor explaining why the person or entity cannot legally obtain a TIN or ITIN; and (ii) the explanation – which can be in any written format and may be submitted electronically or via fax – must be submitted within 30 days of the contractor's request.

2. Provider Response

If the provider timely submits the explanation in section 10.6.7.3(B)(1)(c) above, the contractor shall forward the explanation to its CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL); PEOG will notify the contractor as to how the application should be handled. If the provider fails to timely respond to the contractor's inquiry in either section 10.6.7.3(B)(1)(a) or (c), the contractor shall – unless another CMS instruction directs otherwise - reject the application consistent with the procedures identified in this chapter.

3. Clock Stoppages

When the contractor is <u>required</u> under section 10.6.7.3(B)(2) to contact PEOG, the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision, instruction, or final guidance, as applicable. Interim communication between the contractor and PEOG during such "waiting periods" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

Optional communications---that is, communications with PEOG that are not specifically directed under section 10.6.7.3(B)(2)---do not stop the processing clock.

10.6.8 – Billing Agencies
(Rev. 10868; Issued: 07-14-21; Effective: 08-13-21; Implementation: 08-13-21)

A billing agency is an entity or person that furnishes billing and collection services on behalf of a provider/supplier. A billing agency does not enroll in the Medicare program; rather, it submits claims to Medicare in the name and billing number of the provider/supplier that furnished the service(s). To receive payment directly from Medicare on a provider/supplier's behalf, a billing agency must meet the conditions described in § 1842(b)(6)(D) of the Social Security Act.

The provider/supplier shall complete the Billing Agency section of the Forms CMS-855A, CMS-855B, CMS-855I, CMS-855S and CMS-20134 with information about all billing agents it utilizes. (Note that the billing agency address can be listed as a PO Box on the Form CMS-855 and CMS-20134 applications.) As all Medicare payments must be made via electronic funds transfer, the contractor need not verify the provider's compliance with the "Payment to Agent" rules in CMS Pub. 100-04, chapter 1, section 30.2. The only exception is if the contractor discovers that the "special payments" address in the Practice Location section of the provider's Form CMS-855 or CMS-20134 application belongs to the billing agent or agency. In this situation, the contractor may obtain a copy of the billing agreement if it has reason to believe that the arrangement violates the "Payment to Agent" rules.

For further information on billing agencies, see CMS Pub. 100-04, chapter 1, section 30.2.4.

10.6.9 – Contact Persons
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Unless stated otherwise in this chapter (such as section 10.3) or in another CMS directive -- or unless the provider requests that the contractor communicate with only a specific individual (e.g., an authorized official) or via specific means (e.g., only via the correspondence address e-mail) -- the contractor has the discretion to use the contact persons collected via the Forms CMS-855A, CMS-855B, CMS-855I, CMS-855O, CMS-855S and CMS-20134 for all written and oral communications (e.g., mail, e-mail, telephone) related to the provider's Medicare enrollment. Such communication need not be restricted to a particular enrollment application of the provider's that the contractor is currently processing. Nor is the contractor required (again, unless either CMS or the provider directs otherwise) to send certain materials to the correspondence mailing or e-mail address rather than the contact person's mailing or e-mail address.

The provider may have as many contact persons as it wishes.

If the contractor discovers that a particular contact person qualifies as an owning or managing individual, the provider shall list the person in the Individual Ownership and/or Managing Control section of the application.

If multiple contact persons are listed, the contractor has the discretion to select the individual to contact unless the provider indicates otherwise via any means. In addition:

(i) The contractor may use multiple contact persons throughout the enrollment process; it need not use the same individual for the entire duration unless, again, the provider indicates otherwise.

(ii) All contact persons shall be stored in PECOS and shall not be removed unless the provider requests the removal via letter, e-mail, fax, or---if the applicable Form CMS-855 contains an option for deleting a contact person---the Form CMS-855. Irrespective of whether the applicable Form CMS-855 contains such a deletion option, the contractor may accept end-dates of a contact person via telephone, email, fax, or mail from the provider, the authorized or delegated official, or a current contact person on file. The contractor shall document in the comment section in PECOS who requested the termination, how it was requested (email, phone, or fax) and when it was requested. The addition of contact persons must still be reported via the appropriate Form CMS-855.

10.6.10 – Medicare Payment

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Electronic Fund Transfers (EFT)

If a provider does not have an established enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS) and wants to change any of its EFT information (e.g., bank routing number), it must submit a complete Form CMS-855 or Form CMS-20134 before the contractor can effectuate the change.

It is immaterial whether the provider or the bank was responsible for triggering a change to EFT data (e.g., bank routing number).

Under 42 CFR § 424.510(d)(2)(iv) and § 424.510(e):

(i) All providers (including federal, state and local governments) enrolling in Medicare must use EFT in order to receive payments. However, a revalidating provider/supplier need not submit the most current version of the Form CMS-588 with its application unless: (1) it has no Form CMS-588 on file at all; or (2) it is changing any of its existing Form CMS-588 data.

(ii) If a provider is already receiving payments via EFT and is located in a jurisdiction that is undergoing a change of Medicare contractors, the provider must continue to receive payments via EFT. However, the change in contractors does not require the provider to submit a new Form CMS-588 unless CMS states otherwise.

(iii) For PECOS applications, the Form CMS-588 shall be submitted via PECOS.

The contractor shall also follow the EFT instructions in sections 10.3(C)(2) and 10.6.23 of this chapter.

B. Assignment of Part B Provider Transaction Access Numbers (PTANs)

1. Paper Applications - The contractor shall only assign the minimum number of PTANs necessary to ensure that proper payments are made. The contractor shall not assign additional PTAN(s) to a supplier merely because the individual or entity requests one - the only exception being for hospitals that request separate billing numbers for their hospital departments in the Identifying Information/Hospitals Only section of the Form CMS-855B. However, a hospital requesting an additional PTAN must associate the new PTAN with a National Provider Identifier (NPI) in the Practice Location Information section of the Form CMS-855B.

2. PECOS Applications – See section 10.3 of this chapter for information regarding the issuance of PTANs

C. NPI-Legacy Combinations

If the contractor determines that a provider is having claim payment issues due solely to an incorrect NPI-PTAN combination or NPI-CMS Certification Number (CCN) combination entered into PECOS, the contractor shall request that the provider submit the correct NPI-legacy combination via a Form CMS-855 or CMS-20134 change of information. The change request can be faxed, although the contractor shall verify the faxed signature against the provider's or authorized/delegated official's signature on file before any changes are made in PECOS.

The contractor shall not use this process to resolve any enrollment issue other than the correction of the NPI-legacy identifier combination. Moreover, the contractor shall not use this process for providers that have not submitted a complete Form CMS-855 or CMS-20134 enrollment application during or after May 2006. For instance, assume a provider first enrolled in Medicare in December 2005 and has not submitted a complete enrollment application after that date. The provider would be unable to utilize the process described in this section.

10.6.11 – Participation (Par) Agreements and the Acceptance of Assignment – General Information

(Rev. 11307; Issued: 03- 25-2022; Effective: 03-04-22; Implementation: 04-25-22)

All providers/suppliers must choose to be either Par or Non-Par when initially enrolling and must maintain the same Par status across all lines of business.

Individual physicians and non-physician practitioners who reassign benefits to a clinic/group practice inherit the Par status established by the clinic/group practice. However, if the individual physician or non-physician practitioner maintains a private practice (separate from the reassignment of benefits agreement), he/she may designate their own Par status. See Publication 100-04, chapter 1, section 30 for guidance on applying the correct Par status to clinic/group practices, organizations, and individuals in private practice.

The contractor shall follow the instructions in CMS Publication 100-04, chapter 1, sections 30 through 30.3.12.3 when handling issues related to par agreements and assignment. Queries related to the interpretation of such instructions shall be referred to the responsible CMS component.

Physicians and Part B organizations should be entered as Par in PECOS based on the submission of a signed Form CMS-460 (Medicare Participating Physician or Supplier Agreement) upon initial enrollment or during a change to their Par status during the annual Medicare Open Enrollment period. Non-Physician Practitioners that are considered mandatory participation and individual physicians and non-physician practitioners that reassign all of their benefits to a Par organization should not be entered as Par in PECOS.

10.6.12 – Opting-Out of Medicare

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Physicians and practitioners are typically required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. They are also not permitted to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare-covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to CMS Pub. 100-02, Chapter 15, sections 40 - 40.39 for more information regarding the maintenance of opt-out affidavits and the effects of improper billing of claims during an opt-out period.

The instructions in this section 10.6.12 address the contractor's processing of opt-out affidavits. (See Pub. 100-02, chapter 15, section 40.8 for private contract definitions and requirements.)

A. Who May Opt-Out of Medicare

Only the following physicians and practitioners (sometimes collectively referenced as "eligible practitioners" in this section) can "opt-out" of Medicare:

Physicians who are:

- Doctors of medicine or osteopathy,
- Doctors of dental surgery or dental medicine,
- Doctors of podiatry, or
- Doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the state in which such function or action is performed.

Non-physician practitioners who are:

- Physician assistants,
- Nurse practitioners,
- Clinical nurse specialists,
- Certified registered nurse anesthetists,
- Certified nurse midwives,
- Clinical psychologists,
- Clinical social workers,
- Registered dietitians or nutrition professionals who are legally authorized to practice by the state and otherwise meet Medicare requirements,

- Mental health counselors, or
- Marriage and family therapists

(Organizations are not permitted to opt-out of Medicare.)

This means that neither the eligible practitioner nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the eligible practitioner out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the eligible practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. (The contract, though, must be signed before the services are provided so the beneficiary is fully aware of the eligible practitioner's opt-out status.) Moreover, the eligible practitioner must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The contractor's provider enrollment unit must process these affidavits.

Eligible practitioners who opt-out of Medicare are not the same as non-participating physicians/suppliers. The latter are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment-related basis as required by law (e.g., for drugs, ambulance services, etc.). Non-participating physicians/suppliers must therefore comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Opt-out eligible practitioners, on the other hand, are excused from the mandatory claim submission, assignment, and limiting charge rules, though **only** when they maintain compliance with all of the requirements for opting out.

In an emergency care or urgent care situation, an eligible practitioner who has opted-out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the eligible practitioner must complete a Form CMS-855 application.

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, chapter 15, section 40.9, the affidavit shall state that, upon signing the affidavit, the eligible practitioner agrees to the following requirements:

- Except for emergency or urgent care services, during the opt-out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;

- The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary;

- During the opt-out period, the eligible practitioner understands that he/she may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible practitioner has privately contracted, whether

as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- An eligible practitioner who opts out of Medicare acknowledges that, during the opt-out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;

- On acknowledgment by the eligible practitioner to the effect that, during the opt- out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;

- Acknowledge that the eligible practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the eligible practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the eligible practitioner has not previously privately contracted) without regard to any payment arrangements the eligible practitioner may make;

- With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

- Acknowledge that the eligible practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services;

- Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and

- Be filed with all MACs that have jurisdiction over claims the eligible practitioner would otherwise file with Medicare; the initial two-year opt-out period will begin the date on which the affidavit meeting the requirements of 42 C.F.R. § 405.420 is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs his or her first private contract with a Medicare beneficiary.

(See Pub. 100-02, chapter 15, section 40.9 for more information on the requirements of opt-out affidavits. See also section 10.6.12(B)(5) below for acceptable opt-out formats.)

The contractor shall review initial opt-out affidavits to ensure that they contain the following information about the eligible practitioner to create an affidavit record in PECOS:

- Full name (first, middle and last),
- Birthdate,
- Address, telephone number, and e-mail address
- License information,
- NPI (if one has been obtained),
- SSN (if no NPI has been issued, though note that this cannot be an individual tax

identification number (ITIN)), and
- Contact person name, telephone number, and e-mail address (if different from the opting-out physician or practitioner)

If, to create a PECOS affidavit record, the contractor needs to obtain data that is missing from an affidavit, it may (1) obtain this information from other sources (such as the state license board) or (2) contact the eligible practitioner only **one time** directly. The contractor shall **not** use Internet-based PECOS or the Form CMS-855 to secure the data from the eligible practitioner, for the eligible practitioner **is not** enrolling in Medicare. If the eligible practitioner is requested to submit missing information to permit the processing of the affidavit and fails to do so within 30 days, the contractor shall reject the opt-out affidavit.

2. Opting-Out and Ordering/Certifying/Referring

If an eligible practitioner who wishes to opt-out elects to order/certify/refer Medicare items or services, the contractor shall develop for the date of birth (if not provided on the affidavit):

If this information is requested but not received, the eligible practitioner's affidavit can still be processed; however, he/she cannot be listed as an ordering/certifying/referring provider.

3. Adverse Actions

The contractor shall review the List of Excluded Individuals and Entities (LEIE) and the System for Award Management (SAM) for all eligible practitioners who submit opt-out affidavits. Excluded eligible practitioners may opt-out of Medicare but cannot order certify/refer.

As noted in 42 CFR § 405.425(i) and (j), individuals who are revoked from Medicare cannot order, certify, or refer Part A or B services or items to Medicare beneficiaries if they opt-out of Medicare after revocation.

4. No Dual Status

a. Form CMS-855O - Eligible practitioners cannot be enrolled via the Form CMS-855O and actively opted-out simultaneously. Prior to processing an initial Form CMS-855O or opt-out affidavit submission, therefore, the contractor shall confirm that an approved Form CMS-855O enrollment or valid opt-out affidavit does not exist in PECOS. If an approved enrollment or affidavit indeed exists, the contractor shall return the pending application.

b. Form CMS-855I – A Form CMS-855I enrollment can simultaneously exist with a valid opt-out affidavit **only** if the Form CMS-855I is to bill for emergency services. If a Form CMS-855I is received **and** an opt-out affidavit is active, the contractor shall contact the eligible practitioner (via any means) to clarify if he/she submitted the application to solely bill for emergency services provided to a beneficiary. If so, the application shall be processed via normal procedures. If not, the application may be returned. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

An eligible practitioner who has opted out of Medicare need not also enroll via the Form CMS-855O if he/she wishes to order/refer/certify (e.g., providing the necessary information on his/her affidavit per this section 10.6.12).

5. Acceptable Opt-Out Affidavit Formats

The contractor may provide a sample opt-out affidavit form for eligible practitioners to complete. The opt-out affidavit form must provide spaces for the eligible practitioners to furnish their personal information.

Eligible practitioners may also create their own affidavit. If he/she elects to do so, he/she should include information found in section 10.6.12(B)(1) to ensure timely processing of the opt-out affidavit.

The contractor and eligible practitioners may use the information below as an opt-out affidavit form.

I, {Enter Physician/Non-Physician Practitioner Name}, being duly sworn, depose and say:

- Opt-out is for a period of two years. At the end of the two year period, my opt-out status will automatically renew. If I wish to cancel the automatic extension, I understand that I must notify my Medicare Administrative Contractor (MAC) in writing at least 30 days prior to the start of the next two-year opt-out period.

- Except for emergency or urgent care services (as specified in the Medicare Benefit Policy Manual Publication 100-02, Chapter 15 §40.28), during the opt-out period I will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services.

- I will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will I permit any entity acting on my behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 40.28.

- During the opt-out period, I understand that I may receive no direct or indirect Medicare payment for services that I furnish to Medicare beneficiaries with whom I have privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under Medicare Advantage.

- I acknowledge that during the opt-out period, my services are not covered under Medicare and that no Medicare payment may be made to any entity for my services, directly or on a capitated basis.

- I acknowledge and agree to be bound by the terms of both the affidavit and the private contracts that I have entered into during the opt-out period.

- I acknowledge and understand that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by myself during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom I have not previously privately contracted) without regard to any payment arrangements I may make.

- I acknowledge that if I have signed a Part B participation agreement, that such agreement terminates on the effective date of this affidavit.

- I acknowledge and understand that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if I furnish such services.

- I have identified myself sufficiently so that the MAC can ensure that no payment is made to me during the opt-out period. If I have already enrolled in Medicare, I have included my Medicare PTAN, if one has been assigned. If I have not enrolled in Medicare, I have included the information necessary to opt-out.

- I will file this affidavit with all MACs who have jurisdiction over claims that I would otherwise file with Medicare and the initial two- year opt-out period will begin the date the affidavit meeting the requirements of 42 C.F.R. §405.420 is signed, provided the affidavit is filed within 10 days after the physician/practitioner signs his or her first private contract with a Medicare beneficiary.

Eligible practitioners should also be encouraged to include the following information (to complete an affidavit record in PECOS): Medicare Identification Number (if issued); date of birth; specialty; e-mail address; any request to order/certify/refer.

C. Effective Date of an Opt-Out Period

As noted in Pub. 100-02, chapter 15, section 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

Eligible practitioners need not enroll prior to opting-out of Medicare. If a non-enrolled eligible practitioner submits an opt-out affidavit, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

2. Non-Participating Practitioners

If an eligible practitioner who is a non-participating provider decides to terminate his/her active Medicare billing enrollment and instead opt-out of Medicare, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

3. Participating Practitioners

If an eligible practitioner who is a participating provider (one who accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. Per 42 CFR § 405.410(d), an eligible practitioner may opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in 42 CFR § 405.420 is submitted to the applicable contractor(s) at least 30 days before the beginning of the selected calendar quarter. (The contractor shall, however, add 5 calendar days to the 30-day period to allow for mailing.) An opt-out affidavit must therefore be submitted at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is submitted within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, for the affidavit was not submitted at least 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

4. Opt-Out After Enrollment

(This section 10.6.12(C)(4) applies notwithstanding any instruction to the contrary in this chapter.)

If an enrolled physician or eligible practitioner is now opting-out, the existing PECOS enrollment record shall be end-dated the same day as the affidavit effective date.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, he/she must apply for enrollment via the Form CMS-855I. Once he/she receives his/her PTAN, he/she must submit the claim(s) for any emergency or urgent care service furnished. The contractor shall contact its PEOG BFL for additional guidance when this type of situation arises. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

E. Termination of an Opt-Out Affidavit

As noted in Pub. 100-02, chapter 15, section 40.35, an eligible practitioner who has not previously opted-out may terminate his/her opt-out period early. However, he/she must submit written notification thereof (with his/her signature) no later than 90 days after the effective date of the initial 2-year opt-out period. To properly terminate an affidavit, moreover, the eligible practitioner must:

1. Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of his/her opt-out);
2. Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;

3. Notify all beneficiaries (or their legal representation) with whom the eligible practitioner entered into private contracts of the eligible practitioner's decision to terminate his/her opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period and;
4. Refund to each beneficiary with whom the physician or practitioner has privately contracted all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.

For eligible practitioners who were previously enrolled to bill Medicare for services, the contractor shall reactivate the eligible practitioner's enrollment record in PECOS and reinstate his/her PTAN as if no opt-out affidavit existed. The eligible practitioner may bill for services provided during the opt-out period.

For eligible practitioners who were not previously enrolled to bill Medicare for services, the contractor shall remove the affidavit record from PECOS; this will help ensure that the eligible practitioner can submit the appropriate application(s) (via PECOS or paper Form CMS-855 for individual and/or reassignment enrollment) in order to establish an enrollment record in PECOS and thus bill for services rendered during the opt-out period.

F. Opt-Out Period Auto-Renewal and Cancellation of the Opt-Out Affidavit

1. General Policies

Eligible practitioners who initially opted-out or renewed an affidavit on or after June 16, 2015 need not submit a renewal of their affidavit. The opt-out will be automatically renewed for another 2-year period. Yet if the eligible practitioner decides to cancel his/her opt-out, he/she must submit a written notice to each contractor to which he or she would file claims (absent the opt-out) not later than 30 days before the end of the current 2 year opt-out period.

If the eligible practitioner decides to enroll in Medicare after his/her opt-out is canceled, he/she must submit a Form CMS-855I application. The effective date of enrollment, however, cannot be before the cancellation date of the opt-out period. (For example, suppose an eligible practitioner submits a cancellation of her opt-out to end the period on March 31, which is two years from the eligible practitioner's opt-out affidavit effective date. Her requested effective date of enrollment cannot be before April 1.)

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights.

2. Auto-Renewal Report and Opt-Out Renewal Alert

The contractor shall issue an Opt-Out Renewal Alert Letter (found in section 10.7.14(E) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. For this purpose, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The contractor shall access the report monthly through the Share Point Ensemble site. The contractor shall also review the opt-out report for opted-out eligible practitioners that will auto-

renew in the next three-and-a-half months. In addition, the contractor shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date; the eligible practitioner will thus have at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide (1) the date on which the current opt-out period will be auto renewed and (2) the date by which the eligible practitioner will need to submit a cancellation request. The letter will also furnish the eligible practitioner appeal rights if he/she fails to submit a cancellation request and the opt-out renews.

The contractor shall (1) complete the Opt-Out Renewal Alert Letter Report to include the date the Alert Letter was issued, (2) post its reports no later than the 15th of the following month to the Share Point Ensemble site, and (3) email its PEOG BFL when the report has been posted.

If an opted-out eligible practitioner submits a Form CMS-855I without submitting a cancellation request of his or her opt-out, the contractor shall develop for the cancellation notice. Once the cancellation notice is received, the contractor shall then process the application(s).

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights using the Late Cancellation Request return letter. In addition, if the eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date, the contractor shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

G. Failure to Properly Cancel or Terminate Opt-Out

Eligible practitioners who fail to properly cancel or terminate their opt-out may appeal the decision to continue (1) the auto-renewal of the opt-out or (2) the eligible practitioner's initial opt-out period.

Opt-out approval letters include appeal rights for eligible practitioners who initially opt-out and fail to properly terminate the opt-out within 90 days of the approval.

10.6.13 – Ordering/Certifying Suppliers
(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Ordering/Certifying Suppliers– Background

1. Who Can Order/Certify

Pursuant to CMS Final Rule 6010-F (published April 27, 2012), to order or certify for Medicare items and services, a provider or supplier must be enrolled (i.e., in an approved or valid opt-out status) in PECOS.

Generally, depending upon state law, the following physicians and non-physician practitioners are permitted to order or certify items or services for Medicare beneficiaries:

- Doctors of medicine or osteopathy
- Doctors of dental surgery or dental medicine
- Doctors of podiatry
- Doctors of optometry
- Physician assistants
- Certified clinical nurse specialists
- Nurse practitioners
- Clinical psychologists
- Certified nurse midwives
- Clinical social workers
- Residents meeting eligibility criteria (Pursuant to CMS Final Rule CMS-6010-F, residents (as defined in 42 CFR § 413.75 and which includes interns and fellows) who are enrolled in an accredited graduate medical education program in a state that licenses or otherwise enables such individual to practice or order these items or services may enroll in Medicare to order and certify).

Most physicians and non-physician practitioners enroll in Medicare so they can receive reimbursement for covered services to Medicare beneficiaries. However, some physicians and non-physician practitioners who are not enrolled in Medicare via the Form CMS-855I may wish to order or certify items or services for Medicare beneficiaries. These individuals can become eligible to do so by completing the Form CMS-855O via paper or PECOS.

NOTE: It is important to observe that physicians and non-physician practitioners that complete the Form CMS-855O do not and will not send claims to a Medicare contractor for services they furnish. They are not afforded Medicare billing privileges for the purpose of submitting claims to Medicare directly for services that they furnish to beneficiaries. Such persons may be:

- Employed by the Department of Veterans Affairs (DVA)
- Employed by the Public Health Service (PHS)
- Employed by the Department of Defense (DOD) Tricare
- Employed by the Indian Health Service (IHS) or a tribal organization

- Employed by a federally qualified health center (FQHC), rural health clinic (RHC), or critical access hospital (CAH)

- Licensed residents and physicians in a fellowship (see subsection B)

- Dentists, including oral surgeons

- Pediatricians

B. Requirements for Suppliers to Maintain Ordering and Certifying Documentation

1. Background

Under 42 CFR § 424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation (see next paragraph) for 7 years from the date of service, and

- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

In addition, under § 424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain the documentation described in the previous paragraph for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request.

If the provider, supplier, physician or eligible professional (as applicable) fails to maintain this documentation or to furnish this documentation upon request, the contractor may revoke enrollment under § 424.535(a)(10).

2. Contractors Requests for Documentation of Ordering or Certifying

Absent a CMS directive to the contrary, the contractor shall request the documentation described in subsection (A) if it has reason to believe that the provider, supplier, physician, or other eligible professional (hereinafter collectively referred to as “provider”) is not maintaining the documentation in accordance with § 424.516(f)(1) or (2). Examples of when a request might be appropriate include, but are not limited to:

- The contractor has detected an unusually high number of denied claims involving the provider, or the Fraud Prevention System has generated an alert with respect to the provider.

- The provider has been the subject of a recent Unified Program Integrity Contractor referral.

- The provider maintains an elevated surety bond amount.

These are, of course, only examples of when a request could perhaps be warranted. Ultimately, the contractor would have to consider the surrounding circumstances of each case, including those involving situations not addressed in the aforementioned examples. The contractor may always contact its PEOG BFL if it is uncertain as to whether a particular documentation request should be made.

NOTE: Documentation cannot be requested for written orders and certifications dated prior to July 6, 2010.

3. Requirement for Providers and Suppliers to Maintain and Provide Access to Documentation

Under § 424.516(f), CMS or a Medicare contractor may request access to documentation described in §424.516(f). The term "access to documentation" means that the documentation is actually provided or made available in the manner requested by CMS or a Medicare contractor. All providers and suppliers who either furnish, order, or certify the items described in section 10.6.13(B)(1) are subject to this requirement and are individually responsible for maintaining these records and providing them upon request.

For example, if a Medicare contractor requests copies of all orders for wheelchairs from an ordering physician for all beneficiaries with dates of service from November 1, 2014 through November 10, 2014, the ordering physician must provide the copies, in full, according to the specific request. If copies cannot be provided because the physician or other eligible professional did not personally maintain the records or can only be partially provided, then the requirement to maintain this documentation and provide access to it will not have been met and the provider, supplier, physician, or other eligible professional may be revoked under § 424.535(a)(10).

Examples of Sufficient and Deficient Access may include, but are not limited to:

Sufficient Access:

- All documentation requested

- Documentation specific to the order(s) or certification(s), as requested

- Documentation for the dates of service or billing periods requested

Deficient Access

- Providing none of the requested documentation
- Providing none of the requested documentation
- Providing similar documentation that does not contain the order or certification requested
- Providing other documents NOT requested by CMS or a Medicare contractor and/or not specifically directing attention to the requested documentation

The CMS recognizes that providers and suppliers often rely upon an employer or another entity to maintain these records on their behalf. However, it remains the responsibility of the individual or entity to whom/which the request has been made to provide documentation. All individuals and entities subject to this documentation requirement are responsible for ensuring that documents are provided upon request and may ultimately be subject to the revocation basis associated with non-compliance with the documentation request.

4. Process to Request Documentation of Ordering or Certifying

If the contractor believes that a request for documentation is warranted, it shall prepare and send a request letter (refer to model letters at the end of this chapter) to the provider via certified mail. If the provider:

- Fails to respond within 30 calendar days of the contractor's request (i.e., a complete non-response), the contractor shall revoke enrollment using § 424.535(a)(10) as the basis. Prior approval from the contractor's PEOG BFL is not necessary. A 1-year re-enrollment bar shall be imposed.
- Timely furnishes documentation that the contractor nevertheless deems inadequate, the contractor shall send a developmental letter via mail, the PCV, e-mail, or fax to the provider that requests more sufficient documentation. If the provider fails to submit such documentation (either via a complete non-response or by submitting additional inadequate documentation), the contractor shall refer the matter (including the documentation submitted to date) to its PEOG BFL. CMS will determine whether a revocation is warranted and will notify the contractor via e-mail of its decision.
- Furnishes documentation that the contractor deems adequate, the contractor need not take further action other than to upload the documentation and the documentation request letter(s) in PECOS.

5. Additional Guidance Regarding Documentation of Ordering or Certifying

The contractor shall also abide by the following:

a. When preparing the letter referred to in section 10.6.13(B)(4) above, the contractor shall use the appropriate model language in section 10.7.17 and 10.7.17 (A) of this chapter. Note,

however, that while the letters request copies of orders, the contractor has the discretion to ask for different or additional documentation (e.g., documentation that supports the legitimacy of a particular service or the payment of a particular claim). Copies of orders need not be requested in every situation. As alluded to in section 10.6.13(B)(2) above, the contractor would have to examine the facts of each case in determining the type(s) of documentation to be requested.

b. There may be situations in which CMS directs the contractor to request documentation in a particular case. The contractor shall follow the instructions in this section 10.6.13(B) with respect to doing so.

c. The contractor shall contact its CMS PEOG BFL if it has questions as to whether particular submitted documentation is adequate or legitimate – specifically, whether it falls within the category of documentation described in section 10.6.12(B)(3) above.

10.6.14 – Application Fees

(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)

(The contractor shall review section 10.3 of this chapter for special instructions regarding application fee and waiver submissions with PECOS applications.)

A. Background

Pursuant to 42 CFR § 424.514 - and with the exception of physicians, non-physician practitioners, physician group practices, non-physician group practices, and Medicare Diabetes Prevention Program (MDPP) suppliers – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR § 424.515 (regardless of whether the revalidation application was requested by CMS or voluntarily submitted by the provider or supplier), must submit with their application:

- An application fee in an amount prescribed by CMS, and/or
- A request for a hardship exception to the application fee.

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR § 424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations), Form CMS-855S, or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. A physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

For a list of fee requirements broken out by provider/supplier and application type, refer to the Application Fee Matrix.

Except as otherwise noted, nothing in this section 10.6.14 supersedes any other CMS directive to the contractor pertaining to application fees.

(For purposes of this section 10.6.14, the term "provider" will be used in lieu of "institutional provider.")

B. Contractor Activities Upon Receipt

Upon receipt of a paper or PECOS application from a provider that is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

1. Determine whether the provider has: (1) paid the application fee via Pay.gov (all payments must be made via Pay.gov); and/or (2) included a hardship exception request with the application or certification statement.

2. Outcomes

i. The provider has neither paid the fee nor submitted the hardship exception request-- The contractor shall send a development letter to the provider notifying it that: (A) it has 30 days from the date of the letter to pay the application fee via Pay.gov and any other items that may be missing or needed; and (B) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations).

ii. The provider has submitted a hardship exception request but has not paid a fee - The contractor shall send the request and all documentation accompanying the request via e-mail to its PEOG BFL. If CMS:

- Denies the hardship exception request – CMS will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall determine whether the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR § 424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR § 424.535(a)(6) (revalidations).

  (The contractor shall begin processing the application as normal if, at any time during this 30-day period: (1) for paper applications, the provider submits a Pay.gov receipt as proof of payment; or (2) for PECOS applications, the provider pays the fee via PECOS.)

- Approves the hardship exception request - CMS will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall continue processing the application as normal.

iii. Has submitted a hardship exception request and has paid a fee - The contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its

PEOG BFL. As the fee has been paid, the contractor shall begin processing the application as normal.

3. PECOS Applications

(For PECOS applications, the provider must submit any required application fee (i.e., initials, revalidations, new practice locations) or hardship waiver via PECOS at the time it submits its application; otherwise, PECOS will not accept the application. Some of the instructions in subsection (B)(2) may therefore be inapplicable to PECOS applications.)

As stated in section 10.3 of this chapter, application fees can be combined if multiple enrollment records are implicated by the submission (e.g., consolidated application), but each application still requires a separate fee. To illustrate, suppose an entity is enrolling 5 different IDTFs, and the fee amount is $631 per IDTF. The provider can submit separate $631 fees or can combine them into a $3,155 payment. In the case of hardship waivers, however, 5 separate hardship waivers – one for each enrollment – must be submitted; they cannot be combined into one waiver request.

C. Fee Amount

1. General Background

Except as stated in subsection (C)(2), the application fee must be in the amount prescribed by CMS for the calendar year (1) in which the application is submitted (for PECOS applications) or (2) of the postmark date (for paper applications). The current fee amount can be found via PECOS at the following link: https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do

Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year. CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

2. Transition to Subsequent Year

There can be situations where the provider submits an application in the previous calendar year without a required fee, the contractor develops for the fee, and the provider submits the fee in the subsequent year. The submitted fee must be that for the subsequent year and not the preceding year.

D. Non-Refundable

Per 42 CFR § 424.514(d)(2)(v), the application fee is non-refundable unless it was submitted with one of the following:

1. A hardship exception request that is subsequently approved;

2. An application that was rejected prior to the contractor's initiation of the screening process; or

3. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR § 424.570.

(For purposes of section 10.6.14(D) only, the term "rejected" includes applications that are returned.)

In addition, the fee should be refunded if: (i) it was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number); or (ii) it was not part of an application submission.

E. Format

The provider must submit the application fee electronically through https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do, either via credit card, debit card, or electronic check.

Should the provider submit an application with a paper check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in section 10.4(C) of this chapter (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via.Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.

F. Practice Locations

DMEPOS suppliers, federally qualified health centers (FQHCs), independent diagnostic testing facilities (IDTFs), and certain other provider and supplier types described in this chapter must individually enroll each site. The enrollment of each site thus requires a separate fee. For **all other providers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. (This includes the addition of a hospital unit – such as a psychiatric unit – in the Practice Location section of the Form CMS-855A.) If multiple locations are being added on a single application, however, only one fee is required; indeed, the fee for providers that are not required to separately enroll each location is based on the application submission, not the number of locations listed on a single application.

G. Other Application Fee Policies

1. PECOS Enrollment Records

a. Paper Applications - The fee is based on the Form CMS-855 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In the Identifying Information/hospital type section of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.

b. PECOS Applications – In a similar vein, the fee is based on the number of applications involved. Even if the provider submits one set of data into PECOS, it may involve several different applications, thus requiring separate fees. To illustrate, assume a provider exists in Tennessee, Arkansas, and Missouri, each of which is in a separate contractor jurisdiction. As discussed in section 10.3 of this chapter, the group may submit a consolidated application (e.g., one set of data encompassing all three enrollments), which PECOS would then split into three separate applications. Three fees must be paid, however, because three separate enrollment applications are involved.

2. Group Practices/Clinics

A physician/non-physician practitioner clinic or group practice enrolling via the Form CMS-855B is exempt from the fee even if it is tribally-owned/operated or hospital-owned. Yet if a hospital is adding a physician/non-physician practitioner clinic or group practice to its Form CMS-855A enrollment, a fee is required because the hospital is adding a practice location.

3. Change of Ownership via Form CMS-855B or Form CMS-855S

A provider or supplier need not pay an application fee if the application is reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

4. Reporting a Change in Tax Identification Number

A provider need not pay an application fee if the application is reporting a change in TIN for a Part A, Part B, or DMEPOS provider or supplier.

5. Requesting a Reactivation

A provider need not pay an application fee to reactivate Medicare billing privileges unless the provider/supplier was deactivated for failing to respond to a revalidation request, in which case the resubmitted application constitutes a revalidation (not a reactivation) application, hence requiring a fee.

6. Changing the Physical Location of an Existing Practice Location

A provider need not pay an application fee when changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

The application fee requirement is separate and distinct from the site visit requirement and risk categories discussed in this chapter. Physicians, non-physician practitioners, physician groups, and non-physician practitioner groups are exempt from the application fee even if they fall within the "high" level of categorical screening per 42 CFR § 424.518. Likewise, physical therapists enrolling as individuals or group practices need not pay an application fee even though they fall within the "moderate" level of categorical screening and are subject to a site visit.

H. Refund Requests

Unless otherwise approved by CMS, the provider must request a refund no later than 150 days from the date it submitted its application. In its request, the provider shall include documentation acceptable to process the refund request. For credit card refunds, the provider shall include its Pay.gov receipt or the Pay.gov tracking ID number.

If a refund is requested and the fee was paid via ACH Debit, the contractor shall collect from the provider a completed "Authorization and Payment Information Form for Electronic Funds Transfer" form (previously furnished to contractors) and submit it to the PEMACReports@cms.hhs.gov mailbox. In the subject line of this e-mail, the contractor shall: (1) identify the provider's legal business name, National Provider Identifier (NPI), and the Pay.gov Tracking ID; and (2) include the completed, previously-mentioned form.

I. Institutional Provider and Fee: Year-to-Year Transition

There may be isolated instances where, at the end of a calendar year, a provider pays the fee amount for that year (Year 1) but the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider must pay the Year 2 fee. The contractor shall thus: (1) send an e-mail to its PEOG BFL requesting a full refund of the fee and including any pertinent documentation in support of the request; and (2) send a letter to the provider notifying it that (i) it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) via Pay.gov and (ii) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

J. Hardship Exception

1. Background

A provider requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via PECOS, the hardship exception letter must accompany the application (i.e., the provider must upload the letter and supporting documentation into PECOS). Hardship exception letters shall not be considered if they were submitted separately from the application. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider; and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee generally should not represent a significant burden for an adequately capitalized provider. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including furnishing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that may suggest that a hardship exception is appropriate include the following:

a. Considerable bad debt expenses,

b. Significant amount of charity care/financial assistance furnished to patients,

c. Presence of substantive partnerships (whereby clinical and/or financial integration are present) with those who furnish medical care to a disproportionately low-income population,

d. Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or

e. Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. CMS has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. CMS will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 10.6.14(K) below.

If the provider fails to submit appropriate documentation to support its request, the contractor need not contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG BFL. It is ultimately the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

K. Appeals of Hardship Determinations

A provider may appeal CMS' denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with CMS' decision to deny a hardship exception request, it may file a written reconsideration request with CMS within 60 calendar days from receipt of the notice of initial determination (e.g., CMS' denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity.

Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Notwithstanding the filing of a reconsideration request, the contractor shall still implement the post-hardship exception request instructions in this section 10.6.14(K). A reconsideration request, in other words, does not stay the implementation of section 10.6.14(K)'s instructions.

The CMS has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be: (a) conducted by a CMS staff person who was independent from the initial decision to deny the hardship exception request; and (b) based on CMS' review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, CMS will send a letter to the provider to acknowledge receipt of its request. In its acknowledgment letter, CMS will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

If CMS denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If CMS approves the reconsideration request, it will notify the provider of this via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

i. If the application has already been rejected, request that the provider resubmit the application without the fee, or

ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services

Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request but the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request but the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such requests shall be filed within 60 days from receipt of the notice of the DAB's decisi**(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)**

(The contractor shall review section 10.3 of this chapter for special instructions regarding application fee and waiver submissions with PECOS applications.)

A. Background

Pursuant to 42 CFR § 424.514 - and with the exception of physicians, non-physician practitioners, physician group practices, non-physician group practices, and Medicare Diabetes Prevention Program (MDPP) suppliers – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR § 424.515 (regardless of whether the revalidation application was requested by CMS or voluntarily submitted by the provider or supplier), must submit with their application:

- An application fee in an amount prescribed by CMS, and/or

- A request for a hardship exception to the application fee.

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR § 424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations), Form CMS-855S, or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. A physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

For a list of fee requirements broken out by provider/supplier and application type, refer to the Application Fee Matrix.

Except as otherwise noted, nothing in this section 10.6.14 supersedes any other CMS directive to the contractor pertaining to application fees.

(For purposes of this section 10.6.14, the term "provider" will be used in lieu of "institutional provider.")

B. Contractor Activities Upon Receipt

Upon receipt of a paper or PECOS application from a provider that is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

1. Determine whether the provider has: (1) paid the application fee via Pay.gov (all payments must be made via Pay.gov); and/or (2) included a hardship exception request with the application or certification statement.

2. Outcomes

i. <u>The provider has neither paid the fee nor submitted the hardship exception request</u>-- The contractor shall send a development letter to the provider notifying it that: (A) it has 30 days from the date of the letter to pay the application fee via Pay.gov and any other items that may be missing or needed; and (B) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations).

ii. <u>The provider has submitted a hardship exception request but has not paid a fee</u> - The contractor shall send the request and all documentation accompanying the request via e-mail to its PEOG BFL. If CMS:

- Denies the hardship exception request – CMS will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall determine whether the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR § 424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR § 424.535(a)(6) (revalidations).

  (The contractor shall begin processing the application as normal if, at any time during this 30-day period: (1) for paper applications, the provider submits a Pay.gov receipt as proof of payment; or (2) for PECOS applications, the provider pays the fee via PECOS.)

- Approves the hardship exception request - CMS will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall continue processing the application as normal.

iii. Has submitted a hardship exception request and has paid a fee - The contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. As the fee has been paid, the contractor shall begin processing the application as normal.

3. PECOS Applications

(For PECOS applications, the provider must submit any required application fee (i.e., initials, revalidations, new practice locations) or hardship waiver via PECOS at the time it submits its application; otherwise, PECOS will not accept the application. Some of the instructions in subsection (B)(2) may therefore be inapplicable to PECOS applications.)

As stated in section 10.3 of this chapter, application fees can be combined if multiple enrollment records are implicated by the submission (e.g., consolidated application), but each application still requires a separate fee. To illustrate, suppose an entity is enrolling 5 different IDTFs, and the fee amount is $631 per IDTF. The provider can submit separate $631 fees or can combine them into a $3,155 payment. In the case of hardship waivers, however, 5 separate hardship waivers – one for each enrollment – must be submitted; they cannot be combined into one waiver request.

C. Fee Amount

1. General Background

Except as stated in subsection (C)(2), the application fee must be in the amount prescribed by CMS for the calendar year (1) in which the application is submitted (for PECOS applications) or (2) of the postmark date (for paper applications). The current fee amount can be found via PECOS at the following link: https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do

Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year.

CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

2. Transition to Subsequent Year

There can be situations where the provider submits an application in the previous calendar year without a required fee, the contractor develops for the fee, and the provider submits the fee in the subsequent year. The submitted fee must be that for the subsequent year and not the preceding year.

D. Non-Refundable

Per 42 CFR § 424.514(d)(2)(v), the application fee is non-refundable unless it was submitted with one of the following:

1. A hardship exception request that is subsequently approved;

2. An application that was rejected prior to the contractor's initiation of the screening process; or

3. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR § 424.570.

(For purposes of section 10.6.14(D) only, the term "rejected" includes applications that are returned.)

In addition, the fee should be refunded if: (i) it was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number); or (ii) it was not part of an application submission.

E. Format

The provider must submit the application fee electronically through https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do, either via credit card, debit card, or electronic check.

Should the provider submit an application with a paper check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in section 10.4(C) of this chapter (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via.Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.

F. Practice Locations

DMEPOS suppliers, federally qualified health centers (FQHCs), independent diagnostic testing facilities (IDTFs), and certain other provider and supplier types described in this chapter must

individually enroll each site. The enrollment of each site thus requires a separate fee. For **all other providers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. (This includes the addition of a hospital unit – such as a psychiatric unit – in the Practice Location section of the Form CMS-855A.) If multiple locations are being added on a single application, however, only one fee is required; indeed, the fee for providers that are not required to separately enroll each location is based on the application submission, not the number of locations listed on a single application.

G. Other Application Fee Policies

1. PECOS Enrollment Records

a. Paper Applications - The fee is based on the Form CMS-855 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In the Identifying Information/hospital type section of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.

b. PECOS Applications – In a similar vein, the fee is based on the number of applications involved. Even if the provider submits one set of data into PECOS, it may involve several different applications, thus requiring separate fees. To illustrate, assume a provider exists in Tennessee, Arkansas, and Missouri, each of which is in a separate contractor jurisdiction. As discussed in section 10.3 of this chapter, the group may submit a consolidated application (e.g., one set of data encompassing all three enrollments), which PECOS would then split into three separate applications. Three fees must be paid, however, because three separate enrollment applications are involved.

2. Group Practices/Clinics

A physician/non-physician practitioner clinic or group practice enrolling via the Form CMS-855B is exempt from the fee even if it is tribally-owned/operated or hospital-owned. Yet if a hospital is adding a physician/non-physician practitioner clinic or group practice to its Form CMS-855A enrollment, a fee is required because the hospital is adding a practice location.

3. Change of Ownership via Form CMS-855B or Form CMS-855S

A provider or supplier need not pay an application fee if the application is reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

4. Reporting a Change in Tax Identification Number

A provider need not pay an application fee if the application is reporting a change in TIN for a Part A, Part B, or DMEPOS provider or supplier.

5. Requesting a Reactivation

A provider need not pay an application fee to reactivate Medicare billing privileges unless the provider/supplier was deactivated for failing to respond to a revalidation request, in which case the resubmitted application constitutes a revalidation (not a reactivation) application, hence requiring a fee.

6. Changing the Physical Location of an Existing Practice Location

A provider need not pay an application fee when changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

The application fee requirement is separate and distinct from the site visit requirement and risk categories discussed in this chapter. Physicians, non-physician practitioners, physician groups, and non-physician practitioner groups are exempt from the application fee even if they fall within the "high" level of categorical screening per 42 CFR § 424.518. Likewise, physical therapists enrolling as individuals or group practices need not pay an application fee even though they fall within the "moderate" level of categorical screening and are subject to a site visit.

H. Refund Requests

Unless otherwise approved by CMS, the provider must request a refund no later than 150 days from the date it submitted its application. In its request, the provider shall include documentation acceptable to process the refund request. For credit card refunds, the provider shall include its Pay.gov receipt or the Pay.gov tracking ID number.

If a refund is requested and the fee was paid via ACH Debit, the contractor shall collect from the provider a completed "Authorization and Payment Information Form for Electronic Funds Transfer" form (previously furnished to contractors) and submit it to the PEMACReports@cms.hhs.gov mailbox. In the subject line of this e-mail, the contractor shall: (1) identify the provider's legal business name, National Provider Identifier (NPI), and the Pay.gov Tracking ID; and (2) include the completed, previously-mentioned form.

I. Institutional Provider and Fee: Year-to-Year Transition

There may be isolated instances where, at the end of a calendar year, a provider pays the fee amount for that year (Year 1) but the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider must pay the Year 2 fee. The contractor shall thus: (1) send an e-mail to its PEOG BFL requesting a full refund of the fee and including any pertinent documentation in support of the request; and (2) send a letter to the provider notifying it that (i) it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) via Pay.gov and (ii) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of

the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

J. Hardship Exception

1. Background

A provider requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via PECOS, the hardship exception letter must accompany the application (i.e., the provider must upload the letter and supporting documentation into PECOS). Hardship exception letters shall not be considered if they were submitted separately from the application. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider; and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee generally should not represent a significant burden for an adequately capitalized provider. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including furnishing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that may suggest that a hardship exception is appropriate include the following:

a. Considerable bad debt expenses,

b. Significant amount of charity care/financial assistance furnished to patients,

c. Presence of substantive partnerships (whereby clinical and/or financial integration are present) with those who furnish medical care to a disproportionately low-income population,

d. Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or

e. Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. CMS has 60 calendar days from the date of the contractor's receipt of the hardship

exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. CMS will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 10.6.14(K) below.

If the provider fails to submit appropriate documentation to support its request, the contractor need not contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG BFL. It is ultimately the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

K. Appeals of Hardship Determinations

A provider may appeal CMS' denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with CMS' decision to deny a hardship exception request, it may file a written reconsideration request with CMS within 60 calendar days from receipt of the notice of initial determination (e.g., CMS' denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity. Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Notwithstanding the filing of a reconsideration request, the contractor shall still implement the post-hardship exception request instructions in this section 10.6.14(K). A reconsideration request, in other words, does not stay the implementation of section 10.6.14(K)'s instructions.

The CMS has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be: (a) conducted by a CMS staff person who was independent from the initial decision to deny the hardship exception request; and (b) based on CMS' review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, CMS will send a letter to the provider to acknowledge receipt of its request. In its acknowledgment letter, CMS will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

If CMS denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If CMS approves the reconsideration request, it will notify the provider of this via

letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

i. If the application has already been rejected, request that the provider resubmit the application without the fee, or

ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request but the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request but the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such requests shall be filed within 60 days from receipt of the notice of the DAB's decision.

10.6.15 – Risk-Based Screening

(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

Consistent with 42 CFR § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, revalidates its enrollment information, or, in certain circumstances, changes all or part of its ownership.

A. Specific Screening Categories

1. Limited Risk

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- Home infusion therapy suppliers
- Hospitals (including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Organ procurement organizations
- Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics

For providers and suppliers in the "limited" category, the contractor shall process initial, revalidation, and new location applications in accordance with existing instructions.

2. Moderate Risk

a. General Information

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Newly Enrolling Opioid Treatment Program (OTP) that were SAMSHA certified prior to October 24, 2018
- Revalidating home health agencies (HHAs)
- Revalidating hospices
- Revalidating DMEPOS suppliers
- Revalidating MDPP suppliers
- Revalidating OTP providers
- Revalidating SNFs
- Pursuant to § 424.518(b)(1)(ix), revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in § 424.518(c)(2)(ii) upon the provider's or supplier's—
    - New/initial enrollment; or
    - Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in § 424.518(c)(1)(viii), when the provider or supplier initially enrolled in Medicare. (See subsection (A)(5) below for more information.)

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 10.6.15(A)(4) of this chapter or another CMS directive applies): (1) process initial, revalidation, and new location applications in accordance with existing instructions; and (2) order an NSVC site visit through PECOS consistent with subsection 2(b) below. (Unless stated otherwise in this chapter, the scope of the site visit shall be consistent with existing instructions.)

b. Provider/Supplier-Specific Information

(i) <u>Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups</u>

If the supplier submits an initial application, revalidation application, or application to add a new practice location, the contractor shall order a site visit. (For new location additions, the site visit shall be of the new location.) The contractor shall not make a final decision regarding the application (or, for initial applications, shall not convey Medicare billing privileges) prior to the completion of the NSVC's site visit and the contractor's review of the results.

(ii) CMHCs, CORFs, Hospices and PXRSs

For site visits regarding these four provider/supplier types, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.1, 10.2.1.2, 10.2.1.7, and 10.2.2.8 of this chapter.

(iii) IDTFs

Initial applications - The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 10.2.2(O)(15) of this chapter.

Revalidations - The NVSC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 10.2.2(I)(15) of this chapter.

IDTF Code Changes - The NSVC will conduct site visits for IDTF code changes as specified in section 10.2.2(I)(17) of this chapter.

(iv) Revalidating HHAs and SNFs

For site visits regarding revalidating HHAs and SNFs, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.6 and 10.2.1.14 of this chapter.

(v) Revalidating DMEPOS Suppliers

A site visit of the DMEPOS supplier shall be conducted prior to the NSC making a final decision regarding the revalidation application.

(vi) Revalidating MDPP Suppliers

If an MDPP supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

(vii) Revalidating OTP Providers

If an OTP provider submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. High Risk

a. General Information

Pursuant to 42 CFR § 424.518, the "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs (including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))
- Newly enrolling hospices
- Newly enrolling MDPP suppliers
- Newly enrolling OTP providers that were SAMSHA certified after October 24, 2018
- Newly enrolling SNFs
- DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, SNFs, and hospices submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42.
- Except as stated in § 424.518(b)(1)(ix), revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section pursuant to applicable legal authority due to a national, state, or local emergency declared under existing law. (See subsection (A)(5) below for more information.)

For newly enrolling providers and suppliers in the "high" level of categorical screening:

(i) The contractor shall process the application in accordance with existing instructions.

(ii) The NSVC will perform a site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the site visit and the contractor's review of the results.

(iii) Their 5 percent or greater direct and indirect owners must undergo fingerprint-based criminal background checks. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of fingerprinting and the contractor's review of the results.

(iv) The contractor shall, upon switching the provider's or supplier's enrollment record to "Approved," enter the provider's risk category as "moderate" into PECOS.

b. Additional Considerations

(i) Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes.

(ii) The addition of a new HHA branch falls within the "moderate" level of categorical screening. A site visit of the branch shall thus be performed consistent with the instructions in this chapter (including those in section 10.2.1.6).

(iii) The addition of a new MDPP supplier administrative location that does not result in a new PTAN does not require an additional site visit. Any additional MDPP supplier administrative location that results in a new PTAN, either due to being in a new jurisdiction or because of a new CDC organizational code, the contractors shall order a site visit of the location through PECOS. This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. Changes of/in Ownership

As explained above and in more detail in section 10.6.21(E)(3), the "high" screening category includes DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, SNFs, and hospices submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42. Accordingly, any change of/in ownership that meets all of the following criteria would fall under (i) or (ii) above:

- Does not involve the triggering of an initial enrollment (e.g., an HHA or hospice change in majority ownership for which no exception applies requires a new enrollment); and
- The change reports either:

    - For partnerships: A new partner (general or limited) who owns any percentage (even 1 percent) of the provider/supplier; or
    - Excluding partnerships: A new direct or indirect owner of at least 5 percent of the provider/supplier.

Upon receipt of an application described above, the contractor shall process it consistent with the instructions in this chapter and this section 10.6.15. This includes requesting fingerprints from the new owner(s) if the owner has a 5 percent or greater direct or indirect ownership interest. However, the contractor need not also solicit them from the provider/supplier's existing owners; only the new owner(s) need be fingerprinted.

(Note that if a new partner is being reported but the partner owns less than 5 percent of the provider/supplier, the provider/supplier's application must still be processed at the high screening level. However, the new partner need not be fingerprinted. This is because fingerprinting only applies to 5 percent or greater direct or indirect owners. It is therefore possible that, in such a change of ownership transaction, no fingerprinting will have to be conducted at all.)

The contractor shall also order a site visit of the provider/supplier consistent with existing instructions. In terms of the timing of the HHA, SNF, or hospice site visit, however, the contractor shall adhere to the following:

- No State/SOG Location Approval Required – If the ownership change does not require state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1 of this chapter for more information on this topic), the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.
- State/SOG Location Approval Required - If the ownership change requires state or SOG Location approval under existing CMS instructions, the site visit shall be ordered and performed no later than 5 business days after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.

(See section 10.6.21(E)(3) of this chapter for more information.)

4. Elevating Existing Providers and Suppliers into the High-Risk Screening Category

a. Criteria for Raising Providers/Suppliers to High-Risk

Under § 424.518(c)(3), CMS may adjust (or "bump up") a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

(ii) The provider or supplier:

- Has been excluded from Medicare by the Office of Inspector General;
- Had its billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by: (A) enrolling as a new provider or supplier; or (B) obtaining billing privileges for a new practice location;
- Has been terminated or is otherwise precluded from billing Medicaid;
- Has been excluded from any federal health care program; or
- Has been subject to any final adverse action (as defined in § 424.502) within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

b. Extension of Application of a Provider/Supplier's "Bump-Up"

Effective January 6, 2023 (and pursuant to § 424.518(c)(4)), any screening level adjustment under § 424.518(c)(3) also applies to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification number (TIN) as the

provider or supplier for which the screening level under § 424.518(c)(3) was originally raised. To illustrate, suppose an entity is enrolled as an ambulance supplier, a CORF, and a home infusion therapy (HIT) supplier. All three providers/suppliers are under the entity's TIN and LBN. The HIT supplier is under a payment suspension and is thus bumped-up to "high." Pursuant to § 424.518(c)(4), the ambulance supplier and CORF will also be moved to "high" because they have the same LBN and TIN as the HIT supplier.

c. List of Bumped-Up Providers/Suppliers

CMS makes available to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that have been "bumped-up" pursuant to § 424.518(c)(3) and (c)(4). Upon receipt of an initial or revalidation application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions. If the provider or supplier is on the list, the contractor shall process the application using the procedures in the "high" screening category unless the provider is on the list solely because he/she/it was revoked for failing to timely respond to a revalidation request. If such is the case, the contractor shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance as to how the situation should be handled.

d. Post-Moratorium Applications

If the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

5. Prior Waiver from Fingerprinting

During the recent COVID-19 public health emergency (PHE), CMS temporarily waived the requirement for fingerprint-based criminal background checks (FBCBCs) for 5 percent or greater owners of newly enrolling providers and suppliers falling within the high-risk screening category in § 424.518(c). CMS seeks to perform FBCBCs for high-risk providers and suppliers that initially enrolled during the PHE upon their revalidation once the PHE ends. This was not previously possible under our prior regulations because the revalidation applications would only be screened at the moderate-risk level. Pursuant to our regulatory revisions in the CMS CY 2024 Home Health Prospective Payment System final rule, however, CMS --- effective January 1, 2024 ---- may fingerprint the 5 percent or greater direct/indirect owners of these providers/suppliers. Specifically:

(i) Revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements pursuant to a legally declared national, state, or local emergency declared under existing law --- These

providers/suppliers fall within the high-risk screening category and are subject to the fingerprinting requirement as part of their revalidation requirement.

(ii) Once the providers/suppliers in (i) have been fingerprinted, they fall within the moderate-risk category.

Upon receipt of an application from a revalidating OTP that has not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS supplier, revalidating HHA, revalidating MDPP supplier, revalidating SNF, or revalidating hospice, the contractor shall determine whether the provider/supplier was waived from the fingerprinting requirement pursuant to applicable legal authority due to a national, state, or local emergency declared under existing law. If the provider/supplier was waived and has not yet been undergone fingerprinting, the contractor shall process the revalidation using the high-risk screening procedures. If the provider/supplier was not so waived or has otherwise undergone fingerprinting after a waiver, the revalidation application shall be processed consistent with the moderate-risk screening procedures.

Note that any such waiver must have been directed by CMS.

B. Changes of Information (Including Additions and Changes of Practice Locations)

(This subsection (B) does not apply to ownership changes that qualify as a mere change of information (e.g., reporting a new 10 percent owner).) These transactions are addressed in subsection (C) below.)

1. Limited

Changes of information (including additions of practice locations) submitted by providers/suppliers in the "limited" level of categorical screening shall be processed consistent with existing instructions.

2. Moderate

Changes of information submitted by providers/suppliers in the "moderate" level of categorical screening shall be processed consistent with existing instructions, although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15. The site visit shall be performed consistent with the applicable instructions in this chapter (e.g., section 10.2.1.2 for CORFs). The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

3. High

Except as stated below, changes of information submitted by providers/suppliers in the "high" level of categorical screening shall be processed consistent with existing instructions, although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15. The site visit shall be performed consistent with the

applicable instructions in this chapter. The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

For purposes of this requirement:

- A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.

- If the provider/supplier's physical location is not changing (e.g., the provider's street name is changing but its actual office space is not), no site visit is required.

- A DMEPOS supplier that is adding a new practice location falls within the "high" screening category. This is because each location must be separately enrolled. The enrollment of a new location thus constitutes an initial enrollment.

- A DMEPOS supplier undergoing a change in TIN with no change in ownership falls within the "moderate screening category.

C. Change of Ownership

1. **Limited**

Changes of ownership (regardless of whether a new TIN is triggered) shall be processed consistent with existing instructions.

2. Moderate

If a provider or supplier is undergoing a change of ownership resulting in a new TIN, the contractor shall:

a. Process the application consistent with existing instructions, and

b. Order a site visit through PECOS in accordance with the following:

- For ownership changes that must be approved by the state or SOG Location under current CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1) of this chapter), the site visit shall be ordered and performed after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

- For ownership changes that do not require state or SOG Location approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.

3. High

See subsection (A)(3)(c) for information on processing changes of/in ownership applications from DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, SNFs, and hospices.

D. Reactivations

a. Limited

Form CMS-855 reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

b. Moderate

Form CMS-855 reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening – including existing DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, and SNFs – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

c. High

Form CMS-855 reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

10.6.16 – Temporary Moratoria
(Rev. 10524; Issued: 12-17-20; Effective: 11-13-20; Implementation: 11-13-20)

Under §424.570(a), CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. The announcement of a moratorium will be made via the Federal Register, though the contractor will be separately notified of the moratorium.

The contractor shall abide by all CMS directives and instructions issued pursuant to the imposition or lifting of a particular moratorium.

10.6.17 – Deceased Practitioners
(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Reports of Death from the Social Security Administration (SSA)

Contractors, including DME MACs, will receive from CMS a monthly file that lists individuals who have been reported as deceased to the SSA. To help ensure that Medicare maintains current enrollment and payment information and to prevent others from utilizing the enrollment data of deceased individuals, the contractor shall undertake the activities in this section 10.6.17.

B. Erroneous Report of Death

In the event of an erroneous report of death, the contractor shall contact its PEOG BFL for guidance.

C. Verification Activities for Individuals Other than Physicians, Non-Physician Practitioners, and/or DMEPOS Suppliers

(If the person is an owner, sole owner of his/her professional corporation or professional association, managing employee, director, officer, authorized official, etc., the contractor shall verify and document in PECOS that the person is deceased using the process described in section 10.6.17(D)(1).)

Once the contractor verifies the report of death, it shall notify the provider or supplier organization with which the individual is associated that it needs to submit a Form CMS-855 change request that deletes the individual from the provider or supplier's enrollment record. If the provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's Medicare billing privileges in accordance with 42 CFR § 424.540(a)(2). (For DMEPOS Suppliers - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with 42 CFR § 424.57(c)(2).) The contractor need not, however, solicit a Form CMS-855 change request if the organization is enrolled with another contractor. Instead, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 10.6.17.

D. Reports of Death from Third-Parties

1. Verification of Death

If a contractor (including DME MACs) receives a report of death from a third-party (e.g., state provider association, state medical society, academic medical institution, etc.), the contractor shall verify that the physician, non-physician practitioner, or DMEPOS supplier is deceased by:

- Obtaining oral or written confirmation of the death from an authorized or delegated official of the group practice to which the physician, non-physician practitioner or DMEPOS supplier had reassigned his or her benefits;

- Obtaining an obituary notice from the newspaper;

- Obtaining oral or written confirmation from the state licensing board (e.g., telephone, e-mail, computer screen printout);

- Obtaining oral or written confirmation from the State Bureau of Vital Statistics; or

- Obtaining a death certificate, Form SSA-704, or Form SSA-721 (Statement of Funeral Director).

All verification shall be documented in PECOS per section 10.6.19(I) (and, as applicable, section 10.3) of this chapter; in addition, any documents that were used to confirm the death (e.g., obituary notice) shall be uploaded into PECOS.

2. Deceased Individuals: Post-Confirmation Actions

Once the contractor verifies the death, it shall:

a. Undertake all actions normally associated with the deactivation of a supplier's billing privileges.

b. Search PECOS to determine whether the individual is listed therein as an owner, managing employee, director, officer, partner, authorized official, or delegated official of another supplier.

c. If the person is not in PECOS, no further action with respect to that individual is needed.

d. If the supplier is indeed identified in PECOS as an owner, sole owner of his/her professional corporation or professional association, officer, etc., the contractor shall notify the organization with which the person is associated that it needs to submit a Form CMS-855 change request that deletes the individual from the entity's enrollment record. If a provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's billing privileges in accordance with § 424.540(a)(2). (For DMEPOS Suppliers - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with § 424.57(c)(2).) The contractor need not, however, ask for a Form CMS-855 change request if the organization is enrolled with another contractor. Instead, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 10.6.17.

E. Deceased Individuals: Education & Outreach

Contractors (including DME MACs) shall conduct outreach to state provider associations, state medical societies, academic medical institution, and group practices, etc., regarding the need to promptly inform contractors of the death of physicians and non-physician practitioners participating in the Medicare program.

F. Process to Deactivate NPI Due to a Death

1. Trustees/Legal Representatives

The trustee/legal representative of a deceased physician, non-physician practitioner, or DMEPOS supplier's estate may deactivate the NPI of the deceased provider by providing written documentation to the NPI enumerator.

2. Special Payment Address: Process to Update to an Estate Upon a Death

In situations where a physician, non-physician practitioner, or DMEPOS supplier has died, the contractor can make payments to the individual's estate per the instructions in Pub. 100-04, chapter 1. When the contractor receives a request from the trustee or other legally-recognized representative of the physician, non-physician practitioner, or DMEPOS supplier's estate to change the deceased's special payment address, the contractor shall, at a minimum, ensure that the following information is furnished:

- Form CMS-855 change of information request that updates the "Special Payment" address in the application. The Form CMS-855 can be signed by the trustee/legal representative.

- Any evidence – within reason - verifying that the physician, non-physician practitioner, or DMEPOS supplier is in fact deceased.

- Legal documentation verifying that the trustee/legal representative has the legal authority to act on behalf of the provider, non-physician practitioner, or DMEPOS supplier's estate.

The policies in this section 10.6.17(F) and (G) apply only to physicians, non-physician practitioners. and DMEPOS suppliers who operated their business as sole proprietors. It does not apply to solely-owned corporations, limited liability companies, etc., nor to situations in which the physician or non-physician practitioner reassigned his or her benefits to another entity.

All verification shall be documented in PECOS per section 10.6.19(I) of this chapter; in addition, any documents that were used to confirm the death (e.g., obituary notice) shall be uploaded into PECOS.

G. Other Enrollment Information

1. Reassignment and Revoked/Deceased Physicians and Non-Physician Practitioners

There are situations where a physician/non-physician practitioner (the "owning physician/practitioner") owns 100% of his/her own practice, employs another physician (the "employed physician/practitioner") to work with him/her, and accepts reassigned benefits from the employed physician/practitioner. Should the sole proprietor or sole owner die or have his/her billing privileges revoked and the provider/supplier fails to submit an updated Form CMS-855 within 90 days, the practice is automatically dissolved for purposes of Medicare enrollment and all reassignments to the practice are automatically terminated as well. Neither the owning physician/practitioner nor the practice is enrolled in Medicare any longer and the enrollments for both shall be deactivated in accordance with the deactivation procedures outlined in this chapter. (It is immaterial whether the practice was established as a sole proprietorship, a professional corporation, a professional association, or a solely-owned limited liability company.) In addition, the contractor shall end-date the reassignment using, as applicable, the date of death or the effective date of the revocation.

Besides deactivating the enrollments of the owning physician/practitioner and the practice, the contractor shall notify the employed physician/practitioner that:

a. The practice's billing privileges have been deactivated;

b. Any services furnished by him/her on behalf of the practice after the date of the owning physician/practitioner's death or date of revocation or deactivation will not be paid; and

c. If the employed physician/practitioner wishes to provide services at the former practice's location, he/she must submit a Form CMS-855I change of information request to add the owning physician/practitioner's practice location as a new location of the employed physician/practitioner. For purposes of this section 10.6.17(G)(1)(c) only, submission of an initial Form CMS-855I and a terminating Form CMS-855R application are not required – even if the employed physician/non-physician practitioner had reassigned all of his/her benefits to the practice.

H. Proof of Life Documentation

On rare occasions, erroneous death information may be received through the DMF process that results in systematic enrollment deactivations in PECOS or records populated on the Deceased Associates reports in PECOS for contractor deactivation actions. In order for the providers/suppliers to reactivate their enrollments and have the date of death removed from their PECOS records, the contractor shall request documentation that supports "proof of life" (for example, Retirement, Survivors, and Disability Insurance document issued by SSA). If the provider/supplier is unable to obtain such documentation, the contractor shall submit a request to their PEOG BFL containing the provider/supplier's name, date of birth, and SSN so that CMS can confirm proof of life with SSA.

10.6.18 – Appeals Process

(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Review Procedures for Determinations that Affect Participation in the Medicare Program

1. Background

This review process of initial determinations applies to all providers and suppliers and ensures that all current and prospective providers and suppliers receive a fair and full opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request Administrative Law Judge (ALJ) review of a reconsideration decision within the Civil Remedies Division of the Departmental Appeals Board (CRD DAB). Providers and suppliers may thereafter seek review of the ALJ decision in the Appellate Division of the Departmental Appeals Board (DAB) and may then request judicial review in Federal District Court.

For purposes of this chapter, in accordance with 42 C.F.R. § 498.3, an initial determination includes: (1) the denial of enrollment in the Medicare program; (2) the revocation of a provider's or supplier's Medicare billing privileges; and (3) the effective date of participation in the

Medicare program.

Any corrective action plan (CAP) or reconsideration request that purports to challenge an enrollment action other than the initial determinations identified above (including inclusion on the CMS Preclusion List and Opt-Out Status) shall be forwarded to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt. The Medicare Administrative Contractor (MAC) shall take no action on the provider's or supplier's information on its enrollment record regarding an appeal submission for revocations forwarded to CMS for processing unless otherwise instructed by the Provider Enrollment and Oversight Group (PEOG).

A provider or supplier dissatisfied with the initial determinations referenced above, may challenge the determination. All properly submitted requests shall be reviewed at the enrollment level. As a result, if one letter attempts to challenge the initial determination for a group enrollment in addition to individual practitioner enrollment(s), each enrollment shall receive a separate decision. All submissions shall be processed in the order in which they are received. All CAPs and/or reconsideration requests will be reviewed by an individual separate and apart from the individual involved in the implementation of the initial determination.

Depending on the regulatory authority under which an initial determination is issued, providers and suppliers may be entitled to submit a CAP and/or a reconsideration request. A CAP is a plan that allows a provider or supplier an opportunity to demonstrate compliance with all applicable Medicare requirements by correcting the deficiencies (if possible) that led to the initial determination, specifically either the denial of enrollment into the Medicare program under 42 C.F.R. § 424.530(a)(1) or the revocation of Medicare billing privileges pursuant to 42 C.F.R. § 424.535(a)(1). While CAPs may only be submitted in response to a denial under 42 C.F.R. § 424.530(a)(1) or a revocation under 42 C.F.R. § 424.535(a)(1), all initial determinations allow for the submission of a reconsideration request. A reconsideration request allows the provider or supplier an opportunity to demonstrate that an error was made in the initial determination at the time the initial determination was implemented. In contrast to a CAP, a reconsideration request does not allow a provider or supplier the opportunity to correct the deficiencies that led to the initial determination.

Any CAPs and/or reconsideration requests received in response to initial determinations involving the following, either in whole or in part, shall be forwarded to CMS for review within 10 business days of the date of receipt. The CAP and/or reconsideration request shall be sent to the PEOG Provider Enrollment Appeals inbox at ProviderEnrollmentAppeals@cms.hhs.gov.

- All CAPs and reconsideration requests for certified providers/suppliers (as defined in Sections 10.2.1 and 10.2.2 of this chapter) and institutional providers/suppliers which have been revoked (as defined in Section 10.4(M)(2)(e) of this chapter);

- CAPs and reconsideration requests for Independent Diagnostic Testing Facilities;

- CAPs and reconsideration requests for Medicare Diabetes Prevention

Programs (MDPP);

- CAPs and reconsideration requests for Opioid Therapy Programs (OTPs);

- Reconsideration requests for enrollment denials pursuant, in whole or in part, to 42 C.F.R. § 424.530(a)(2), (3), (6), (11), (12), (13), (14), (15), and (17)

- Reconsideration requests for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(a)(2), (3), (4), (7), (8), (10), (12), (13), (14), (15), (17), (18), (19), (20), (21), and (22);

- Requests for reversals of denials pursuant to 42 C.F.R. § 424.530(c) and/or revocations pursuant to 42 C.F.R. § 424.535(e);

- Reconsideration requests for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(j);

- Reconsideration requests challenging the addition of years to an existing re-enrollment bar;

- Reconsideration requests challenging whether an individual or entity other than the provider or supplier that is the subject of the second revocation was the actual subject of the first revocation;

- Reconsideration requests challenging an individual or entity being included on the CMS Preclusion List as defined in § 422.2 or § 423.100; and

- Reconsideration requests regarding opt-out status.

(NOTE: As indicated in section 10.4.7.4(D) of this chapter – and notwithstanding any other instruction to the contrary in this chapter (including in this section 10.6.18(A)(1)) -- the MAC shall make all reconsideration determinations for denials under § 424.530(a)(18) and revocations under § 424.535(a)(23).)

If the provider or supplier is denied enrollment or has its Medicare billing privileges revoked, under 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1), (5), (9), in conjunction with any denial or revocation reason(s) listed above, those CAPs and/or reconsideration requests should also be forwarded to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt and the determination will be rendered by CMS. If the provider or supplier only submits a CAP for the noncompliance portion of any initial determinations listed above, the CAP must be sent to CMS at ProviderEnrollmentAppeals@cms.hhs.gov for review within 10 business days of the date of receipt, even if the provider or supplier does not submit a reconsideration request. The MAC shall not process the CAP if it is required to be forwarded to CMS. If the provider or supplier later submits a reconsideration request, the reconsideration request must also be sent to CMS at ProviderEnrollmentAppeals@cms.hhs.gov within 10 business days of the date of receipt.

All CAPs and reconsideration requests received by the MACs that are not specifically identified above as being required to be forwarded to CMS for review, shall be processed and a decision rendered by the MACs. However, CMS may exercise its discretion to review any CAP and/or reconsideration request and issue a decision regardless of the basis for the initial determination.

(**NOTE:** This includes all CAPs and reconsideration requests for DMEPOS suppliers that fit the criteria identified above. In addition, as also indicated above, CAPs may only be submitted for denials pursuant to 42 C.F.R. § 424.530(a)(1) and revocations pursuant to 42 C.F.R. § 424.535(a)(1). However, in the event a CAP is submitted for revocations pursuant, in whole or in part, to 42 C.F.R. § 424.535(a)(2), (3), (4), (7), (8), (10), (12), (13), (14), (15), (17), (18), (19), (20), (21), or (22) the submission should still be forwarded to CMS within 10 business days of the date of receipt to the PEOG Provider Enrollment Appeals inbox at ProviderEnrollmentAppeals@cms.hhs.gov.)

PEOG shall notify the MAC via email when it receives a CAP and/or reconsideration request for a provider or supplier that has not been previously forwarded to PEOG by the MAC. The MAC shall not take any action on a provider or supplier's information on its enrollment record if there is a CAP and/or reconsideration request pending for a revocation action unless otherwise instructed by PEOG. The MAC shall email ProviderEnrollmentAppeals@cms.hhs.gov with any inquiries, questions, or requests.

All documentation related to CAPs and reconsideration requests (including, but not limited to, the decisions) shall be saved in PDF format. The date on the CAP and reconsideration request decisions should be the same date as the date the decision is issued to the provider/supplier/representative.

2. Reopening and Revising CAP and Reconsideration Determinations

Once a CAP and/or reconsideration decision is issued, the MAC shall not reopen and revise a CAP and/or reconsideration decision without PEOG's prior approval, even if the MAC rendered the CAP or reconsideration decision independently. The MAC shall send all requests to reopen and revise a CAP and/or reconsideration decision to ProviderEnrollmentAppeals@cms.hhs.gov and await further instruction before taking any action regarding the CAP and/or reconsideration decision.

3. Requests to the MACs

The MAC shall work with and provide PEOG and the Office of General Counsel (OGC), when applicable, all necessary documentation related to any and all CAPs, reconsideration requests, ALJ appeals, DAB appeals, or requests for judicial review.

The following are examples of information the MAC may be asked to provide. This is not an exhaustive list.

- A copy of the initial determination letter**;**
- A chronological timeline outlining: (1) the processing of applications; (2)

the date they began providing services at the newest assigned location; and (3) if there were development requests;

- The hearing officer's decision as well as the provider or supplier's CAP and/or reconsideration request;

- A complete copy of all application Form CMS-855s, and any supporting documentation submitted with the provider or supplier's application;

- All background information and investigative data the hearing officer used to make their decision. Including any on-site visit reports; the MAC's recommendation for administrative action based on the on-site visit;

- Contact information for the person(s) who signed both the revocation and reconsideration decision letters.

The MAC shall supply PEOG or OGC with all requested documentation within 5 business days of receipt of the request, unless requested sooner.

All requested documentation shall be provided in PDF format (if possible) and saved with a file name that identifies the content of the document.

If a CAP and/or reconsideration decision requires the MAC to take action on a provider's or supplier's enrollment, such as reinstating the provider's or supplier's enrollment to an active status, the MAC shall complete all updates to the provider's or supplier's enrollment within 10 business days of the date the CAP and/or reconsideration decision is issued unless additional documentation is needed to update the enrollment. If a CAP or reconsideration decision requires the provider or supplier to submit further information before the enrollment can be updated, such as an enrollment application, the MAC shall allow 30 calendar days for the provider or supplier to submit the necessary information. The MAC shall complete all updates to the provider's or supplier's enrollment within 10 business days of the date of receipt of the additional information/documentation. If the provider or supplier does not submit the necessary information within 30 calendar days, the MAC shall contact PEOG by emailing ProviderEnrollmentAppeals@cms.hhs.gov for further instruction.

4. Timing of CAP and Reconsideration Request Submissions

A provider or supplier who wishes to submit a CAP must file its request in writing within 35 calendar days of the date of the initial determination. A provider or supplier who wishes to submit a reconsideration request must file its request in writing within 65 calendar days of the date of the initial determination. The date on which CMS or the MAC receives the submission is considered to be the date of filing. See section D below for information on calculating timely submissions.

The mailing and email address for all CAPs and reconsideration requests to be rendered by CMS identified in section 10.6.18(A) is:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review, and may result in the dismissal of any untimely submitted reconsideration request. The time limit may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows or the party alleges and the record does not negate that the delay in filing was due to circumstances outside of the provider's or supplier's control such as the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

If a reconsideration request is not timely filed, as required in 42 C.F.R. § 498.22, CMS will make a determination as to whether good cause exists. If a MAC receives an untimely CAP and/or reconsideration request that it believes is entitled to a good cause exception related to untimeliness, the hearing officer must request approval from PEOG by emailing ProviderEnrollmentAppeals@cms.hhs.gov with an explanation as to why good cause is believed to exist before making a finding of good cause or taking any other action regarding the CAP and/or reconsideration request. The MAC shall not take action on the CAP and/or reconsideration request until it receives a response from CMS regarding the good cause exception request.

5. Time Calculations

Per 42 C.F.R. § 498.22(b)(3), the date of receipt of an initial determination is presumed to be 5 calendar days after the date on the initial determination notice unless there is a showing that it was, in fact, received earlier or later.

A CAP must be received by the MAC or CMS within 35 calendar days of the date of the initial determination. A reconsideration request must be received by the MAC or CMS within 65 calendar days of the date of the initial determination. If the 35th day (for a CAP) or 65th day (for a reconsideration request), falls on a weekend, or Federally recognized holiday, the CAP and/or reconsideration request shall be considered timely filed if received on the next business day. In the case of an email submission of a CAP and/or reconsideration request, the filing date is presumed to be the date of receipt of the email. Consider the following example:

An initial determination letter is dated April 1. The provider is presumed to have received the

initial determination on April 6. The provider submits a CAP and/or reconsideration request by mail that is received on June 10, 65 calendar days after April 6. This is considered timely because it is presumed that the provider did not receive the initial determination letter until April 6.

It is the provider or supplier's responsibility to timely update its enrollment record to reflect any changes to the provider or supplier's enrollment information, including its correspondence address. Failure to timely update a correspondence address or other address included in the enrollment record does not constitute an "in fact" showing that an initial determination letter was received after the presumed date of receipt.

6. Signatures

A CAP and/or reconsideration request must be submitted in the form of a letter that is signed by the individual provider, supplier, the authorized or delegated official, or a properly appointed representative, as defined in 42 C.F.R. § 498.10. If the representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier. This statement is sufficient to constitute notice. If the representative is not an attorney, the provider or supplier must file written notice of the appointment of a representative with the contractor. This notice of appointment must be signed by the individual provider or supplier, or the authorized or delegated official. The signature need not be original and can be electronic.

Authorized or delegated officials for groups cannot sign and submit a CAP and/or reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

(**NOTE:** The provider or supplier's contact person (as listed in section 13 of the Form CMS-855) does not qualify as a "representative" for purposes of signing a reconsideration request without the requisite appointment statement and signature by the individual provider or supplier.)

If the CAP and/or reconsideration request is not appropriately signed or if a statement from the attorney or written notice of representation is not included in the submission, the MAC shall send a development request for a proper signature or the missing statement/written notice (using the applicable model letter) before dismissing the CAP and/or reconsideration request. The MAC shall allow 15 calendar days from the date of the development request letter for the CAP and/or reconsideration request submitter to respond to the development request.

If the CAP and/or reconsideration request submission is not appropriately signed and no response is timely received to the development request (if applicable), the MAC shall dismiss the CAP and/or reconsideration request using the applicable model dismissal letter.

7. Representative for CAP and/or Reconsideration Request

Per 42 C.F.R. § 498.10, a provider or supplier may appoint as its representative any individual that is not disqualified or suspended from acting as a representative in proceedings before the Secretary of the Department of Health and Human Services or otherwise prohibited by law to engage in the appeals process. If this individual is an attorney, the attorney's statement that he or

she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative. If the representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with CMS or the MAC. Once a representative has been properly appointed, the representative may sign and/or submit a CAP, reconsideration request, request for reversal, or a request for good cause exception on behalf of the provider or supplier.

8. Submission of Enrollment Application while a CAP and/or Reconsideration Request is Pending/Submission Timeframe has not Expired

If a provider or supplier's enrollment application is denied, the provider or supplier must wait until the time period in which to submit a CAP and/or reconsideration request has ended before submitting a new enrollment application, change of information, or provides any additional information to update their enrollment record. If the MAC receives an enrollment application, change of information, or additional information to update a provider's or supplier's enrollment record prior to the conclusion of the time period in which to submit a CAP and/or reconsideration request, the MAC shall return the application unless the application is received as part of the provider's or supplier's CAP and/or reconsideration request submission. The MAC shall not modify the enrollment record of a provider or supplier that currently has a pending CAP and/or reconsideration request for revocations or is still within the submission time period for denials unless instructed by CMS to do so. Any applications received while the provider or supplier is in a revoked status should be returned to the provider or supplier and not processed pursuant to Section 10.4(H)(1).

B. Corrective Action Plans (CAPs)

1. Background

A CAP is a plan that allows a provider or supplier an opportunity to demonstrate compliance by correcting the deficiencies (if possible) that led to the initial determination. CAPs may only be submitted in response to enrollment denials pursuant to 42 C.F.R. § 424.530(a)(1) and revocation of Medicare billing privileges pursuant to 42 C.F.R. § 424.535(a)(1).

2. Requirements for CAP Submission

CAP submission:

(a) Must contain, at a minimum, verifiable evidence that the provider or supplier is in compliance with all applicable Medicare requirements;

(b) Must be received within 35 calendar days from the date of the initial determination (see section 10.6.18(A)(4) for clarification on timing). The contractor shall accept a CAP via hard-copy mail, email, and/or fax;

(c) Must be submitted in the form of a letter that is signed by the individual provider or supplier, the authorized or delegated official that has been reported within your Medicare enrollment record, or a properly appointed representative;

(d) Should include all documentation and information the provider or supplier would like to be considered in reviewing the CAP.

(e) For denials, the denial must be based on 42 C.F.R. § 424.530(a)(1);

i. For denials based on multiple grounds of which one is § 424.530(a)(1), the CAP may only be accepted with respect to § 424.530(a)(1), but not with respect to the other grounds. If the provider or supplier submits a CAP that does not comply with this paragraph, the MAC shall address this in the acknowledgement email or letter sent to the provider or supplier using the model acknowledgement letter (If multiple grounds are involved of which one is § 424.530(a)(1), the MAC shall:

A. Only consider the portion of the CAP pertaining to § 424.530(a)(1). The other denial bases may only be reviewed as a reconsideration.

(f) For revocations, the revocation must be based on 42 C.F.R. § 424.535(a)(1);

i. Consistent with § 405.809, CAPs for revocations based on grounds other than § 424.535(a)(1) shall not be accepted.

A. For revocations based on multiple grounds of which one is § 424.535(a)(1), the CAP may be accepted with respect to 424.535(a)(1), but not with respect to the other grounds. If the provider or supplier submits a CAP that does not comply with this paragraph, the MAC shall address this in the acknowledgment email or letter sent to the provider or supplier using the model acknowledgment letter. (If multiple grounds are involved of which one is § 424.535(a)(1), the MAC shall:

1. Only consider the portion of the CAP pertaining to § 424.535(a)(1). The other revocation bases may only be reviewed as a reconsideration.

3. Receipt Acknowledgment of CAP

If the MAC receives an acceptable CAP for a provider or supplier, the MAC shall use the model acknowledgment letter to email (if a valid email address is available) and send a hard-copy letter to the address included on the CAP submission letter or if no address is listed on the CAP submission letter, then the return address on the envelope from which the CAP was submitted within 14 calendar days of the date of receipt of the CAP, informing the provider, supplier, or its representative that a CAP decision will be rendered within 60 calendar days of the date of receipt of the CAP. If no address is listed in the CAP, then an acknowledgment letter should be sent to the correspondence address on the provider's or supplier's enrollment record.

If the provider's or supplier's CAP cannot be accepted due to untimeliness, an improper signature (including a failure to respond to development for the required statement or signed declaration from a representative), or any other reason, the MAC shall **not** send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall dismiss the CAP using the applicable model dismissal letter.

4. Dismissing a CAP

A CAP shall be dismissed when the provider or supplier does not have the right to submit a CAP for the initial determination, or when the provider or supplier submitted the CAP improperly or untimely (see Section 10.6.18(B)(2)). As a result, the CAP shall not be reviewed. The MAC shall use the model dismissal letter when dismissing a CAP. All unacceptable CAPs shall be dismissed as soon as possible.

If a provider or supplier concurrently submits a CAP and reconsideration request, but the initial determination being appealed does not afford CAP rights or the CAP submission is untimely, the MAC shall dismiss the CAP using the No CAP Rights Dismissal Model Letter or Untimely CAP Dismissal Model Letter and review the reconsideration request in accordance with the instruction in Section 10.6.18(C).

5. CAP Analysis

The MAC shall only review the CAP as it relates to denial of enrollment pursuant to 42 C.F.R. § 424.530(a)(1) or a revocation of billing privileges pursuant to § 424.535(a)(1). The MAC must determine whether or not the information and documentation submitted with the CAP establishes that the provider or supplier has demonstrated compliance with all applicable Medicare rules and requirements by correcting the deficiency that led to the initial determination. If the MAC finds that the CAP corrects the deficiency that led to the initial determination, then the MAC shall overturn the initial determination as it relates to the denial reasons under 42 C.F.R. § 424.530(a)(1) or revocation under 42 C.F.R. § 424.535(a)(1). If the denial of enrollment is overturned completely, the MAC shall continue processing the previously denied enrollment application in accordance with standard processing procedures. If the revocation is overturned completely, the MAC shall reinstate the provider's or supplier's enrollment to an approved status based on the date the provider or supplier came into compliance. Consider the following example:

Example 1: A provider or supplier is denied enrollment under 42 C.F.R. § 424.530(a)(1) or revoked under 42 C.F.R. § 424.535(a)(1) because its required license has been suspended. The provider timely submits a CAP in which it provides evidence that its licensure has been reinstated and is currently active. After confirming the status of current licensure, the MAC should render a favorable CAP decision because the provider or supplier has corrected the licensure issue that led to enrollment denial or revocation.

If the provider or supplier submitted a CAP for reasons in addition to 42 C.F.R. § 424.535(a)(1), the MAC shall include in the decision letter that the CAP was reviewed only in regards to the 42 C.F.R. § 424.535(a)(1) basis.

If the provider or supplier does not submit information that establishes compliance with all applicable Medicare rules and requirements by correcting the deficiency that led to the initial determination, the MAC need not contact the provider or supplier for the missing information or documentation. The MAC shall instead deny the CAP. Under 42 C.F.R. § 405.809(a)(2), with respect to the revocation basis, the supplier has only one opportunity to correct all deficiencies that served as the basis of its revocation through a CAP.

6. Processing and Approval of CAPs

The time to submit a reconsideration request continues to run even though the MAC has received a CAP and is reviewing the CAP. Therefore, the time period in which to submit a reconsideration request does not stop once a CAP is received and while the CAP is being reviewed. The provider or supplier must submit a reconsideration request within 65 days of the date of the initial determination, even if a CAP is timely submitted and accepted.

The hearing officer shall issue a written decision within 60 calendar days of the date of receipt of the accepted CAP. The hearing officer shall email and mail a hard copy of the CAP decision to the provider or supplier or the individual that submitted the CAP, unless an email address is unavailable or the email is returned, then only a hard copy letter shall be mailed to the return address on the reconsideration request/envelope or the mailing address on the provider's/supplier's enrollment record if no return address is included on the reconsideration request. The MAC should also send the CAP decision letter via fax if a valid fax number is available.

If the MAC approves a CAP, it shall notify the provider or supplier by issuing a favorable decision letter following the applicable model CAP letter. The MAC shall continue processing the enrollment application under standard processing timelines or restore billing privileges (as applicable) within 10 business days of the date of the CAP decision or the date of receipt of additional documentation, if needed.

For denials – and unless stated otherwise in another CMS directive or instruction – the effective date is the later of either the date of the filing of the enrollment application or the date on which services were first rendered. Consider the following examples:

a. Denials

A physician's initial enrollment application is denied on March 1, 2018. The physician submits a CAP showing that, as of March 20th, the physician was in compliance with all Medicare requirements. If the MAC or CMS approves the CAP, the effective date of for the physician's Medicare billing privileges should be March 20th, as that is the day on which the physician came into compliance with all Medicare requirements. The 30-day retrospective billing provision should not be applied in this situation because the rule assumes that the provider was in compliance with Medicare requirements during the 30-day period. This was not the case here. The physician was not in compliance with all Medicare requirements until March 20.

b. Revocations

A physician's medical license is suspended on June 1st. The physician's Medicare enrollment is revoked under 42 C.F.R. § 424.535(a)(1) on June 15th. The physician then submits a CAP showing that, as of July 1st, the physician is currently licensed. If the MAC or CMS approves the CAP, the effective date for reactivation of the physician's Medicare billing privileges should be July 1st as that is the day on which physician came into compliance with all Medicare requirements. The 30-day retrospective billing provision does not be apply in this situation.

The MAC shall ensure that the applicable CMS Regional Office is notified of the outcome of any CAP decision that involves the revocation of Medicare billing privileges for a certified provider or supplier.

If additional information/documentation is needed prior to reinstating the provider or supplier, the MAC shall document these next steps in their CAP decision letter. The MAC shall not reinstate the provider's or supplier's enrollment until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the CAP decision letter, the MAC shall contact the provider or supplier via the applicable model letter to again request the additional information/documentation within 10 calendar days of not receiving a response. If no response is received within 30 calendar days of the second request for additional information/documentation, the MAC shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

7. Withdrawal of CAP

The provider, supplier, or the individual who submitted the CAP may withdraw the CAP at any time prior to the mailing of the CAP determination. The withdrawal of the CAP must be postmarked prior to the CAP determination date. The request to withdraw the CAP must be made in writing, signed, and filed with the MAC or CMS. If the MAC receives a request to withdraw a CAP, it shall send a letter or e-mail to the provider or supplier acknowledging receipt of the request to withdraw the CAP and advising that the request has been dismissed, utilizing the applicable model letter.

8. Concurrent Submission of CAP and Reconsideration Request

If a provider or supplier submits a CAP and a reconsideration request concurrently in response to any denial of enrollment under 42 C.F.R. § 424.530(a)(1) or any revocation of billing privileges under 42 C.F.R. § 424.535(a)(1), the MAC shall first process and make a determination regarding the CAP, only as it relates to the denial and/or revocation under 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1). If the MAC renders a favorable decision as it relates to 42 C.F.R. § 424.530(a)(1) or 42 C.F.R. § 424.535(a)(1), the MAC shall only render a reconsideration decision on the remaining authorities not addressed by the favorable CAP decision. Processing timelines still apply.

If a CAP and a reconsideration request (see Section 10.6.18(B)(8)below) are submitted concurrently, the MAC shall coordinate the review of the CAP and reconsideration request to ensure that the CAP is reviewed and a decision rendered before a reconsideration decision is rendered (if the initial determination is not resolved in its entirety by the CAP decision).

If the CAP is approved and resolves the basis for the initial determination in its entirety, the model CAP decision letter shall be sent to the provider or supplier with a statement that the reconsideration request will not be evaluated because the initial determination has been overturned. If the CAP decision does not fully resolve the initial determination or results in a gap in the provider's or supplier's billing privileges, the MAC shall also process the reconsideration request.

If the CAP is denied:

- There are no further appeal rights; therefore, the CAP decision cannot be appealed. As a result, do not include further appeal rights for a CAP only decision.

- The MAC shall notify the provider or supplier of the denial of the CAP via the applicable CAP model letter.

- The provider or supplier may continue with the appeals process if it has filed a reconsideration request or is preparing to submit such a request and has not exceeded the timeframe in which to do so.

- The reconsideration request, if properly submitted, shall be processed.

C. Reconsideration Requests

1. Background

A reconsideration request allows the provider or supplier an opportunity to demonstrate that an error was made in the initial determination at the time the initial determination was implemented. In contrast to a CAP, a reconsideration request does not allow a provider or supplier the opportunity to correct the deficiencies that led to the initial determination.

2. Requirements for Reconsideration Request Submission

a. Must contain, at a minimum, state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement;

b. Must be received within 65 calendar days from the date of the initial determination (see Section 10.6.19(A)(4) for clarification on timing). The contractor shall accept a reconsideration request via hard-copy mail, email, and/or fax;

c. Must be submitted in the form of a letter that is signed by the individual provider or supplier, the authorized or delegated official that has been reported within your Medicare enrollment record, or a properly appointed representative;

d. Should include all documentation and information the provider or supplier would like to be considered in reviewing the reconsideration request;

3. Receipt Acknowledgement of Reconsideration Request

Upon receipt of a properly submitted reconsideration request, the MAC shall send an email (if a valid email address is available) and hard-copy letter, to the individual that submitted the reconsideration request to acknowledge receipt of the reconsideration request using the applicable model acknowledgment letter within 14 calendar days of the date of receipt of the reconsideration request. The MAC shall send a hard-copy letter to the address listed in the reconsideration request submission or the return address listed on the reconsideration request submission envelope if no address is included on the reconsideration request letter. If no address

is listed in the reconsideration request or on the envelope, then an acknowledgment letter should be sent to the correspondence address on the provider's or supplier's enrollment record. In the acknowledgment letter/email (if applicable), the MAC shall advise the requesting party that the reconsideration request will be reviewed and a determination will be issued within 90 calendar days from the date of receipt of the reconsideration request. The MAC shall include a copy of the acknowledgment letter and email (if applicable) in the reconsideration file. If the reconsideration should have been submitted to CMS, the MAC shall not send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall forward the appeal to CMS within 10 business days of the date of receipt of the reconsideration request (as specified in Section 10.6.18(A)(1)).

If the provider's or supplier's reconsideration request cannot be accepted due to untimeliness, an improper signature (including a failure to respond to development for the required statement or signed declaration from a representative, or any other reason), the MAC shall not send the provider or supplier an acknowledgment email or letter. Instead, the MAC shall dismiss the reconsideration request using the applicable model dismissal letter.

4. Reconsideration Determination

The MAC shall review all documentation in the record relevant to the initial determination and issue a written determination within 90 calendar days of the date of receipt of the accepted reconsideration request.

A proper reconsideration request must be received by the MAC or CMS within 65 calendar days of the date of the initial determination. Refer to Section 10.6.18(A)(4) for receipt date determinations. However, consistent with 42 C.F.R. § 498.24(a), the provider or supplier, may submit corrected, new, or previously omitted documentation or other facts in support of its reconsideration request at any time prior to the reconsideration decision being issued. The hearing officer must determine whether an error was made in the initial determination at the time the initial determination was implemented, based on all of the evidence presented. This includes:

- The initial determination itself,
- The findings on which the initial determination was based,
- The evidence considered in making the initial determination, and
- Any other written evidence submitted under § 498.24(a), taking into account facts relating to the status of the provider or supplier subsequent to the initial determination.

If the appealing party has additional information that it would like the hearing officer to consider during the reconsideration or, if necessary, an administrative law judge (ALJ) to consider during a hearing, the party must submit that information with its request for reconsideration. This is the party's only opportunity to submit information during the administrative appeals process; the party will not have another opportunity to do so unless an ALJ specifically allows the party to do so under 42 C.F.R. § 498.56(e).

5. Issuance of Reconsideration Determination

The hearing officer shall issue a written decision within 90 calendar days of the date of receipt of the accepted reconsideration request. The hearing officer shall email and mail a hard copy of the reconsideration decision to the provider or supplier or the individual that submitted the reconsideration request, unless an email address is unavailable or the email is returned, then only a hard copy letter should be mailed to the return address on the reconsideration request/envelope or the mailing address on the provider's/supplier's enrollment record if no return address is included on the reconsideration request. The MAC should also fax the CAP decision letter if a valid fax number is available. The reconsideration letter shall follow the applicable model letter and include:

- The regulatory basis to support each reason for the initial determination;
- A summary of the documentation that the provider or supplier provided, as well as any additional documentation reviewed as part of the reconsideration process;
- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in its initial determination;
- A clear explanation of why the hearing officer is upholding or overturning the initial determination in sufficient detail for the provider or supplier to understand the hearing officer's decision and, if applicable, the nature of the provider's or supplier's deficiencies. This explanation should reference the specific regulations and/or sub- regulations supporting the decision, as well as any documentation reviewed;
- If applicable, an explanation of how the provider or supplier does not meet the Medicare enrollment criteria or requirements;
- Further appeal rights, regardless of whether the decision is favorable or unfavorable, procedures for requesting an ALJ hearing, and the addresses to which the written appeal must be mailed or e-mailed. Further appeal rights shall only be provided for reconsideration decisions. There are no further appeals rights related to CAP decisions; and
- Information the provider or supplier must include with its appeal (name/legal business name; supplier number (if applicable); tax identification number/employer identification number (TIN/EIN); NPI; and a copy of the reconsideration decision).

Example 1: If a provider or supplier submits a reconsideration request in response to a revocation pursuant to 42 C.F.R. § 424.535(a)(5), the MAC shall review the initial determination, the enrollment application preceding the site visit, the site investigation report(s), the reconsideration request and supporting documentation, as well as any other relevant information, to determine if

an error was made in the implementation of the initial determination (e.g., if an error was made during the site visit, or the site visit was conducted at the wrong location.) If the MAC finds that an error was made during the site visit, which found the provider or supplier to be non-operational, the MAC shall order an additional site visit. If an additional site visit is ordered, the MAC shall await the findings of the site investigator, via the site visit report, before issuing a reconsideration decision. If the site visit report finds the provider or supplier to be operational then the MAC shall overturn the revocation of the provider's or supplier's Medicare billing privileges as it relates to 42 C.F.R. § 424.535(a)(5) using the applicable model letter.

If the MAC overturns the initial determination, the MAC shall reinstate the provider's or supplier's billing privileges to an approved status as of the effective date determined in the reconsidered determination or continue processing the enrollment application (as applicable). Unless otherwise instructed by PEOG, the MAC shall only send the favorable reconsideration decision to the provider or supplier, authorized or delegated official, or its representative at the return address included on the reconsideration request. The reconsideration decision is sufficient for providing notice to the provider or supplier of the enrollment action being taken. All enrollment updates shall be completed within 10 business days of the date the reconsideration decision was issued or the date of receipt of additional documentation, if needed.

For initial enrollments, the effective date of Medicare billing privileges is based on the date the provider or supplier is found to be in compliance with all Medicare requirements or the receipt date of the application – subject, of course, to any applicable retrospective billing provisions. (See Section 10.6.2 of this chapter for more information.) The MAC shall use the receipt date of the reconsideration request as the receipt date entered in the Provider Enrollment, Chain and Ownership System (PECOS). For DMEPOS suppliers, the effective date is the date awarded by the applicable contractor.

The MAC shall ensure that the applicable CMS Regional Office is notified of the outcome of any reconsideration decision that involves the revocation of Medicare billing privileges for a certified provider or supplier.

If additional information/documentation is needed prior to reinstating the provider or supplier, the MAC shall document these next steps in their reconsideration decision letter. The MAC shall not reinstate the provider's or supplier's enrollment until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the reconsideration decision letter, the MAC shall contact the provider or supplier via the applicable model letter to again request the additional information/documentation within 10 calendar days of not receiving a response. If no response is received within 30 calendar days of the second request for additional information/documentation, the MAC shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

6. Withdrawal of Reconsideration Request

The provider, supplier, or the individual who submitted the reconsideration request may withdraw the reconsideration request at any time prior to the mailing of the reconsideration decision. The withdrawal of a reconsideration request must be postmarked prior to the reconsideration decision date. The request to withdraw the reconsideration request must be made

in writing, signed, and filed with the MAC or CMS. If the MAC receives a request to withdraw a reconsideration request, it shall send a letter or e-mail to the provider or supplier acknowledging receipt of the request to withdraw the reconsideration request and advising that the request has been dismissed, utilizing the applicable model letter.

7. Requests for Reversal under 42 C.F.R. § 424.530(c)/424.535(e)

Under 42 C.F.R. § 424.530(c)/424.535(e), a provider or supplier may request reversal of a denial of enrollment or revocation of billing privileges if the denial or revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program. The revocation may be reversed, at the discretion of CMS, if the provider or supplier terminates and submits proof that it has terminated its business relationship with the individual or organization against whom the adverse action is imposed within 15 days of the revocation determination. (For reversal of denials, the timeframe within 30 days of the denial notification.) Information that may provide sufficient proof includes, but is not limited to, state corporate filings, IRS documentation, sales contracts, termination letters, evidence of unemployment benefits, board governance documents, and payroll records.

If the MAC receives a CAP and/or reconsideration request from a provider or supplier to reverse or rescind a denial or enrollment or revocation due to the termination of the business relationship between the provider or supplier and the individual against whom the adverse action is imposed, the MAC shall not take any action. The MAC shall forward the CAP and/or reconsideration request to ProviderEnrollmentAppeals@cms.hhs.gov within 10 business days of receipt. The MAC shall not take any action pursuant to the request until further instruction is provided by CMS.

8. Not Actionable CAPs and Reconsideration Requests

If the issue in the initial determination is resolved prior to a CAP and/or reconsideration decision being rendered, the basis of the initial determination may become moot and the CAP and/or reconsideration request will be not actionable. The MAC will be notified if an action has been taken that would render a CAP and/or reconsideration request not actionable as CMS would contact the MAC to rescind the revocation or reinstate the provider or supplier's Medicare billing privileges. If the MAC receives such a notification, then the MAC shall review to determine if a CAP and/or reconsideration request has become not actionable. If so, the MAC shall send a hard copy letter should be mailed to the return address on the CAP or reconsideration request, as well as the provider's or supplier's correspondence address using the applicable not actionable model letter. The MAC shall also send an email if a valid email address is available. The MAC may also send via fax if a valid fax number is available. The MAC shall attach a copy of the letter informing the provider or supplier of the enrollment action which led to the CAP and/or reconsideration request becoming not actionable. If there is a scenario not captured in the not actionable model letter and the MAC believes a CAP and/or reconsideration request has become not actionable, the MAC should email ProviderEnrollmentAppeals@cms.hhs.gov for guidance.

9. Requesting Guidance Related to CAPs and Reconsideration Requests

If the MAC encounters a situation that is not addressed by these instructions, the MAC shall contact the ProviderEnrollmentAppeals@cms.hhs.gov inbox for guidance before taking any action.

D. Further Appeal Rights for Reconsidered Determinations

1. Administrative Law Judge (ALJ) Hearing

The CMS or a provider or supplier dissatisfied with a reconsidered determination is entitled to review by an ALJ with the CRD DAB. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. To request final ALJ review, the provider or supplier must file an appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision. A provider or supplier may file an appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, the provider or supplier must first register a new account by:

(a) Clicking Register on the DAB E-File home page;
(b) Entering the information requested on the "Register New Account" form; and
(c) Clicking Register Account at the bottom of the form. If the provider or supplier has more than one representative, each representative must register separately to use DAB E-File on his/her/its behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, a provider or supplier may file an appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

Pursuant to 42 C.F.R. § 405.809(a)(2), a provider or supplier may not appeal an adverse

determination for a CAP, if one was made.

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of a request for an ALJ hearing, an ALJ at the CRD DAB will issue a letter by certified mail to the supplier, CMS and the OGC acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney to represent CMS during the appeals process; he/she will also serve as the DAB point of contact. Neither CMS nor the Medicare contractor are required to participate in the pre-hearing conference, but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The MAC shall work with and provide the OGC attorney with all necessary documentation. This includes compiling and sending all relevant case material to the OGC attorney upon the latter's request within 5 calendar days of said request.

Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS. If CMS agrees to settle a provider enrollment appeal, CMS will notify the contractor of appropriate next steps (e.g., changing the effective date of billing privileges or reinstating a provider's billing privileges). This may result in PEOG providing specific instructions to the contractor to modify model letter language to appropriately notify the provider of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

If an ALJ decision is rendered that overturns and/or modifies the initial determination establishing an effective date, revocation or denial of billing privileges, or remands a case back to CMS, this may also result in PEOG providing specific instructions to the contractor to draft and issue a revised reconsideration decision and/or modify the model letter language to appropriately notify the provider or supplier of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

The MAC shall complete all steps associated with the settlement or ALJ decision no later than 10 business days from the date it received PEOG's specific instructions.

2. Departmental Appeals Board (DAB) Hearing

The CMS or a provider/supplier dissatisfied with the ALJ hearing decision may request a Board review by the DAB. Such a request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a DAB review is deemed to be a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, a transcript will be prepared and made available to any party upon request.

When CMS receives a decision or order from the DAB, as appropriate, PEOG will notify the MAC of appropriate next steps (i.e., changing an effective date or reinstating a provider's billing privileges). This may also result in PEOG providing specific instructions to the contractor to draft and issue a revised reconsideration decision and/or modify the model letter language to appropriately notify the provider of changes to its enrollment status, revocation effective date, or effective date of billing privileges.

The MAC shall complete all steps associated with the DAB decision no later than 10 business days from the date it received PEOG's specific instructions.

3. Judicial Review

A supplier dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such a request shall be filed within 60 days from receipt of the notice of the DAB's decision.

E. External Monthly Reporting Requirements for CAPs and Reconsideration Requests

Using the provider enrollment appeals reporting template, the MAC shall complete all columns listed for all appeal submissions except those submissions that are referred to CMS for processing (CAPs and reconsideration requests). No column shall be left blank. If the contractor is unable to complete all columns for a given appeal submission, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within five business days of discovery to seek further guidance.

The response in column A labelled, "Initial Determination Type," shall be one of the following:

- **Denial:** CAP or Reconsideration Request that challenges the denial of a Medicare enrollment application pursuant to 42 C.F.R. § 424.530(a)(1)-(18).

- **Revocation:** CAP or Reconsideration Request that challenges the revocation of Medicare billing privileges or provider/supplier number pursuant to 42 C.F.R. § 424.535(a)(1)-(23).

- **Effective Date:** Reconsideration request that challenges an initial determination that establishes an effective date of participation in the Medicare program, including the effective date of reactivation after deactivation.

- **Other:** CAP or reconsideration request that does not fall under the three categories listed above. If other is listed, an explanation shall be provided in the "Comments" column N and "N/A" in column G.

The response in Column L labelled, "Final Decision Result," shall be one of the following (If a final decision has not been issued, the column shall read as "In Process." If the appeal submission is referred to CMS for processing then the appeal should not be included on the MAC Monthly Appeals Report

1. Not Actionable: Appeal is no longer actionable (moot) because the basis for the initial determination has been resolved. (Ex: Fingerprints have received a passed designation, initial determination has been reopened and revised).

2. Favorable (to provider/supplier): MAC has determined that an error was made in the implementation of the initial determination. Therefore, the initial determination was overturned and the enrollment record has been placed in approved status, the effective date modified, or application processing has continued.

3. Unfavorable (to provider/supplier): MAC upholds the initial determination resulting in the enrollment remaining in a revoked or denied status, or the effective date remaining the same.

4. Dismissed: The appeal does not meet the appeal submission requirements. (Ex: incorrect signature, untimely, not appealable, etc.)

5. Rescinded: MAC has received instruction from CMS to rescind the initial determination and return the enrollment record to an approved status.

6. Withdrawn: Provider/supplier has submitted written notice of its intent to withdraw its appeal (CAP or reconsideration request).

The response in Column M labelled, "Date Final Decision Issued," shall be "In Process" if a final decision has not been issued at the time the monthly report is sent to CMS.

The response in Column K labelled, "Date Receipt Acknowledgement Sent to Provider/Supplier/Legal Representative," shall be "Not yet sent" if a receipt acknowledgement email/letter has not been sent to the provider/supplier/legal representative at the time the monthly report is sent to CMS. The response shall be "N/A" if a receipt acknowledgement email/letter is not required for that case.
The response in Column F labelled, "MAC (Including Jurisdiction)," shall be in one of the following formats:

1. **CGS**
2. **FCSO**
3. **NGS JK**
4. **NGS J6**
5. **Palmetto JM**
6. **Palmetto JJ**
7. **NSC**
8. **WPS J8**

9. **WPS J5**

10. **Noridian JE**

11. **Noridian JF**

12. **Novitas JL**

13. **Novitas JH**

The response in Column G, "Regulatory Authority (As identified on initial determination)," shall be in the following format (the authorities will need to be modified based on the type of initial determination):

- For Effective Date appeal: 424.520;
- For Denial appeal with only one authority cited in the initial determination: 424.530(a)(1-18);
- For Denial appeal with multiple authorities cited in the initial determination: 424.530(a)(1-18)(1-18)
- For Revocation appeal with only one authority cited in the initial determination: 424.535(a)(1-23)
- For Revocation appeal with multiple authorities cited in the initial determination: 424.535(a)(1-23)(1-23).
- For Other appeal: N/A with an explanation in the Comments column N.

The reports shall be sent to CMS via email at ProviderEnrollmentAppeals@cms.hhs.gov no later than the 15th of each month; the report shall include the prior month's appeal submissions, as well as outcomes for all submissions previously received that were not yet completed and reported to CMS (e.g., the February report shall cover all January CAPs/reconsideration requests). All submissions shall remain on the monthly report until a final outcome/decision has been reported to CMS. If this day falls on a weekend or a holiday, the report must be submitted the following business day.

10.6.19 – Other Medicare Contractor Duties

(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

(The contractor also shall review section 10.3 of this chapter regarding the topics in this section 10.6.19. In the event of a conflict, those instructions take precedence over those in this section 10.6.19.)

The contractor shall adhere to all instructions in this chapter and other CMS provider enrollment directives (e.g., technical direction letters). The contractor shall also assign the appropriate number of staff to the Medicare enrollment function to ensure that all such instructions and directives - including application processing timeframes and accuracy standards - are complied with and met.

A. Training

The contractor shall provide (1) training to new employees, and (2) refresher training (as necessary) to existing employees to ensure that each employee processes enrollment applications in a timely, consistent, and accurate manner. Training shall include, at a minimum:

- An overview of the Medicare program
- A review of all applicable regulations, manual instructions, and other CMS guidance
- A review of the contractor's enrollment processes and procedures
- Training regarding PECOS.

For new employees, the contractor shall also:

- Provide side-by-side training with an experienced provider enrollment analyst
- Test the new employee to ensure that he or she understands Medicare enrollment policy and contractor processing procedures, including the use of PECOS
- Conduct end-of-line quality reviews for 6 months after training or until the analyst demonstrates a clear understanding of Medicare enrollment policy, contractor procedures, and the proper use of PECOS.

For existing employees, the contractor shall perform periodic quality reviews and refresher trainings.

B. PECOS

The contractor shall:

- Process all enrollment actions (e.g., initials, changes, revalidations, revocations, appeals, denials) through PECOS
- Deactivate or revoke the provider or supplier's Medicare billing privileges in the Multi-Carrier System or the Fiscal Intermediary Shared System only if the provider or supplier is not in PECOS; if the provider does not exist in MCS or FISS, the contractor shall contact its PEOG BFL prior to taking action.
- Close or delete any aged logging and tracking (L & T) records older than 120 days for which there is no associated enrollment application
- Participate in user acceptance testing for each PECOS release
- Attend scheduled PECOS training when requested

- Report PECOS validation and production processing problems through the designated tracking system for each system release

- Develop (and update as needed) a written training guide for new and current employees on the proper processing of Form CMS-855 and Form CMS-20134 applications, opt-out affidavits, and the appropriate entry of data into PECOS.

C. Customer Service

1. Responding to Provider Enrollment Inquiries

The contractor's customer service unit may handle provider enrollment inquiries that do not involve complex enrollment issues. Examples of inquiries that can be processed by customer service units include:

- Application status checks (e.g., "Has the contractor finished processing my application?") (The contractor may wish to establish electronic mechanisms by which providers can obtain updates on the status of their enrollment applications via the contractor's web site or automated voice response (AVR).

- Furnishing information on where to access Form CMS-855 or Form CMS-20134 applications (and other general enrollment information) online

- Explaining to providers/suppliers which Form CMS-855 or CMS-20134 applications should be completed.

2. Contractor's Responsiveness to Inquiries

Excluding matters pertaining to application processing (e.g., development for missing data) and appeals (e.g., appeal of revocation), the contractor is encouraged to respond to all enrollment-related provider/supplier correspondence (e.g., e-mails, letters, telephone calls) within 30 business days of receipt.

D. Contractor Outreach to Providers

The contractor is strongly encouraged to establish e-mail "list serves" with the provider community to disseminate important information thereto, such as contractor address changes, new CMS enrollment policies or internal contractor procedures, reminders about existing policies, etc. By being proactive in distributing information to its providers and suppliers on a regular basis (e.g., weekly, bi-weekly), the contractor can reduce the number of policy inquiries it receives and help facilitate the submission of complete and accurate Form CMS-855 and Form CMS-20134 applications.

E. Encouraging Use of Internet-based PECOS

When a prospective provider or supplier contacts the contractor to obtain a paper enrollment Form CMS-855 or Form CMS-20134, the contractor shall encourage the provider or supplier to

submit the application using Internet-based PECOS. The contractor shall also notify the provider or supplier of:

- The CMS Web site at which information on Internet-based PECOS can be found and at which the paper applications can be accessed (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index?redirect=/MedicareProviderSupEnroll/).
- The contractor's address so that the applicant knows where to return the paper application.
- Any supporting documentation required for the applicant's provider/supplier type.
- Other required forms as described in sections above. Notification can be given in any manner the contractor chooses.

F. Adherence to Responsibilities Based Upon Jurisdiction - Audit and Claims Contractors

1. Background

For purposes of enrollment via the Form CMS-855A, there are generally two categories of contractors: audit contractors and claims contractors. The audit contractor enrolls the provider, conducts audits, etc. The claims contractor pays the provider's claims. In most cases, the provider's audit contractor and claims contractor will be the same. On occasion, though, they will differ. This can happen, for instance, with provider-based entities, whereby the parent provider's contractor (audit contractor) will process the provider's enrollment application and a different contractor will pay the provider's claims (claims contractor).

Should the audit and claims contractors differ, the audit contractor shall process all changes of information, including all Form CMS-588 changes. The audit contractor shall notify the applicant during the initial enrollment process that all future changes of information must be sent to the audit contractor, not the claims contractor. If the provider inadvertently sends a change request to the claims contractor, the latter shall return the application per the instructions in this chapter.

2. Process

If the audit contractor approves the Form CMS-855A transaction in question (e.g., initial enrollment), it shall:

(i) Send an e-mail to the claims contractor identifying the specific Form CMS-855A transaction involved and confirming that the information has been updated in PECOS. Pertinent identifying information, such as the provider name, CCN, and NPI, shall be included in the e-mail notification. The audit contractor need not include any supporting documentation in the e-mail because PECOS will contain any documents (e.g., approval letters from the state).

(ii) As applicable, fax, mail, or email an encrypted copy of the submitted Form CMS-588 to the appropriate claims contractor.

Upon receipt of the e-mail notification, the claims contractor shall access PECOS, review the enrollment record, and, as needed, update its records accordingly.

The audit contractor shall ensure that all original copies of Form CMS-855A paperwork and supporting documentation (including all Form CMS-588s), approval letters from the state, and other written documents related to the application are uploaded in PECOS.

If the provider's audit contractor and claims contractor are different, the audit contractor shall e-mail or fax a copy of all SOG Location approval/denial notices/letters it receives to the claims contractor. This is to ensure that the claims contractor is fully aware of the SOG Location's action, as some may only send copies of the approval letters to the audit contractor. If the audit contractor chooses, it can simply contact the claims contractor by phone or e-mail and ask if the latter received the tie-in notice.

It is imperative that audit and claims contractors effectively communicate and coordinate with each other in all payment-related and program integrity matters involving the provider.

G. Online Presence – Web Sites

The contractor must provide a link to CMS' provider/supplier enrollment Web site located at https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/index.html?redirect=/medicareprovidersupenroll/ . The link shall: (1) be available on the contractor's existing provider outreach Web site (which should be an established sub-domain of the contractor's current commercial Web site), and (2) comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications (PCOM) Budget and Performance Requirements (BPRs). Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194 and with CMS' Contractor Website Standards and Guidelines posted on CMS's web site.

The CMS Provider/Supplier Enrollment Web site gives users access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment website and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its website that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis (specifically, no later than the 15th day of January, April, July, and October), each contractor shall review and provide updates regarding its contact information shown at URL: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/contact_list.pdf. If the contractor services several states with a universal address and telephone number, the contractor shall report that information. In situations where no updates are needed, a response from the contractor is still required (i.e., the contact information is accurate). In addition, only such information that

pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the contractor's PEOG BFL.

H. Document Uploading and Retention

1. Introduction

To ensure that proper internal controls are maintained and that important information is recorded in case of potential litigation, the contractor shall maintain documentation as outlined in this section 10.6.19(H) and, as applicable, section 10.3. CMS cannot stress enough how crucial it is for contractors to document their actions as carefully and thoroughly as possible.

The requirements in this section 10.6.19(H) are in addition to, and not in lieu of, all other documentation or document maintenance requirements that CMS has mandated.

The contractor shall maintain and store all documents relating to the enrollment of a provider into Medicare. These documents include, but are not limited to, Medicare enrollment applications and all supporting documents, attachments, correspondence, and correspondence tracking documentation, and appeals submitted in conjunction with an initial enrollment, reassignment, change of enrollment, revalidation, etc.

Supporting documentation includes, but is not limited to:

- Copies of federal, state and/or local (city/county) professional licenses, certifications and/or registrations;
- Copies of federal, state, and/or local (city/county) business licenses, certifications and/or registrations;
- Copies of professional school degrees or certificates or evidence of qualifying course work;
- Copies of CLIA certificates and FDA mammography certificates;
- Copies of any entry found on the MED report that leads to a provider or supplier's revocation, and;
- Copies of Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) recognition letters or certificates indicating full or MDPP preliminary recognition.

See section 10.6.19(I) below for additional document uploading requirements.

2. Document Disposal

The contractor shall dispose of the aforementioned records as described below:

i. Provider/Supplier and Durable Medical Equipment Supplier Application

a. Rejected applications as a result of provider failing to provide additional information

Disposition: Destroy when 7 years old.

b. Approved applications of provider/supplier

Disposition: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier

Disposition: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but the billing number was subsequently revoked

Disposition: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

Disposition: Destroy 15 years after deactivation.

f. Provider/Supplier dies

Disposition: Destroy 7 years after date of death.

ii. Electronic Mail and Word Processing System Copies

a. Copies that have no further administrative value after the recordkeeping copy is made. These include copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: Delete within 180 days after the recordkeeping copy has been produced.

b. Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy.

Disposition: Delete when dissemination, revision, or updating is complete.

I. Keeping Record of Activities

As with document retention as described in subsection (H) above, it is important that the contractor maintains records of its written and telephonic communications. The contractor shall thus adhere to the instructions in this subsection (I).

1. Written Communications

(For purposes of this section 10.6.19(I)(1), "written correspondence" includes mailed, faxed, and e-mailed correspondence. Note that this is different from supporting documentation accompanying an enrollment application, the requirements for which are addressed in subsection (H) above.)

Except as stated in this subsection (I)(1), the contractor shall:

- Retain copies of all written correspondence pertaining to the provider, regardless of whether the correspondence was initiated by the contractor, the provider, CMS, state officials, etc.

- Document when it sends written correspondence to providers. For instance, if the contractor crafts an approval letter to the supplier dated March 1 but sends it out on March 3, the contractor shall note this in PECOS.

- Document all referrals to CMS, the UPIC, or the OIG

In cases where the written correspondence is sent directly via or to PECOS (e.g., PCV), the contractor need not separately document this; PECOS will retain this information (date, time, etc.). For all other written correspondence not sent via or to PECOS, the contractor (1) shall upload a copy of the correspondence into PECOS (e.g., fax, a printed copy of the e-mail) and (2) shall note in PECOS:

- The type of correspondence (e.g., approval letter)
- The form of correspondence (e.g., fax, e-mail)
- The date and time the correspondence was sent
- The party to whom the correspondence was sent (e.g. provider name, contact person)

2. Telephonic or Face-to-Face Contact

(Telephonic or face-to-face contact is hereafter referred to as "oral communication.")

The contractor shall document any and all actual or attempted oral communication with the provider, any representative thereof, or any other person or entity regarding a provider. This includes, but is not limited to, the following situations:

- Telephoning a provider about its application. (Even if the provider official was unavailable and a voice mail message was left, this must be documented.)

- Requesting information from the state or another contractor concerning the applicant or enrollee

- Contacting the UPIC for an update concerning a particular case

- Phone calls from the provider

- Conducting a meeting at the contractor's headquarters/offices with officials from a hospital concerning problems with its application

- Telephoning PEOG, the state agency, or the SOG Location and receiving instructions therefrom about a problem the contractor is having with an applicant or an existing provider

- Telephoning the provider's billing department with a question about the provider.

When documenting oral communications, the contractor shall indicate (1) the time and date of the call or contact, (2) who initiated the contact, (3) who was spoken with, and (4) what the conversation pertained to. Concerning the last requirement, the contractor need not write down every word that was said during the conversation. Rather, the documentation should merely be adequate to reflect the contents of the conversation.

The documentation requirements in this subsection (I)(2) only apply to enrolled providers and to providers that have already submitted an enrollment application. In other words, these documentation requirements go into effect only after the provider submits an initial application. To illustrate, if a hospital contacts the contractor requesting information concerning how it should enroll in the Medicare program, this need not be documented because the hospital has not yet submitted an enrollment application.

All oral communications addressed in this subsection (I)(2) shall be documented in PECOS.

If an application is returned, the contractor shall document this. The manner of documentation lies within the contractor's discretion.

J. Documenting Verification of Data Elements

Once the contractor has completed its review of the Form CMS-855 and Form CMS-20134 applications (e.g., approved/denied application, approved change request) as well as opt-out affidavits, it shall document that it has: (1) verified all data elements on the application, and (2) reviewed all applicable names on the above- mentioned forms against the OIG/LEIE and the System for Access Management (SAM). It can be drafted in any manner the contractor chooses so long as it certifies that the above-mentioned activities were completed.

For each person or entity that appeared on the OIG/LEIE or SAM, the contractor shall document any positive findings via a screen printout and upload it into PECOS. In all other situations, the contractor is not encouraged to document their reviews via screen printouts. Simply using the verification statement described above is sufficient. Although the contractor has the discretion to use screen prints if it so chooses, the aforementioned verification statement is still required.

K. Release of Information

On October 13, 2006, CMS published System of Records Notice for PECOS in the Federal Register. Consistent with this notice, once the provider has submitted an enrollment application (as well as after it has been enrolled), the contractor shall not release – either orally or in writing - provider-specific data to any outside person or entity unless specified otherwise in this chapter. (Provider-specific data includes, but are not limited to, owners/managers, adverse legal history, practice locations, group affiliations, effective dates, etc.) Examples of outside persons or entities include, but are not restricted to, national or state medical associations or societies, clearinghouses, billing agents, provider associations, or any person within the provider's organization other than the provider's authorized official(s), delegated official(s), or contact persons. The only exceptions to this policy are:

- A routine use found in the aforementioned System of Records applies.

- The provider (or, in the case of an organizational provider, an authorized or delegated official): (1) furnishes a signed written letter on the provider's letterhead stating that the release of the provider data is authorized; and (2) the contractor has no reason to question the authenticity of the person's signature. The letter can be mailed, faxed, or e-mailed to the contractor. The contractor shall upload the letter in PECOS.

- The release of the data is specifically authorized in some other CMS instruction or directive.

(These provisions also apply in cases where the provider requests a copy of any Form CMS-855 or CMS-20134 paperwork the contractor has on file that the provider does not already have access to in PECOS. For instance, if the provider already uses PECOS for application submissions, the contractor can simply refer the provider to PECOS if the document in question is in PECOS. If the provider does not use PECOS, the contractor shall not require the provider to do so in order to access the document(s) but shall follow the above instructions; the latter shall also be followed if the provider uses PECOS but the requested document is not in PECOS.)

It is recommended that the contractor notify the provider of the broad parameters of the aforementioned policy as early in the enrollment process as possible.

The following information shall be made available over-the-phone to a caller who is able to provide a provider/supplier's name, PTAN, TIN/SSN, and NPI number; the caller need not be listed on the provider/supplier's enrollment record as a contact person:

- Revalidation status (i.e., whether or not a provider/supplier has been revalidated)

- Revalidation due date

- Revalidation approval date

- The specific information related to a revalidation development request

- The date a provider/supplier was deactivated due to non-response to a revalidation or non-response to a development request.

In addition:

- When sending emails, the contractor shall not transmit sensitive data, such as SSNs or EINs, without first encrypting the email.

- The contractor may not send PECOS screen printouts to the provider.

- With the exception of Form CMS-855S applications, if any contact person listed on the provider's enrollment record requests a copy of a provider's Medicare approval letter or revalidation notice and the contact person does not have access to PECOS, the contractor shall send to the contact person via email, fax or mail. (This excludes certification Letters from the state agency, for the contractor does not generate these approvals.) If the contact person has access to PECOS, the contractor can simply refer him/her to PECOS. If the contact person does not use PECOS, the contractor shall not require the contact person to do so in order to access the document(s) but shall follow the above instructions; the latter shall also be followed if the contact person uses PECOS but the requested document is not in PECOS.)

L. Security

The contractor shall ensure that the highest level of security is maintained for all systems and its physical and operational processes in accordance with the CMS/Business Partners Systems Security Manual (BPSSM) and the Program Integrity Manual.

Applications shall never be removed from the controlled area to be worked on at home or in a non-secure location. Also, provider enrollment staff must control and monitor all applications accessed by other contractor personnel.

All contractor staff shall be trained on security procedures as well as relevant aspects of the Privacy Act and the Freedom of Information Act. This applies to all management, users, system owners/managers, system maintainers, system developers, operators and administrators - including contractors and third parties - of CMS information systems, facilities, communication networks, and information.

Note that these instructions are in addition to, and not in lieu of, all other CMS instructions regarding security.

M. Establishment of Relationships

To the maximum extent possible, and to help ensure it becomes aware of recent felony convictions of practitioners and owners of health care organizations, the contractor shall establish relationships with appropriate state government entities – such as, but not limited to, Medicaid fraud units, state licensing boards, and criminal divisions –to facilitate the flow of felony information from the state to the contractor. For instance, the contractor can request that the state inform it of any new felony convictions of health care practitioners.

N. Monitoring Information from State Licensing Boards

To help ensure that only qualified physicians and non-physician practitioners are enrolled in Medicare, the contractor shall undertake the activities described below. (For purposes of this section, the term "practitioner" includes both physicians and non-physician practitioners. In addition, the instructions in this section, apply only to these practitioners.)

No later than the 15th day of each month, the contractor shall review state licensing board information for each state within its jurisdiction to determine whether any of its currently enrolled practitioners have, within the previous 60 days:

- Had his/her medical license revoked, suspended, or inactivated (due to retirement, death, or voluntary surrender of license);

- Otherwise lost his/her medical license or have had his/her license expire.

For those practitioners who no longer have a valid medical license, the contractor shall take the necessary steps pursuant to this chapter.

The mechanism by which the contractor performs these monthly licensure reviews lies within its discretion, though the most cost-effective method shall be used.

O. Regarding Potential Identity Theft or Other Fraudulent Activity

If --when conducting the verification activities described in this chapter -- the contractor believes that a case of identity theft or other fraudulent activity likely exists, the contractor shall notify its PEOG BFL immediately; the BFL will instruct the contractor as to what, if any, action shall be taken (For example, a physician indicates that she is not establishing a new practice location or changing her EFT information, and that the application submitted in his/her name is false.)

10.6.20 – Screening: On-site Inspections and Site Verifications
(Rev. 12514; Issued: 02-22-24; Effective: 03-25-24; Implementation: 03-25-24)

The contractor shall review section 10.3 of this chapter for special instructions regarding site visits. In the event of a conflict, those instructions take precedence over those in this section 10.6.20.

A. DMEPOS Suppliers and IDTFs

The scope of site visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

(For purposes of this section 10.6.20, the term "contractor" refers to the Medicare Administrative Contractor; the term "SVC" refers to the site visit contractor.)

B. Provider and Supplier Types Other Than DMEPOS Suppliers and IDTFs

For provider/supplier types other than DMEPOS suppliers and IDTFs – that must undergo a site visit pursuant to this section 10.6.20 and § 424.518, the SVC will perform such visits consistent with the procedures in this section 10.6.20. This includes all of the following:

(1) Documenting the date and time of the visit, and including the name of the individual attempting the visit.

(2) Photographing the provider/supplier's business for inclusion in the provider/supplier's file. All photographs will be date/time stamped.

(3) Fully documenting observations made at the facility, which could include facts such as (a) the facility was vacant and free of all furniture, (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company.

(4) Writing a report of the findings regarding each site verification.

(5) Including a signed site visit report stating the facts and verifying the completion of the site verification.

In terms of the extent of the visit, the SVC will determine whether the following criteria are met: (i) the facility is open; (ii) personnel are at the facility; (iii) customers are at the facility (if applicable to that provider or supplier type); and (iv) the facility appears to be operational. This will require the site visitor(s) to enter the provider/supplier's practice location/site rather than simply conducting an external review. If any of the four elements ((i) through (iv)) listed above are not met, the contractor will, as applicable - and using the procedures outlined in this chapter and in existing CMS instructions - deny the provider's enrollment application pursuant to § 424.530(a)(5)(i) or (ii) or revoke the provider's Medicare billing privileges under § 424.535(a)(5)(i) or (ii).

C. Operational Status

When conducting a site verification to determine whether a practice location is operational, the SVC shall make every effort to limit its verification to an external review of the location. If the SVC cannot determine whether the location is operational based on this external review, it shall conduct an unobtrusive site verification by limiting its encounter with provider or supplier personnel or medical patients.

The contractor must review and evaluate the site visit results received from the SVC prior to making a final determination. If it is determined (during the review and evaluation process) that the location is non-operational based on the site visit results but there is reason to proceed with the enrollment, the contractor shall provide the appropriate justification in the comment section of the Validation Checklist in PECOS. (For example, a second site visit determined the location to be operational; the provider only renders services in patient's homes; etc.).

If the contractor is unsure of how to proceed based on its evaluation of the site visit results, it shall contact its PEOG BFL and copy its contracting officer's representative (COR).

D. Timing

Site verifications should be done Monday through Friday (excluding holidays) during their posted business hours. If there are no hours posted, the site verification should occur between 9 a.m. and 5 p.m. If, during the first attempt, there are obvious signs that the facility is no longer operational, no second attempt is required. If, on the first attempt, the facility is closed but there are no obvious indications that the facility is non-operational, a second attempt on a different day during the posted hours of operation should be made.

E. Documentation

As indicated previously, when conducting site verifications to determine whether a practice location is operational, the SVC shall:

(i) Document the date and time of the attempted visit and include the name of the individual attempting the visit.

(ii) As appropriate, photograph the provider/supplier's business for inclusion in the provider/supplier's file on an as-needed basis. All photographs should be date/time stamped.

(iii) Fully document all observations made at the facility (e.g., the facility was vacant and free of all furniture, a notice of eviction or similar documentation was posted at the facility, the space is now occupied by another company, etc.).

(iv) Write a report of its findings regarding each site verification.

F. Determination

(In the event an instruction in this subsection F is inconsistent with guidance in section 10.6.6, 10.4.7 et seq., or 10.4.8, the latter three sections of instructions shall take precedence.)

If a provider/supplier is determined not to be operational or in compliance with the regulatory requirements for its provider/supplier type, the contractor shall revoke the provider/supplier's Medicare billing privileges - unless the provider/supplier has submitted a change of information request that notified the contractor of a change in practice location. Within 7 calendar days of CMS or the contractor determining that the provider/supplier is not operational, the contractor shall update PECOS or the applicable claims processing system (if the provider/supplier does not have an enrollment record in PECOS) to revoke Medicare billing privileges and issue a revocation notice to the provider/supplier. The contractor shall afford the provider/supplier applicable appeal rights in the revocation notification letter.

For non-operational status revocations, the contractor shall use either 42 CFR § 424.535(a)(5)(i) or 42 CFR § 424.535(a)(5)(ii) as the legal basis for revocation. Consistent with 42 CFR § 424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider/supplier is no longer operational. The contractor shall establish a 2-year reenrollment bar for providers/suppliers that are not operational.

For regulatory non-compliance revocations, the contractor shall use 42 CFR § 424.535(a)(1) as the legal basis for revocation. Consistent with 42 CFR § 424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider/supplier is no longer in compliance with regulatory provisions for its provider/supplier type. The contractor shall establish a 2-year enrollment bar for providers/suppliers that are not in compliance with provisions for their provider/supplier type.

G. Multiple Site Visits

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall not order a site visit if the specific location to be visited has already passed a site visit within the last 12 months and the applicable provider/supplier is in an approved status.

Consider the following illustrations:

Example 1 - A single-site home health agency (HHA) undergoes a revalidation site visit on February 1. The HHA submits a change of information request on July 1 to add a branch location. The contractor shall order this site visit because the visit will occur at a location (i.e., the branch location) different from the main location (i.e., the location that underwent the February 1 revalidation visit).

Example 2 - A DMEPOS supplier undergoes a revalidation site visit on April 1. It submits an initial Form CMS-855S application on May 1 to enroll a second location. The new location shall undergo a site visit because: (1) it is different from the first (revalidated) location; and (2) it is/will be separately enrolled from the first location.

Example 3 - A physical therapy (PT) group has three locations – X, Y, and Z. As part of a revalidation, the contractor elects to order a site visit of Location Y rather than X or Z. The visit was performed on June 1. On October 4, the group submits a Form CMS-855B to report a change of ownership, thus requiring a site visit under this chapter. However, the contractor shall not order a visit for Location Y because this site has been visited within the past 12 months. Location X or Location Z must instead be visited.

Example 4 - An IDTF undergoes an initial enrollment site visit on July 1. On September 24, it submits a Form CMS-855B application to change its practice location; this mandates a site visit under this chapter. The site visit shall be performed even though the initial visit took place within the past 12 months. This is because the second visit will be of the new location, whereas the first visit was of the old location.

H. Certified Providers/Suppliers – Address Validation Error

Notwithstanding any other instruction to the contrary in this chapter, the contractor need not order a site visit for a certified provider/supplier prior to making a recommendation to the state if an address validation error is received in PECOS. The contractor shall override the error message and notate in the referral package that the address was unverifiable. This avoids multiple site visits being performed (that is, pre-enrollment, survey, and post enrollment).

10.6.21 – Miscellaneous Enrollment Topics
(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

This section 10.6.21 addresses additional provider enrollment policies. Except as otherwise stated, the instructions in this section supersede any other instructions to the contrary in this chapter. It is anticipated that the provisions in this section 10.6.21 will eventually be moved to those sections of this chapter most applicable to their respective subject matter. For organizational reasons, section 10.6.21 is merely a placeholder section of chapter 10.

A. Special Form CMS-855S Instructions

1. Addresses

If an address (e.g., correspondence address, practice location) on the Form CMS-855S lacks a city, state, or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

2. Insurance

With respect to the comprehensive liability insurance supplier standard in 42 CFR § 424.57(a)(10), the contractor shall: (1) verify with the insurance agent that the insurance policy is active and current; and (2) ensure that the contractor (i.e., the NPE contractor) is listed as the policy holder on the certificate. The contractor may contact the insurance agent via any manner it chooses; however, verification shall be documented consistent with section 10.6.19 of this chapter (e.g., documenting telephonic communications).

B. Transitioned Certified Providers and Suppliers – E-Mails to PEOG for Final Application Review and/or Approval

As described in this chapter, the contractor must refer various matters involving transitioned certified provider/supplier enrollment applications to PEOG for final application review and approval (e.g., system updates, assignment of CCN, etc.) When making such referrals---and notwithstanding any other instruction to the contrary in this chapter---the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.) This instruction, to reiterate, only applies to e-mails to PEOG involving: (1) transitioned certified providers/suppliers; and (2) instances where the contractor is explicitly required per this chapter to send the matter PEOG for final review, approval, and/or denial of an application (e.g., initial application, CHOW, certain COIs) and to wait for PEOG's determination. (See, for example, section 10.6.1.2(A)(3)(a) of this chapter.)

C. Contacting State or SOG Location for Updates

1. "Transitioned" Certified Providers/Suppliers - In situations where the contractor recommends approval to the state (initial applications, CHOWs, certain changes of information, etc.), the

contractor---if it has not received the state's recommendation within 120 days after the contractor sent its recommendation---may contact the state to ascertain whether said recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to determine the recommendation's status.

2. "Non-Transitioned" Certified Providers/Suppliers – If, as described in subsection (H)(1) above, the contractor recommends approval to the state, the contractor may contact the state for an update on the recommendation's status beginning 120 days after the recommendation was sent and every 30 days thereafter. If the state informs the contractor (via any means) that the application has been forwarded to the SOG Location, the contractor may contact the SOG Location for a status update every 30 days beginning on the date the contractor received this notice from the state.

D. Survey and Certification Documents – All Certified Providers and Certified Suppliers

1. Documents from the State/AO

As applicable to the provider/supplier type in question, the state or accrediting organization (AO) must provide the signed CMS-1561 (or other/similar contract) and copy of the HHS-690 to the contractor with its approval recommendation. (Note that the contractor can accept a CMS-1561 or HHS-690 from either the state or AO.)

If the state/AO neither furnished said documents **nor** otherwise indicated that they were uploaded into the Automated Survey Process Environment (ASPEN)/Internet Quality Improvement and Evaluation System (IQIES), the contractor shall contact the state/AO via any means for the applicable document(s). If the state/AO responds within 10 days of the contractor's request by either (a) sending the document(s) to the contractor or (b) stating that it has uploaded the document(s) into ASPEN/IQIES, the contractor can continue processing the application consistent with applicable instructions. (If the state/AO indicated (b) above, the contractor shall note this in its referral to PEOG.) If the state/AO does neither (a) nor (b) within this 10-day period, the contractor shall: (1) proceed with sending the referral to PEOG consistent with existing instructions; and (2) include evidence of the state/AO's lack of responsiveness (e.g., e-mail evidence of the contractor's request).

2. AO Documents to PEOG

As applicable to the situation and provider/supplier type, the contractor shall include the AO deeming letter in referrals to PEOG that are required under this chapter (e.g., initial approvals).

10.6.21.1 – Additional Miscellaneous Enrollment Topics

(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

(The instructions in this section 10.6.21.1 take precedence over all other contrary instructions in this chapter, including, but not limited to, the existing guidance in sections 10.3.1 et al. The policies in this section will eventually be incorporated into the sections of this chapter that are applicable to the subject matter.)

A. Type of Practice Location

For Form CMS-855A, CMS-855B, and CMS-855I applications, the contractor may collect the practice location type in Section 4 of the application via telephone or---if the practice location type is otherwise apparent---may forgo development altogether.

B. Voluntary Terminations for Non-Certified Suppliers

If a non-certified supplier wishes to voluntarily withdraw from Medicare (including deactivating all active PTANs), the supplier must submit the applicable Form CMS-855/20134 to do so. It cannot make this request via letter, phone, etc.

C. Initial Enrollments with Multiple Locations

(This section 10.6.21.1(C) takes precedence over all other instructions in this chapter excluding section 10.3.)

If a high or moderate-risk provider or supplier (hereafter "provider") is initially enrolling in Medicare and has multiple practice locations, the SVC will conduct a site visit of each location rather than simply one selected location. In such instances, the contractor shall note the following:

1. Certified Providers/Suppliers – If, per this chapter, the site visits are to be performed after the contractor receives a recommendation of approval from the state, the contractor shall wait until all site visits are completed before taking the next required step (e.g., referring the application to PEOG to final review).

2. Site Visit Failure – If one of the locations fails its site visit, the contractor shall follow existing guidance for handling such situations (e.g., approving the application but without the failed location).

D. Verification of Telephone Numbers

Except when the provider or supplier has a regulatory supplier standard regarding maintenance of a telephone number (e.g., § 410.33(g)(5) for IDTFs), the contractor need not verify the provider's or supplier's phone number listed on the application, though the provider or supplier must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

If a regularly supplier standard concerning telephone numbers is implicated, the contractor shall not call the supplier's phone number as a means of verification. However, all other applicable means of validating the phone number remain intact.

E. Sales Agreement

For any reported <u>direct</u> ownership change in Section 5 or 6 of the Form CMS-855A – and except as otherwise directed by CMS -- the provider must submit a copy of the legal document(s) that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1(B) of chapter 10 for more information on such documents.) This

requirement, however, does not apply to: (1) indirect ownership changes; and (2) ownership changes that are not otherwise required to be reported (e.g., less than 5 percent owner of a corporation).

F. Survey and Certification Application Referrals to PEOG

Per existing guidance and as required, the contractor shall complete and submit the Survey and Certification Checklist with survey and certification applications referred to PEOG for accuracy and completion (e.g., in the instance described in section 10.2.1.7(B)(3)). This is in addition to, and not in lieu of, all other documents the contractor is required to submit with the application (e.g., Form CMS-855A, provider-signed Form CMS-1561) per this chapter or other CMS directive.

10.6.22 - Non-Transitioned Certified Provider/Supplier Changes of Ownership

(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

(Until further notice, the contractor shall continue to follow these instructions for CHOWs involving those certified provider and certified supplier types that have not "transitioned" as described in section 10.6.1.1 of this chapter.)

All references to the SOG Location (formerly the "RO") in this section 10.6.22 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

Changes of ownership (CHOWs) are officially defined in and governed by 42 CFR § 489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). The SOG Location – not the contractor – makes the determination as to whether a CHOW has occurred (unless this function has been delegated).

Except as otherwise specified, the term "CHOW" - as used in this section 10.6.22 - includes CHOWs, acquisitions/mergers, and consolidations.

Though the Change of Ownership (CHOW) Information section of the Form CMS-855A separates the applicable transactions into CHOWs, acquisition/mergers and consolidations for ease of disclosing and reporting, they fall within the general CHOW category under 42 CFR § 489.18 (e.g., an acquisition/merger is a type of CHOW under § 489.18).

A. Definitions for CHOWs

For purposes of provider enrollment only, there are three main categories of CHOWs captured on the Form CMS-855A application:

1. "Standard" CHOW

This occurs when a provider's CMS Certification Number (CCN) and provider agreement are transferred to another entity as a result of the latter's purchase of the provider. To illustrate, suppose Entity A is enrolled in Medicare, but Entity B is not. B acquires A. Assuming all regulatory requirements are met, A's provider agreement and CCN number will transfer to B.

This is the most frequently encountered change of ownership scenario. As explained in this section 10.6.22, even though it is technically an acquisition (i.e., B bought/acquired A) under § 489.18, this situation falls under the "CHOW" category – as opposed to the "Acquisition/Merger" category – on the Form CMS-855A.

2. Acquisition/Merger

In general, this occurs when two or more Medicare-enrolled entities combine, leaving only one remaining CCN number and provider agreement. For instance, Entity A and Entity B are both enrolled in Medicare, each with its own CCN number and provider agreement. The two entities decide to merge. Entity B's CCN number and provider agreement will be eliminated (leaving only Entity A's CCN number and provider agreement).

If the acquisition results in an existing provider having new owners but keeping its existing provider number, the applicant should check the CHOW box in the Basic Information section of the Form CMS-855A.

Unlike the new owner in a CHOW or consolidation, the new owner in an acquisition/merger need not complete the entire Form CMS-855A. This is because the new owner is already enrolled in Medicare. As such, the provider being acquired should be reported as a practice location in the Practice Location Information section of the new owner's Form CMS-855A.

3. Consolidations

This occurs when the merger of two or more Medicare-enrolled entities results in the creation of a brand new entity. To illustrate, if Entities A and B decide to combine and, in the process, create a new entity (Entity C), the CCN numbers and provider agreements of both A and B will be eliminated. Entity C will have its own CCN number and provider agreement.

Note the difference between acquisitions/mergers and consolidations. In an acquisition/merger, when A and B combine there is one surviving entity. In a consolidation, when A and B combine there are no surviving entities. Rather, a new entity is created – Entity C.

Under 42 CFR § 489.18(a)(4), the lease of all or part of a provider facility constitutes a change of ownership of the leased portion. If only part of the provider is leased, the original provider agreement remains in effect only with respect to the un-leased portion. (See Pub. 100-07, chapter 3, section 3210.1D (4) for more information.)

Note that a provider may undergo a financial or administrative change that it considers to be a CHOW, but does not meet the regulatory definition identified in §489.18.

B. Examining Whether a CHOW May Have Occurred

As stressed previously, the SOG Location – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated). However, in processing the application, the contractor shall perform all necessary background research regarding whether: (1) a CHOW may have occurred, and/or (2) the new owner is accepting assignment of the Medicare assets and liabilities of the old owner. Such research may include reviewing the sales agreement or lease agreement, contacting the provider(s) to request clarification of the sales agreement, etc. (A CHOW determination by the SOG Location is usually not required prior to the contractor making its recommendation.)

While a CHOW is usually accompanied by a tax identification number (TIN) change, this is not always the case. There may be isolated instances where the TIN remains the same. Conversely, there may be cases where a provider is changing its TIN but not its ownership. In short, while a change of TIN (or lack thereof) is evidence that a CHOW may or may not have occurred, it is not the most important factor; rather, the change in the provider's ownership arrangement is. Hence, the contractor should review the sales/lease agreement closely, as this will help indicate whether a CHOW may or may not have occurred.

In addition:

(a) If the provider claims that the transaction in question is a stock transfer and not a CHOW, the contractor reserves the right to request any information from the provider to verify this (e.g., copy of the stock transfer agreement).

If – after performing the necessary research – the contractor remains unsure as to whether a CHOW has occurred and/or whether the new owner is accepting assignment, the contractor may refer the matter to the SOG Location for guidance. Such referrals to the SOG Location should only be made if the contractor is truly uncertain as to whether a CHOW and/or acceptance of assignment may have taken place and should not be made as a matter of course. A SOG Location CHOW determination is usually not required prior to the contractor making its recommendation.

(b) There may be instances where the contractor enters a particular transaction into PECOS as a CHOW, but it turns out that the transaction was not a CHOW (e.g., was a stock transfer; was an initial enrollment because the new owner refused to accept the Medicare liabilities). If the contractor cannot change the transaction type in PECOS, it can leave the record in a CHOW status; however, it should note in the provider's file that the transaction was not a CHOW.

C. Processing CHOW Applications

Unless stated otherwise in this chapter, the contractor shall ensure that all applicable sections of the Form CMS-855A for both the old and new owners are completed in accordance with the instructions on the Form CMS-855A.

1. Previous Owner(s)

The previous owner's Form CMS-855A CHOW application does not require a recommendation for approval. Any recommendations will be based on the CHOW application received from the new owner.

If the previous owner's Form CMS-855A is available at the time of review, the contractor shall examine the information therein against the new owner's Form CMS-855A to ensure consistency (e.g., same names). If the previous owner's Form CMS-855A has not been received, the contractor shall contact the previous owner and request it. However, the contractor may begin processing the new owner's application without waiting for the arrival of the previous owner's application. It may also make its recommendation to the state agency without having received the previous owner's Form CMS-855A. The contractor, of course, shall not make a recommendation for approval unless the new owner has checked on the form that it will assume the provider agreement and the terms of the sales agreement indicate as such.

If a certification statement is not on file for the previous owner, the contractor shall request that the Individual Ownership and/or Managing Control section be completed for the individual who is signing the certification statement.

Note that a previous owner's Form CMS-855A CHOW application is essentially the equivalent of a Form CMS-855 voluntary termination submission, as the seller is voluntarily leaving the Medicare program. As such, the contractor shall not require the seller to submit a separate Form CMS-855 voluntary termination along with its Form CMS-855A CHOW application.

2. New Owner(s)

If a Form CMS-855A is not received from the new owner within 14 calendar days of receipt of the previous owner's Form CMS-855A, the contractor shall contact the new owner. If, within 30 calendar days after the contractor contacted it, the new owner fails to (1) submit a Form CMS-855A and (2) indicate that it accepts assignment of the provider agreement, the contractor shall send an e-mail to its PEOG BFL notifying him/her of the situation. PEOG will determine whether the provider's billing privileges should be deactivated under § 424.540(a)(2) or § 424.550(b) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.

3. Order of Processing

To the maximum extent practicable, Form CMS-855A applications from the previous and new owners in a CHOW should be processed as they come in. The contractor should not wait for applications from both the previous and new owner to arrive before processing them. However, unless the instructions in this chapter indicate otherwise, the contractor should attempt to send the previous and new owners' applications to the state simultaneously, rather than as soon as they are processed. For instance, suppose the previous owner submits an application on March 1. The contractor should begin processing the application immediately, without waiting for the arrival of the new owner's application. Yet it should avoid sending the previous owner's application to the state until the new owner's application is processed. (For acquisition/mergers and consolidations, the contractor may send the applications to the SOG Location separately, since one number is going away.)

4. Sales and Lease Agreements

The contractor shall abide by the following:

(i) Verification of Terms - The contractor shall determine whether: (1) the sales/lease agreement includes the signatures of the buyer and seller and the information contained within is consistent with that reported on the new owner's Form CMS-855A (e.g., same names, effective date), and (2) the terms of the contract indicate that the new owner will assume the provider agreement. In many cases, the sales/lease agreement will not specifically refer to the Medicare provider agreement. Clearly, if the box in the Change of Ownership (CHOW) Information section is checked "Yes" and the sales/lease agreement either confirms that the new owner will assume the agreement or is relatively silent on the matter, the contractor can proceed as normal. Conversely, if the agreement indicates that the assets and liabilities will not be accepted, the contractor should deny the application.

(Note that--

- A bill of sale/lease agreement/sales transfer agreement is a sales/lease business document and should not be confused with a patient transfer agreement.
- The agreement must contain the signatures of both parties to the transaction. If it does not, the contractor shall develop for an agreement containing both signatures.)

(ii) Form of Sales/Lease Agreement - There may be instances where the parties in a CHOW did not sign a "sales" or "lease" agreement in the conventional sense of the term; the parties, for example, may have documented their agreement via a "bill of sale." The contractor may accept this documentation in lieu of a sales/lease agreement so long as the document furnishes clear verification of the terms of the transaction and the information is consistent with that contained in the Form CMS-855A as discussed above.

(iii) Submission of Final Sales/Lease Agreement - The contractor shall not forward a copy of the application to the state until it has received and reviewed the final sales/lease agreement. It need not revalidate the information on the Form CMS-855A, even if the data therein may be somewhat outdated by the time the final agreement is received.

If a final sales/lease agreement is not submitted within 30 days after the contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 30th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what types of responses (short of the actual receipt of the agreement) were obtained.

Unless specified otherwise in this chapter, both the previous and new owners must submit separate Form CMS-855A applications, as well as copies of the interim and final sales/lease agreements.

5. CHOWs Involving Subtypes

On occasion, a CHOW may occur in conjunction with a change in the facility's provider subtype. This frequently happens when a hospital undergoes a CHOW and changes from a general hospital to another type of hospital, such as a psychiatric hospital. Although a change in hospital type is considered a change of information (COI), it is not necessary for the provider to submit separate applications – one for the COI and one for the CHOW. Instead, all information

(including the change in hospital type) should be reported on the CHOW application; the entire application should then be processed as a CHOW. However, if the facility is changing from one main provider type to another (e.g., hospital converting to a skilled nursing facility) and also undergoing a CHOW, the provider must submit its application as an initial enrollment.

NOTE: For Medicare purposes, a critical access hospital (CAH) is a separately-recognized provider type. Thus, a general hospital that undergoes a CHOW while converting to a CAH must submit its Form CMS-855A as an initial enrollment, not as a CHOW.

6. Unreported CHOW

If the contractor learns via any means (including receipt of a tie-in notice or other SOG Location or state notice) that an enrolled provider (1) has been purchased by another entity or has purchased another Medicare enrolled provider, the contractor shall immediately request Form CMS-855A applications from both the previous and new owners. If the new owner fails to submit a Form CMS-855A within the latter of (1) the date of acquisition or (2) 30 days after the request, the contractor shall stop payments to the provider. Payments may be resumed upon receipt of the completed Form CMS-855A.

7. Relocation of Entity

A new owner may propose to relocate the provider concurrent with the CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the SOG Location immediately. Unless the SOG Location dictates otherwise, the provider shall - per CMS Publication 100-07, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the provider as a new applicant), rather than as an address change of the existing provider.

8. Transitioning to Provider-Based Status

Consistent with existing CMS policy, a provider undergoing a CHOW pursuant to 42 CFR § 489.18 may be assigned to a new contractor jurisdiction only if the provider is transitioning from freestanding to provider-based status. In such cases, the contractor for the new jurisdiction (the "new contractor") shall process both the buyer's and seller's Form CMS-855A applications. Should the "old/previous" (or current) contractor receive the buyer's and/or seller's Form CMS-855A application, it shall: (a) forward the application to the new contractor within 5 business days of receipt, and (b) notify the new contractor within that same timeframe that the application was sent.

9. Intervening Change of Ownership (CHOW)

(This section does not apply to home health agencies.)

In situations where (1) the provider submits a Form CMS-855A initial application or CHOW application and (2) a Form CMS-855A CHOW application is subsequently submitted but before the contractor has received the tie-in notice from the SOG Location, the contractor shall abide by the following:

Situation 1 – The provider submitted an initial application followed by a CHOW application, and a recommendation for approval has not yet been made with respect to the initial application – The contractor shall return both applications and require the provider to re-submit an initial application with the new owner's information.

Situation 2 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval has not been made for the first application - The contractor shall process both applications – preferably in the order in which they were received – and shall, if recommendations for approval are warranted, refer both applications to the state/SOG Location in the same package. The accompanying notice/letter to the state/SOG Location shall explain the situation.

Situation 3 - The provider submitted an initial application followed by a CHOW application, and a recommendation for approval of the initial application has been made – The contractor shall:

(i) Return the CHOW application.

(ii) Notify the state/SOG Location via letter (sent via mail or e-mail) that there has been a change of ownership (the new owner should be identified) and that the contractor will be requiring the provider to resubmit a new initial application containing the new owner's information.

(iii) Request via letter that the provider submit a new initial Form CMS-855A application containing the new owner's information within 30 days of the date of the letter. If the provider fails to do so, the contractor shall return the initial application and notify the provider and the state/SOG Location of this via letter. If the provider submits the application, the contractor shall process it as normal and, if a recommendation for approval is made, send the revised application package to the state/SOG Location with an explanation of the situation; the initially submitted application becomes moot. If the newly submitted application is denied, however, the initially submitted application is denied as well; the contractor shall notify the provider and the state/SOG Location accordingly.

Situation 4 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval has been made for the first application - The contractor shall:

(i) Notify the state/SOG Location via e-mailed letter that there has been a change of ownership (the new owner should be identified) and that the contractor will be requiring the provider to resubmit a new initial application containing the new owner's information.

(ii) Process the new CHOW application as normal. If a recommendation for approval is made, the contractor shall send the revised CHOW package to the state/SOG Location with an explanation of the situation; the first CHOW application becomes moot. If the newly submitted CHOW application is denied, the first application is denied as well; the contractor shall notify the provider and the state/SOG Location accordingly.

10. CHOWs and Address Changes

A new owner may propose to relocate the supplier concurrent with a CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the SOG Location immediately. Unless the SOG Location dictates otherwise, the supplier shall - per Pub. 100-07, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the supplier as a new applicant), rather than as an address change of the existing supplier.

D. Form CMS-855A - Entry into PECOS

If the new owner will or will not be accepting assignment as well as the assets and liabilities of the old owner, the contractor shall enter the CHOW information into the new enrollment record that shall be created for the CHOW buyer. If the SOG Location approves the CHOW and sends the tie-in/approval notice to the contractor, the supplier's CCN will be maintained in the new owner's enrollment record once the record is switched to an approved status.

If the CHOW is for a Part B certified supplier, a new enrollment record must be created if a new TIN is created in the CHOW.

E. Form CMS-855A - Electronic Funds Transfer (EFT) Payments and CHOWs

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in/approval notice from the SOG Location. Hence, any application from the old or new owner to change the EFT account or special payment address to that of the new owner shall be rejected. It is the responsibility of the old and new owners to work out any payment arrangements between themselves while the contractor and SOG Location are processing the CHOW. It is advisable that the contractor notify the new owner of this while the application is being processed.

In a CHOW, the existing provider agreement is automatically assigned to the buyer/transferee. If the buyer/transferee does not explicitly reject automatic assignment before the transfer date, the provider agreement is automatically assigned, along with the CCN, effective on the transfer date. The assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued. Among other things, this means that the contractor will continue to adjust payments to the provider to account for prior overpayments and underpayments, even if they relate to services provided before the sale/transfer. If the buyer rejects assignment of the provider agreement, the buyer must file an initial application to participate in the Medicare program. In this situation, Medicare will **never** pay the applicant for services the prospective provides before the date on which the provider qualifies for Medicare participation as an initial applicant.

Depending on the terms of the sale, the buyer/transferee may obtain a new NPI or maintain the existing NPI. After CHOW processing is complete, the seller/transferor will no longer be allowed to bill for services (i.e., services furnished after CHOW processing is complete) and only the buyer is permitted to submit claims using the existing CCN. It is ultimately the responsibility of the old and new owners to work out between themselves any payment arrangements for claims for services furnished during the CHOW processing period.

F. Form CMS-855A CHOW: Pre-Approval Changes of Information

1. CHOW: Regarding Seller

If – prior to the issuance of the tie-in notice – the contractor receives from the seller a Form CMS-855 request to change any of the provider's enrollment data, the contractor shall reject the change request if the information in question involves changing the provider's:

i. EFT or special payment address information to that of the buyer

ii. Practice location or base of operations to that of the buyer

iii. Ownership or managing control to that of the buyer

iv. Legal business name, TIN, or "doing business as" name to that of the buyer

All other "pre-tie-in notice" Form CMS-855 change requests from the seller can be processed normally.

2. CHOW: Regarding Buyer

If – prior to the issuance of the tie-in notice – the contractor receives from the buyer a Form CMS-855 request to change any of the provider's existing enrollment information, the contractor shall reject the change request. Until the tie-in notice is issued, the seller remains the owner of record. Hence, the buyer has no standing to submit Form CMS-855 changes on behalf of the provider.

10.6.22.1 - Non-Transitioned Certified Provider/Supplier Changes of Information

(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

(Until further notice, the contractor shall continue to follow these instructions for changes of information involving all certified provider and certified supplier types that have not "transitioned.")

All references to the SOG Location (formerly the "RO") in this section 10.6.22.1 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

Any instructions in this section 10.6.22.1 concerning the voluntary termination of a sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.22.1 (or, for transitioned providers/suppliers, section 10.6.1.2) when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three

separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Form CMS-855A - Referrals to State/SOG Location

1. Transactions

The following is a list of Form CMS-855A transactions that generally require a recommendation and referral to the state/SOG Location:

- Addition of hospice satellite
- Change in type of Prospective Payment System (PPS)-exempt unit
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Addition of hospital physician/practitioner group practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)
- Excluding hospital physician/practitioner group practice locations, change and/or relocation of a practice location regardless of whether a survey of the new site may be required.
- RHC change of address
- Stock transfer (except as stated below in subsection (A)(2) below)

In these situations, the Provider Enrollment, Chain and Ownership System (PECOS) record should not be switched to "approved" until the contractor receives notice from the SOG Location that the latter has authorized the transaction. However, if the contractor knows that the particular state/SOG Location in question typically does not review, approve, or deny this type of transaction, the contractor need not send the transaction to the state/SOG Location for approval and shall instead follow the instructions in section 10.6.22.1(B) below.

2. Stock Transfers

If the transaction is a stock transfer, the contractor need not send the transaction to the state/SOG Location for approval (and shall instead follow the instructions in section 10.6.22.1(B) below) if the following three conditions are met:

(i) The contractor is confident that the transaction is merely a transfer of stock and not a CHOW,

(ii) The SOG Location in question (based on the contractor's past experience with this SOG Location) does not treat stock transfers as potential CHOWs, and

(iii) The contractor knows that the particular state/SOG Location in question does not review, approve, or deny this type of transaction.

If any of these three conditions are not met, the contractor shall send the transaction to the state/SOG Location for approval.

3. Additional Instructions

SOG Location approval for the transactions listed above in section 10.6.22.1(A)(1) may be furnished to the contractor via tie-in notice, letter, e-mail, fax, or even telephone; the contractor may accept any of these formats.

If the SOG Location (after receiving the transaction from the contractor for review) notifies the contractor that it does not normally review/approve/deny such transactions, the contractor may finalize the transaction (e.g., switch the PECOS record to "approved).

B. Form CMS-855A - Post-Approval SOG Location Contact Required

Form CMS-855A changes that do not mandate a recommendation to the state/SOG Location but do require post-approval correspondence with the SOG Location include:

- Deletions/voluntary terminations of practice locations or hospital subunits

- Legal business name, tax identification number, or "doing business as name" changes that do not involve a CHOW

- Except as described in section 10.6.22.1(A)(1), address changes that do not require a survey of the new location

- The transactions (excluding stock transfers) described in section 10.6.22.1(A)(1) for which the contractor knows that the state/SOG Location does not issue approvals/denials

- Stock transfers for which all three conditions mentioned in section 10.6.22.1(A)(2) are met

- Voluntary terminations of PTANs (except as otherwise stated in this section 10.6.22.1 and in section 10.6.1.3 of this chapter)

For these transactions, the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made, and (2) switch the PECOS record to "approved." The contractor shall also notify the state and SOG Location of the changed information (via any mechanism it chooses, including copying the state/SOG Location on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction. Such notice to the State/SOG Location shall specify the type of information that is changing.

C. Form CMS-855A - All Other Changes of Information

For all Form CMS-855A change requests not identified in section 10.6.22.1(A) or (B), the contractor shall notify the provider via letter, fax, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The state and SOG Location need not be notified of the change.

D. Form CMS-855A Revalidations, Form CMS-855A Reactivations and Complete Form CMS-855A Applications

In situations where the provider submits a: (1) Form CMS-855A reactivation, (2) Form CMS-855A revalidation, or (3) full Form CMS-855A as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state/SOG Location and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in 10.6.22.1(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855A, the contractor shall make a recommendation to the state/SOG Location and await the SOG Location's approval before switching the record to "approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state/SOG Location needs to consider is the new hospital unit.

If the application contains new/changed data falling within one of the categories in section 10.6.22.1(B), the contractor can switch the PECOS record to "approved." It shall also notify the state and SOG Location of the changed information (via any mechanism it chooses, including copying the state/SOG Location on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction.

10.6.23 – Special Instructions for Electronic Funds Transfer (EFT) Accounts and Special Payment Addresses

(Rev. 11682; Issued: 11-04-2022; Effective: 12-05-2022; Implementation:12-05-2022)

(The instructions in this section 10.6.23 take precedence over all other contrary instructions in this chapter, including, but not limited to, the existing guidance in sections 10.3.1.1.4, 10.3.1.2.4, and 10.3.1.3.4. The policies in this section will eventually be incorporated into the sections of this chapter that are applicable to the subject matter.)

A. Enrolled Providers/Suppliers

1. General Policy

A provider/supplier may only have one EFT account and one special payment address (SPA) per enrollment. As a general rule, multiple EFT accounts or SPAs within an existing enrollment will remain in effect only until the provider/supplier submits any update to its EFT information or SPA data, respectively, for any of these accounts or addresses. At that time, the EFT account or SPA for which the provider/supplier submitted the update will become the lone EFT account or SPA (as applicable) for that enrollment.

For purposes of this requirement:

(i) The term "enrollment" means a single enrollment in a single state involving a single provider/supplier type. The particular PTAN arrangement under the enrollment (e.g., a group practice has three practice locations under its Form CMS-855B enrollment, each with a separate PTAN) is irrelevant for purposes of this requirement; again, the requirement is based on the enrollment, not the PTAN.

(ii) Any submitted change to any of the provider/supplier's EFT or SPA data for any EFT account or SPA within an enrollment --- even a change that the provider/supplier did not cause (e.g., a government-generated zip code change) and even if it is for only one of the enrollment's EFT accounts or SPAs --- triggers the aforementioned requirement. The materiality of the change does not matter. However, the changed data must have actually been submitted via the appropriate CMS form to invoke the requirement; using the example in the previous sentence, this zip code change would not trigger the requirement unless and until the provider/supplier reports it via a CMS form.

(iii) If the provider/supplier reports the changed EFT or SPA data as part of a revalidation, reactivation, or other enrollment transaction other than a change of information (COI), the requirement is invoked to the same extent as with a COI.

(iv) The requirement applies only to the precise enrollment (e.g., "Enrollment A") for which the change was submitted. It is inapplicable to the provider/supplier's other enrollments ("Enrollments B and C"), even if B and C have:

- Multiple EFT accounts or SPAs that match those for which the provider/supplier reported a change to its "Enrollment A" EFT or SPA data; and/or
- The same LBN or TIN as "Enrollment A."

(v) A change in EFT data does not invoke the need to "consolidate" the provider/supplier's SPAs if the provider/supplier has multiple SPAs; likewise, a change in SPA data does not require the "consolidation" of the provider/supplier's multiple EFT accounts. (For purposes of this section 10.6.23, the term "consolidate" simply means reducing the provider/supplier's multiple EFT accounts or SPAs to one.)

(vi) Even if the multiple EFT accounts are with the same banking institution, the aforementioned "consolidation" requirement applies.

(vii) Any EFT and/or SPA consolidation under this section 10.6.23 applies to all PTANs under the single enrollment.

(viii) The consolidation requirement applies irrespective of whether the EFT or SPA change that the provider/supplier submitted is approved, denied, rejected, or returned.

(ix) The term "multiple" EFT accounts or SPAs only applies to active EFT accounts/SPAs.

(x) Except as otherwise noted, any consolidation described in this section 10.6.23 becomes effective on the date of the applicable approval, denial, rejection, or return letter (see subsection (A)(2)(i) below).

Consider the following:

EXAMPLE – Provider X is enrolled as a group practice and a HIT supplier (i.e., two separate enrollments) in State Y. Currently:

- The group practice enrollment has two EFT accounts (one with Smith Bank and one with Jones Bank) and two SPAs (1 James Street and 200 Johnson Street)
- The HIT supplier enrollment has the same two EFT accounts and SPAs as the group practice

Provider X submits a change to its Smith Bank account information for the group practice enrollment. In this scenario: (1) the Smith Bank account becomes the lone EFT account for the group practice; (2) the group practice's Jones Bank account becomes inactive in PECOS effective on the date of the notice to the provider/supplier that the originally submitted EFT or SPA change was approved, denied, etc. (see subsection (A)(2)(i) below); (3) the Smith Bank and Jones Bank accounts for the HIT supplier enrollment are unaffected; and (4) the SPAs for Provider X's two enrollments are unaffected.

2. Operational Procedures

If the contractor receives an EFT or SPA change and determines that the provider/supplier has multiple EFT accounts or SPAs (as applicable and consistent with the guidelines described in subsection (A) above) for that enrollment, the contractor shall follow the procedures described below. (The example in subsection (A) will be used as a format.)

Step 1 – The contractor shall process the EFT data change for the group practice's Smith Bank account as normal.

Step 2 – Upon final completion of its processing of the change, the contractor shall:

i. Send the appropriate approval, denial, etc., letter to the provider/supplier consistent with the instructions in this chapter. The contractor shall, however, add the following language to the letter:

"Under CMS policy, a Medicare provider or supplier may only have one ["EFT account" or "special payment address", as applicable] per enrollment. Consistent therewith, [Contractor name] has designated the ["EFT account" or "special payment address", as applicable] for which you reported changed ["EFT" or "special payment address"] information as the sole ["EFT account" or "special payment address"] for this enrollment. This designation is effective as of the date of this letter. All payments previously sent to your other ["EFT account(s)" or "special payment address(es)"] under this enrollment will now be made to the sole designated ["EFT account" or "special payment address"] described above. If you wish to change this sole

designated ["EFT account or "special payment address"], you must submit the applicable [Form CMS-588, Form CMS-855, or Form CMS-20134, as applicable] to do so.

Note that the sole designation described above applies only to the enrollment for which you submitted the requested change to your ["EFT" or "special payment address'] data. It is inapplicable to any other enrollments you have."

The contractor may: (1) notwithstanding any other instruction to the contrary in section 10.7 et seq. of this chapter, alter the forgoing language to conform to the provider/supplier's particular factual situation (prior CMS approval is unnecessary); and (2) insert said language in any part of the letter it chooses.

ii. End-date the "other" EFT account(s) or SPA(s) (as applicable) effective the date of the letter described in subsection (A)(2)(i) above. The contractor shall make all payments under the enrollment to the sole account/SPA beginning the day after the date of the letter.

iii. Apply the PTAN(s) associated with the deleted EFT account/SPA to the sole EFT account/SPA.

iv. Complete all other normal steps required under this chapter for finalizing the transaction in question.

B. Providers/Suppliers Initially Enrolling or Undergoing a CHOW Consistent with Principles of 42 CFR § 489.18

The aforementioned policy that a provider/supplier may only have one EFT account and one SPA per enrollment also applies to: (1) providers/suppliers submitting an initial enrollment application; and (2) new owners in a certified provider/supplier CHOW (i.e., a CHOW consistent with the principles of § 489.18). The contractor shall apply this policy to such applications. If, therefore, the provider/supplier/new owner submits the application with more than one EFT account or SPA, the contractor shall develop for a single EFT account or SPA (as applicable) consistent with the instructions in this chapter. If the provider/supplier/new owner fails to comply within 30 days, the contractor shall reject the application pursuant to 42 CFR § 424.525(a)(1).

10.7 – Model Letters

(Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24)

The contractor shall use the following letters when rejecting, returning, approving or denying an application, or when revoking an entity's Medicare billing privileges. Any exceptions to this guidance shall be approved by the contractor's CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL), unless specified otherwise. The contractor shall document approval received by its PEOG BFL for QASP purposes.

As stated in section 10.3, PECOS will automatically generate and send some of the letters described in this section 10.7 et seq. If any modifications or additions to a certain PECOS-generated letter are required pursuant to the instructions in this section 10.7 et seq. or elsewhere

in this chapter, the contractor shall, of course, ensure that such edits are made before the letter is sent. This includes situations where a particular party is typically copied on a letter but the circumstances of the transaction do not require the party to be copied.

In the event of a conflict between the instructions in section 10.3 and section 10.7, et al, the instructions in section 10.3 take precedence.

A. Issuing Letters - Model Letter Guidance

All letters sent by contractors to providers and suppliers shall contain and/or adhere to the formats/requirements addressed in sections 10.7(A) and (B). Note, however, the following:

(i) For certified provider/supplier types and transactions that have formally "transitioned" as described in section 10.7.5.1, the requirements (e.g., data elements) of the model letters in section 10.7.5.1 take precedence over any contrary instruction in section 10.7. For example, if section 10.7 requires a data element that a specific letter in section 10.7.5.1 pertaining to the same enrollment transaction/situation does not, the section 10.7.5.1 letter requirements supersede the former. Likewise, if section 10.7 requires the removal/addition of language that is/is not in the applicable section 10.7.5.1 letter, the latter controls.

(ii) For certified provider/supplier types and transactions that have not transitioned (and except as otherwise stated in section 10.7 (e.g., subsection (A)(2)(n)), the contractor shall continue to follow the existing instructions in section 10.7 and utilize the letters in section 10.7.5.

1. General Guidance

(a) The CMS logo (2012 version) displayed per previous CMS instructions.

(b) The contractor's logo shall be displayed however the contractor deems appropriate. There are no restrictions on font, size, or location. The only restriction is that the contractor's logo must not conflict with the CMS logo.

(c) All dates in letters, except otherwise specified, shall be in the following format: month/dd/YYYY (e.g., January 26, 2012).

(d) Letters shall contain fill-in sections as well as static, or "boilerplate" sections. The fill-in sections are delineated by words in brackets in italic font in the model letters.

(e) The static sections shall be left as-is unless there is specific guidance for removing a section (e.g., removing a CAP section for certain denial and revocation reasons; removing state survey language for certain provider/supplier types that do not require a survey). If there is no guidance for removing a static section, the contractor must obtain approval from its PEOG BFL to modify or remove such a section.

2. Approval Letters

(a) Part A/B certified provider and supplier paper/web COI and revalidation "referral to state" shall detail the requested changes (e.g., practice location changed to 123 Main Street, Baltimore MD 21244).

(b) For COI and revalidation applications that do not require a tie-in or recommendation but require notification to the SOG Location as a cc, the contractor shall add the additional fields applicable to the letter (e.g., cc the state/SOG Location). The contractor should itemize the changes if it is beneficial to the SOG Location.

(c) Part A/B and DME provider and supplier paper/web COI and revalidation letters shall only list the section title (at the sub-section level) from the paper/web Form CMS-855 and Form CMS-20134 application (e.g., Correspondence Mailing Address, Final Adverse Legal Actions, Remittance Notices/Special Payments Mailing Address, etc.).

(d) If, as part of a revalidation, the provider/supplier only partially revalidates (i.e., a provider has multiple PTANs, and one PTAN is revalidated with the others end-dated), the contractor shall notate the reassignments that were terminated due to non-response and the effective date of termination (i.e., the revalidation due date or the development due date).

(e) If the provider is submitting a change as part of a voluntary termination application (e.g. special payment address, EFT, authorized official), the contractor shall enter the applicable fields into the Medicare Enrollment information table.

(f) Approval letters may include a generic provider enrollment signature and contact information (e.g. customer service line). However, all development letters shall include a provider enrollment analyst's name and phone number for provider/supplier contacts.

(g) Participation status shall only be included in initial and reactivation letters for Part B sole proprietors, Part B sole owners, any Part B organizations and DME suppliers. Change of information approval letters shall only include the participation status if it was changed as part of the application submission.

(h) The contractor shall add lines to the enrollment information tables on any reactivation letter if the provider/supplier has reactivated following non-response to a revalidation and enrollment information was changed on the application.

(i) The contractor shall enter an effective date on all change of information approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality).

(j) The contractor shall add appeal rights to all change of information and revalidation approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality; a new reassignment is created).

(k) If the provider/supplier is revalidating multiple reassignments to different groups, the contractor shall add additional lines to the grid to identify the separate groups and PTANs.

(l) If the provider/supplier revalidates both reassignments and one or more sole proprietorship locations, the contractor shall indicate on the appropriate letter that the approval covers the reassignments and sole proprietorship locations.

(m) In the Part B non-certified supplier letters, the contractor shall populate 42 CFR§ 424.205 for MDPP suppliers or § 424.516 for all other providers/suppliers with the following paragraph: "Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR § 424.516 or 42 CFR§ 424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617."

(n) For all pre-transition and post-transition seller CHOWs (both HHA and non-HHA), the contractor shall use the "M. Approval – Seller CHOW (Part A/B Certified Org") letter in section 10.7.5.1 when voluntarily terminating the seller's enrollment in a 42 CFR § 489.18 CHOW (which includes mergers, acquisitions, and consolidations). The contractor shall use the effective date of the CHOW as the "Effective Date of Enrollment Termination" in the letter.

(o) The contractor shall remove the following language when issuing the Approval – Voluntary Termination (Part B Non-Certified Org or Part B Sole Owner) letter in section 10.7.6(V) for a Part B non-certified supplier: "Reassignments and any physician assistant employment arrangements are also deactivated", unless other active reassignments/employment arrangements exist on the enrollment.

3. Denial/Revocation Letters

(a) The contractor shall populate the fill-in sections with the appropriate information, such as primary regulatory citation, specific denial and revocation reasons, names/addresses, etc.

(b) The fill-in sections shall be indented ½ inch from the normal text of the letter.

(c) All specific or explanatory reasons shall appear in bold type and shall match the federal registry heading. This applies to headings. For example, if the revocation letter contains the following specific explanatory language, the heading should be in bold type and the explanation should be in normal type as shown in the excerpt below:

42 CFR § 424.535(a)(8)(i) – Abuse of Billing Privileges

Data analysis conducted on claims billed by [Dr. Ambassador], for dates of service [Month XX, XXXX], to [Month XX, XXXX], revealed that [Dr. Ambassador] billed for services provided to [XX] Medicare beneficiaries who were deceased on the purported date of service.

(d) There may be more than one primary reason listed.

(e) This subsection (A)(3)(e) applies to certified provider and certified supplier denial or revocation letters that meet both of the following requirements:

- The provider enrollment denial or revocation also requires the denial or termination of the corresponding provider or supplier agreement (e.g., Form CMS-1561, Form CMS-370, etc.)

- The SOG Location is responsible for handling the reconsideration/appeal of the provider/supplier agreement denial or termination.

If these requirements are met -- and notwithstanding any instruction to the contrary in this chapter -- the contractor shall insert the following language into the provider enrollment denial or revocation letter (preferably at the conclusion of the letter's discussion/outline of appeal rights):

"Note that the provider enrollment appeal rights addressed in this letter are unrelated to any appeal rights concerning the [denial or termination, as applicable] of your [provider or supplier, as applicable] agreement. The two processes are separate and distinct, and a successful appeal of your enrollment [denial or revocation, as applicable] does not automatically restore your [provider or supplier] agreement. Any such restoration of the latter is handled by the Survey Operations Group Location and not by CMS' Provider Enrollment & Oversight Group."

4. Voluntary Terminations

If a provider/supplier (certified or non-certified) is voluntarily terminating their enrollment, the contractor shall use the applicable voluntary termination letter.

5. No PEOG Approval

The following letter revisions do not require prior PEOG BFL approval. (Notwithstanding the language in subsection 10.7(A)(i), this includes the letters in section 10.7.5.1 et seq.)

(a) If the contractor cannot format the enrollment information table as provided in these model letters, the contractor may provide the information in a similar non-table format.

(b) Placing a reference n umber or numbers between the provider/supplier address and the salutation. (For Internet-based PECOS applications, the contractor can include its document control number and the Web Tracking ID in this field.)

(c) The contractor shall enter "N/A" or leave blank a data element in an enrollment information table if said field is inapplicable (e.g., doing business as (DBA), effective date for changes).

(d) The contractor shall include the applicable PTAN and NPI for the application submission on the letter. If multiple PTANs or NPIs apply, the contractor should: (1) enter "multiple" in the PTAN and NPI fields; (2) copy and add additional PTAN/NPI rows to the enrollment information tables; or (3) attach a list of any and all PTAN and NPI combinations that apply in the letter.

(e) For individual revalidations in which multiple PTANs may be revalidating from multiple reassignments or individual associations, the contractor may also list the group's LBN and PTAN effective date in connection with the appropriate individual NPI-PTAN combinations. The contractor has flexibility in relaying these fields when multiplicities exist, ensuring they meet the template's reporting requirements.

(f) Appropriate documents attached to specific letters as needed.

(g) Placing language in any letter regarding self-service functions, such as the Provider Contact Center Interactive Voice Response (IVR) system and Electronic Data Interchange (EDI) enrollment process.

6. Rural Emergency Hospitals (REHs)

The contractor shall replace all appeal rights language in any REH initial enrollment denial letter with the following: "In accordance with Title 42, United States Code (U.S.C.) § 1395x(kkk)(9), no administrative or judicial review under Section 1395ff or 1395oo or otherwise is granted based upon a determination of whether a hospital meets the requirements of a rural emergency hospital." This language will notify the facility that it cannot appeal its enrollment denial.

B. Sending Letters

The contractor shall note the following:

1. Except as stated otherwise in this chapter (e.g., certain applications from already-transitioned certified provider/supplier types), the contractor shall issue approval letters within 5 business days of approving the application in PECOS.

2. For all applications other than the Form CMS-855S, the contractor shall send development/approval letters, etc., to the contact person if one is listed. Otherwise, the contractor may send the letter to the provider/supplier at the e-mail, mailing address, or fax provided in the correspondence address or special payments address sections.

3. The contractor may insert an attention field with the contact's name as part of the mailing address, but the letter should still be addressed to the provider/supplier. As applicable, the contractor shall continue to send letters to the DMEPOS supplier's correspondence address until their automated process can be updated to include the contact person as a recipient of the letters.

4. For initial, change of information, revalidation, and voluntary termination applications submitted by sole owners, the contractor should issue one approval letter. However, the Medicare enrollment information table shall distinctly list the individual and sole owner information.

5. If, as part of revalidation, a physician assistant is adding and terminating an employment relationship, one letter shall be issued (approving the revalidation). However, the termination and additional employment relationship shall be noted in the approval letter.

6. The contractor shall issue all denial and revocation letters via certified mail.

7. Notwithstanding any other instruction to the contrary in this chapter, the contractor shall copy via email the applicable accrediting organization (AO) (along with, as currently required, the state agency) on a recommendation for approval letter or final provider/supplier notification letter (e.g., final approval, denial, etc.) letter if: (1) the provider/supplier lists the AO on the Form CMS-855 or ADR application; (2) PEOG notifies the contractor of the AO's involvement; or (3) the contractor otherwise becomes aware of the provider/supplier's AO affiliation.

8. Notwithstanding any other instruction to the contrary in this chapter, DMEPOS suppliers shall send all applicable rebuttals, CAPs, and reconsideration requests to Chags Health Information Technology LLC (C-HIT). The contact information is:

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232
Phone: (800) 245-9206
E-mail: PEARC@c-hit.com
Fax: (866) 410-7404

The NPEs shall ensure that all previous section 10.7 et seq. references to the National Supplier Clearinghouse as the destination for rebuttals, CAPs, and reconsideration requests be replaced with C-HIT consistent with prior CMS guidance.

10.7.1 – Acknowledgement Letters

(Rev. 11637; Issued: 10-07-22; Effective: 12-09-22; Implementation: 12-09-22)

A. Acknowledgement Letter Guidance

Sending an acknowledgement letter is optional for enrollment applications. Acknowledgement letters are required for accepted CAP, Reconsideration Request. See sections 10.7.10, 10.7.11, and 10.7.13 of this chapter.

B. Model Acknowledgement Letter

1. Acknowledgement Example – Application Receipt

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference ID: (Case #, Control Number, etc.)

Dear [Provider/Supplier Name]:

Your Medicare enrollment application(s) was received on [date] and [is/are] currently being reviewed. You will receive a letter within 30 calendar days if we need any additional information.

Additional provider/supplier identification information: NPI, DBA Name, etc.

Please retain this letter in case you must submit additional information to support your application. If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM]

Sincerely,

[Name]
[Title]
[Company]

10.7.2 – Development Letters
(Rev. 11949; Issued: 04-13-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Development Letter Guidance

In the following sentence:

"Please submit the requested revisions and/or supporting documentation preferably within [xx] calendar days of the postmarked date of this letter to the address listed below:"

The value in "xx" may be from **7** to **30**.

Note: Items such as checklists and documents may be attached to the letter.

B. Model Development Letters

Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

We have received your Medicare enrollment application(s). We may reject your application(s) if you do not furnish complete information within 30 calendar days from the postmarked date of this letter pursuant to 42 CFR §424.525. In order to complete processing your application(s), please make the following revisions and/or supply the requested supporting documentation:

[Specify revisions and/or supporting documentation needed]

[If the application was submitted via paper, use the following language:

“Please submit the requested revisions and/or supporting documentation within [xx] days of the postmarked date of this letter to the address listed below:

[Name of MAC]
[Address]
[City], ST [Zip]

Finally, please attach a copy of this letter with your revised application(s).”]

[If the application was submitted via PECOS, use the following language:

“Please submit the requested revisions and/or supporting documentation via PECOS within [xx] days of the date on this letter.”].

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM.

Sincerely,

[Name]
[Title]
[Company]

10.7.3 – Approval Letters

(Rev. 10182; Issued: 06-15-2020; Effective: 09-16-2020; Implementation: 09-16-2020)

Contractors shall use the formatting instructions found in Section 10.7 of this chapter to complete and issue approval letters for all provider and supplier types.

10.7.4 – DME Approval Letter Templates

(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)

A. Approval – Change of Information (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your Change of Information (COI) application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Location Address	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Filing claims electronically? Contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B – CGS, www.cgsmedicare.com
- Jurisdiction C – CGS, www.cgsmedicare.com
- Jurisdiction D – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

B. Approval – Initial (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your initial enrollment application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Filing claims electronically? Contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B – CGS, www.cgsmedicare.com
- Jurisdiction C – CGS, www.cgsmedicare.com
- Jurisdiction D – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

[Centers for Medicare & Medicaid Services]
[Center for Program Integrity]
[Provider Enrollment & Oversight Group]
[ATTN: Division of Provider Enrollment Appeals]
[7500 Security Blvd.]
[Mailstop: AR-19-51]
[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

C. Approval – Reactivation (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your reactivation application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

To file claims electronically, please contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B – CGS, www.cgsmedicare.com
- Jurisdiction C – CGS, www.cgsmedicare.com
- Jurisdiction D – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov..

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

[Centers for Medicare & Medicaid Services]
[Center for Program Integrity]
[Provider Enrollment & Oversight Group]
[ATTN: Division of Provider Enrollment Appeals]
[7500 Security Blvd.]
[Mailstop: AR-19-51]
[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

D. Approval – Revalidation (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]

[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your revalidation application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

To file claims electronically, please contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B – CGS, www.cgsmedicare.com
- Jurisdiction C – CGS, www.cgsmedicare.com
- Jurisdiction D – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence

[To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]		[Centers for Medicare & Medicaid Services]
[Address]	or	[Center for Program Integrity]
[City], ST [Zip]		[Provider Enrollment & Oversight Group]
		[ATTN: Division of Provider Enrollment Appeals]

[7500 Security Blvd.]
[Mailstop: AR-19-51]
[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

E. Approval – Voluntary Termination (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to voluntarily disenroll from the Medicare program.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Termination and Deactivation	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

With this voluntary termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:
[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

10.7.5 – Part A/B Certified Provider and Supplier Approval Letter Templates

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

A. Approval – Change of Information (Part A/B Certified Org, No Referral to State Required)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

[CC: SOG Location and State]

B. Approval - Post Tie-In Change of Information (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your change of information application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

C. Approval - Post Tie-In Change of Ownership (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your change of ownership application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
CHOW Effective Date	
Medicare Year-End Cost Report Date (Part A CHOWs only)	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer

to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and

- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

D. Approval - Post Tie-In/Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your initial enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Medicare Year-End Cost Report Date (Part A only)	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]

[Company]

E. Forwarded to State - Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your initial enrollment application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. *If you have elected to use a CMS approved accreditation organization (AO), the AO will conduct the survey and recommend approval to the State Agency to finalize your certification*. Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As (DBA)	
National Provider Identifier (NPI)	
Provider/Supplier Type	
Practice Location Address	
Medicare Year-End Cost Report Date (Part A only)	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

F. Forwarded to State – Change of Information or Change of Ownership (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your [change of information or change of ownership enrollment] application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information

Legal Business Name (LBN)		
Doing Business As (DBA)		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number (PTAN)		
Medicare Year-End Cost Report Date (Part A only)		
Requested Changes (applicable to COI and CHOW, remove if doesn't apply)	Existing	
	New	
	Effective Date	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name]

[Title]
[Company]

CC: State Agency [and AO, if applicable]

G. Approval – Revalidation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has [approved your revalidation application/assessed your revalidation application and forwarded it to the Centers for Medicare & Medicaid Services (CMS) [City] SOG for a final review].

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
Provider/Supplier National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity

Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

H. Approval – Voluntary Termination (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to voluntarily disenroll from the Medicare program.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Termination and Deactivation	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this voluntary termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

[CC: SOG Location and State for Certified Providers/Suppliers]

I. Approval – Reactivation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your reactivation enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals

7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

10.7.5.1 – Part A/B Certified Provider and Supplier Letter Templates – Post-Transition

(Rev. 13062; Issued: 03-13-25; Effective: 04-11-25; Implementation: 04-11-25)

The model letters in this section 10.7.5.1 pertain to certain enrollment transactions involving certified providers and certified suppliers. Except as otherwise stated, the contractor shall begin utilizing these letters (instead of those in section 10.7.5) upon completion of the transition of the applicable CMS Survey & Operations Group (SOG) function to the contractor and the CMS Provider Enrollment & Oversight Group (PEOG). In other words, once a provider specialty, provider agreement, or provider enrollment transaction type (for example, voluntary terminations) has been transitioned, the contractor shall commence using the section 10.7.5.1 letter(s) pertaining to said transaction. CMS will notify contractors once a particular transition has occurred.

For certified provider/supplier transactions (and transaction outcomes) not specifically addressed in this section 10.7.5.1, the contractor shall continue to use the existing model letters in section 10.7 et seq. (even after the above-mentioned transition).

In addition:

(i) Most of the documents in this section 10.7.5.1 identify parties that must receive a copy of the letter in question. If an inconsistency exists between said copied parties and those listed elsewhere in this chapter concerning a particular letter, the parties identified in this section 10.7.5.1 take precedence. To illustrate, suppose another section of this chapter requires X, Y, and Z to be copied on a certain letter while section 10.7.5.1 only requires X to be copied. The contractor in this situation need only copy X.

(ii) The contractor need only copy an accrediting organization (AO) on a particular letter if the provider/supplier has an AO for the identified provider/supplier specialty. The contractor can typically ascertain this by checking PECOS (for currently enrolled providers/suppliers) or reviewing the application (for initial enrollments) to see if an AO is disclosed. Also, PEOG will

often identify an AO (if one exists) in cases where it must review the transaction before notifying the contractor of its final approval (e.g., CHOWs, certain changes of information, voluntary termination).

(iii) See section 10.7.5.1(P) below for the applicable e-mail addresses of the SOG Locations. The contractor shall insert the relevant e-mail address into any letter in section 10.7.5.1 that addresses the provider/supplier's right to a reconsideration of a provider agreement determination.

(iv) Any data element boxes that the contractor cannot complete because the information is unavailable or inapplicable (e.g., CMS Certification Number (CCN) in certain instances) can be: (1) left blank; (2) denoted with "N/A," "Not applicable," or any similar term; or (3) removed altogether.

(v) The Provider Transaction Access Number (PTAN) box should contain the CCN for all provider/supplier types other than ASCs and PXRSs; the PTAN for the latter two supplier types will be that which the contractor assigns or has assigned.

(vi) The Primary Practice Location Address box shall include the suite number if one was/is listed on the application.

(vii) For the Denial letter in section 15.7.5.1(H), the contractor shall indicate (in any manner it chooses) whether the denial pertains to the buyer's or the seller's application if a prospective CHOW was involved.

(viii) In cases where provider/supplier data has changed and the contractor must list "detailed information or application section titles (as applicable)", the contractor has the discretion to list either (i.e., the info or the section titles).

(ix) Note that some provider/supplier types, such as PXRSs, do not have provider/supplier agreements. In such cases, and as shown in the section 10.7.5.1 model letters, the contractor shall remove references to provider/supplier agreements from these letters. For example, if no provider/supplier agreement is involved, the contractor shall:

- Change the data box heading "Provider/Supplier Agreement-Specific Information" to "Other Information".
- Remove the section regarding provider/supplier agreement appeal rights.

(Quotation marks, of course, should be removed.)

A. Approval – Change of Information (Part A/B Certified Org; No Referral to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]

[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has approved your Change of Information (COI) application.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or application section titles, as applicable.

["Provider/Supplier Agreement-Specific" OR "Other", as applicable] Information	
CMS Certification Number (CCN)	
CCN Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [& Accrediting Organization (AO), if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

B. Approval - State Agency Approved Change of Information (Part A/B Certified; Referral to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the Medicare State Agency. Your change of information application is now approved.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or application section titles, as applicable

[“Provider/Supplier Agreement Specific” OR “Other”, as applicable] Information	
CMS Certification Number (CCN)	
CCN Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the

administrative appeals process unless an ALJ allows additional information to be submitted; and

- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

C. Approval - State Agency Approved Change of Ownership (Part A/B Certified Excluding FQHCs)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]
Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the State Agency. Your change of ownership application is now approved. [If the provider/supplier type has a provider/supplier agreement, insert "The corresponding executed [insert provider/supplier agreement type] is enclosed/attached"]. Your enrollment and [insert provider/supplier agreement-specific OR "other", as applicable] information is outlined below:

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	

["Provider/Supplier Agreement Specific" OR "Other", as applicable] Information	
CMS Certification Number (CCN)	
CCN Effective Date (use effective date of seller's CCN)	
CHOW Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

If you are also requesting a reconsideration of the provider/supplier agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to: [Insert: Name and e-mail address of CMS Location Office]/

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

D. Approval - State Agency Approved Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency. Your initial enrollment application [if applicable to the provider/supplier type, insert "and [provider/supplier agreement"]] [is /are] approved. [If applicable, insert "Your executed [if applicable, insert provider/supplier agreement name] is enclosed/attached."] The effective date is the date you met all federal requirements.

Medicare Enrollment and [insert "Provider/Supplier Specific Participation Agreement" OR "Other" Information]

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	

Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Enrollment Effective Date	

[“Provider/Supplier Agreement Specific” OR “Other”, as applicable] Information	
CMS Certification Number (CCN)	
CCN Effective Date	
Medicare Year-End Cost Report Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor’s web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney’s statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ProviderEnrollmentAppeals@cms.hhs.gov

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

E. Forwarded to State - Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your initial enrollment application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. *If you have elected to use a CMS approved accreditation organization (AO), the AO will conduct the survey and recommend approval to the State Agency to finalize your certification.* Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As (DBA)	
National Provider Identifier (NPI)	
Provider/Supplier Type	
Practice Location Address	

Medicare Enrollment Information	
Medicare Year-End Cost Report Date (Part A only)	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

F. Forwarded to State – Change of Information, Change of Ownership, Revalidation, or Reactivation Containing Changed New/Changed Data that the State Must Review (if applicable) (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your [list type of transaction] enrollment application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	

National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	

["Provider/Supplier Agreement-Specific" OR "Other" Information [as applicable]]		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or Revalidation; remove if inapplicable)	Existing	Seller
	New	Buyer
	Effective Date	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

G. Approval Revalidation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your revalidation application [include if the application was sent to the state: "and forwarded it to the State Agency. The State Agency review has also been completed"]. Your Medicare enrollment information is provided below.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	

Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or application section titles, as applicable.

["Provider/Supplier Agreement-Specific" OR "Other" Information [as applicable]]		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or Revalidation; remove if inapplicable)	Existing	Seller
	New	Buyer
	Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

H. Denial Letter – Post-1539 (Or Other Similar Notice) Received from State Agency for the following application types—Initials, COIs, CHOWs, Revalidations, and Reactivations

(This letter only applies in cases where:

(1) A recommendation to the state was required per the instructions in this chapter (e.g., the application contained information/changes requiring state review), and
(2) The state sends notification to the contractor (e.g., via the 1539 or other notice) that the application should be denied and/or, if applicable, the provider/supplier agreement should be terminated.

As explained in this chapter, certain changes of information and revalidation applications can result in an enrollment revocation and provider agreement termination, though most do not. Accordingly, the contractor shall insert the applicable review result language (e.g., see bracketed options below) in the first paragraph of the letter.)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[The [insert name of State Agency] completed its evaluation of your [initial application] or [change of information] or [change of ownership] or [revalidation] or [reactivation]. [Insert the following language based on the situation involved and the specific result of the state's review:

[INITIAL ENROLLMENT: Your participation in the Medicare Program and your enrollment in the Medicare Program is [denied] for the following reasons]:

[NO REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION INVOLVED: Your application for [insert] is denied for the following reasons]:

[REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION RESULTING FROM THE APPLICATION SUBMISSION. As a result of the state's review, your provider/supplier agreement for participation in the Medicare program is terminated and your enrollment in the Medicare program is revoked for the following reason(s]:

[**INSERT DENIAL OR TERMINATION REASON GIVEN BY THE STATE AGENCY**]

Information about your [if applicable, "provider/supplier agreement" and your] Medicare enrollment [are/is] are outlined in the text box below.

Medicare Administrative Contractor Name & Contractor Number	
Medicare Enrollment Determination	
Status	**DENIED [OR REVOKED]**
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Provider/Supplier Agreement Determination [include this title and the two data elements below only if the provider/supplier type is one that has a provider/supplier agreement]	
Provider/Supplier Agreement	**DENIED [OR TERMINATED]**
CMS Certification Number (CCN)	

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider,

supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

RECONSIDERATIONS REQUEST—MAILING ADDRESSES:

Requests for Reconsideration: Medicare Provider Enrollment: The reconsideration request regarding your Medicare enrollment may be submitted electronically via e-mail to: ProviderEnrollmentAppeals@cms.hhs.gov or addressed as follows:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

Requests for Reconsideration: Medicare Provider/Supplier Agreement: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

[If a failed survey was involved, the contractor shall include the following language here: "Note that any survey deficiencies may only be addressed as part of the provider/supplier agreement reconsideration process."]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

I. Approval – Voluntary Termination (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are voluntarily terminating your provider/supplier agreement **or** [Insert Contractor name [and Contractor number]] has completed processing your application [or letter] to voluntarily disenroll from the Medicare program. Therefore, [if applicable to the provider/supplier type, insert "your provider/supplier agreement has been voluntarily terminated and"] your enrollment in the Medicare program has been voluntarily terminated effective on the date[s] shown below.

Medicare Enrollment [if applicable to the provider/supplier type, add "and Provider/Supplier Agreement"] Information

Medicare Enrollment Termination and Deactivation of Billing Privileges	
Legal Business Name (LBN)	
Doing Business As Name	

Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Enrollment Termination and Deactivation	

Provider/Supplier Agreement Termination [Include this title and the three data elements below only if the provider/supplier type is one that has a provider/supplier agreement]	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:
[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

J. Approval – Reactivation (Part A/B Certified Org)

(This letter should be used for reactivation approvals regardless of whether the application was referred to the state agency for review.)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your reactivation enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	

["Provider/Supplier Agreement Specific" OR "Other" Information [as applicable]]	
CMS Certification Number (CCN)	
CCN Effective Date	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov
[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

Requests for Reconsideration: Medicare Provider/Supplier Agreement: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

(Note: No CC: to State Agency/AO required. Deactivations do not impact certified provider CCN participation status.)

K. Voluntary Termination: Failure to Respond to Request for Information

Month, Day, Year

PROVIDER/SUPPLIER NAME
ADDRESS
CITY, STATE, ZIP

Reference # Application ID

Dear Provider Name (LBN),

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are no longer operational. We have not received a response to the request sent on Month DD, YYYY to update your enrollment information. Therefore, we have disenrolled you from the Medicare program. [Include if provider/supplier type has a provider/supplier agreement: "Your [provider/supplier agreement] has also been terminated."]

Medicare Enrollment [add if applicable "and Provider/Supplier Agreement"] Information

Medicare Enrollment Termination and Deactivation of Billing Privileges Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type/Specialty	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Enrollment Deactivation	

[“Provider/Supplier Agreement” OR “Other”, as applicable] Termination Information	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier’s behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

L. Voluntary Termination Cessation of Business

[Month, Day, Year]

PROVIDER/SUPPLIER NAME
ADDRESS
CITY, STATE, ZIP

Reference Number:

Dear Provider/Supplier Name:

[Insert Contractor name [and Contractor number]] was notified by State Agency Name that on MONTH DD, YYYY, the State Agency attempted to verify if your Type of Provider is operational. The State Agency has reported that your facility was closed, not operational, and/or ceased business at your address of record.

Pursuant to 42 CFR § 489.52(b)(3), CMS considers a cessation of business and providing services to the community to constitute a voluntary withdrawal from the Medicare program.

If you believe that our determination is incorrect and your Type of Provider facility remains operational, you must notify the State Agency and copy this office within 10 days from your receipt of this notice that your facility is still operational and participating in the Medicare program. You must provide the State Agency and this office with information to clarify why your facility was not functional at the address of record at the time the State Agency performed the site survey.

STATE AGENCY NAME
ADDRESS
CITY, STATE, ZIP

We request that you complete and submit a CMS-855 or an application via the Internet-Based Provider Enrollment Chain and Ownership System (PECOS) for a change of information to indicate that your facility/practice location remains open and operational or to request a voluntary termination of your enrollment.

If we do not hear from you, your Medicare enrollment [add if applicable "and corresponding provider/supplier agreement"] will be terminated pursuant to 42 CFR § 489.52(b)(3). With this termination, your billing privileges will also be deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

If you have any questions, please contact our office at:

Sincerely,

[Name]
[Title]
[Company]

M. Approval – Seller CHOW (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the [use "State Agency" or "CMS Survey & Operations Group Location", as appropriate] that the change of ownership involving [insert seller name] is now approved. Therefore, you have been disenrolled from the Medicare program effective on the date shown below.

Medicare Enrollment [add if applicable "and Provider/Supplier Agreement"] Termination Information

Medicare Enrollment Termination	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Enrollment Termination	

["Provider/Supplier Agreement" OR "Other"] Information

CMS Certification Number (CCN)	
Effective Date of CCN Termination	

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

N. Federally Qualified Health Centers (FQHCs) – Initial Enrollment Approval Letter

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use this letter (which was formerly in section 10.7.19 of this chapter) for all FQHC initial enrollment approvals. For all other FQHC transactions (e.g., revalidations), the contractor may use the applicable letters in either 10.7.5 or 10.7.5.1.

[Month, Day, Year]

[FQHC Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [FQHC],

[Insert Contractor] has approved your enrollment as a federally qualified health center (FQHC).

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)/CMS Certification Number (CCN)	
PTAN/CCN Effective Date	
Medicare Year-End Cost Report Date	

Provider/Supplier Agreement Information	
CMS Certification Number (CCN)	

Effective Date of CCN	

Included with this letter is a copy of your "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes to, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Compliance & Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

O. Approval – FQHC Change of Ownership

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]
Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your change of ownership application is now approved. The corresponding executed "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed, is enclosed/attached. Your enrollment and Exhibit 177 information is outlined below:

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	

Provider Agreement Specific Information	
CMS Certification Number (CCN)	
CCN Effective Date (use effective date of seller's CCN)	
CHOW Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.

- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

You may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

P. 36-Month Rule Voluntary Termination Letter

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [HHA or Hospice Seller],

[Insert Contractor name] has [Insert appropriate situation (e.g., reviewed [insert HHA's or hospice's current name] change of ownership application; learned that [insert HHA's or hospice's current name] may have undergone a change in majority ownership pursuant to 42 C.F.R. § 424.550(b)(1); etc.]. After our review, [Insert Contractor name] has determined that [insert HHA's or hospice's current name] has undergone a change in majority ownership under 42 C.F.R. § 424.550(b)(1) and that none of the exceptions described in 42 C.F.R. § 424.550(b)(2) apply to this situation. Pursuant to 42 C.F.R. § 424.550(b)(1), therefore, [insert HHA's or hospice's current name] provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of [insert HHA's or hospice's current name] must instead:

- Enroll in the Medicare program as a new (initial) [insert home health agency or hospice, as applicable] under the provisions of 42 C.F.R § 424.510; and
- Obtain a state survey or an accreditation from an approved accreditation organization.

Consistent with the foregoing, [insert HHA's or hospice's current name] provider agreement [will be/has been] voluntarily terminated and its Medicare billing privileges [will be/have been] deactivated pursuant to 42 C.F.R § 424.540(a)(8) effective [Insert date(s)].

Medicare Enrollment and Provider Agreement Information

Medicare Enrollment Deactivation	
Legal Business Name (LBN)	
Doing Business As Name	

Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Enrollment Deactivation	

Provider Agreement Termination	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address]

[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Q. Applicable SOG Location E-mail Boxes

CMS Locations Corporate Email Addresses		
CMS LOCATION	**BRANCH**	**EMAIL Address**
CMS Boston Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	ACC & LTC	BostonRO-DSC@cms.hhs.gov
CMS Philadelphia Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia	ACC & LTC	ROPHIDSC@cms.hhs.gov
CMS New York New Jersey, New York, Puerto Rico, Virgin Islands	ACC & LTC	RONYdsc@cms.hhs.gov
CMS Atlanta Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee	ACC & LTC	ROATLHSQ@cms.hhs.gov
CMS Chicago Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin	ACC & LTC	ROCHISC@cms.hhs.gov
CMS Kansas City Iowa, Kansas, Missouri, Nebraska	ACC & LTC	ROkcmSCB@cms.hhs.gov

CMS Denver Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming	ACC & LTC	CMSKC_DEN_SOG@cms.hhs.gov
CMS Dallas Arkansas, Louisiana, New Mexico, Oklahoma, Texas	ACC & LTC	RODALDSC@cms.hhs.gov
CMS San Francisco Arizona, California, Hawaii, Nevada, Pacific Territories	ACC & LTC	ROSFOSO@cms.hhs.gov
CMS Seattle Alaska, Idaho, Oregon, Washington	ACCB LTC	CMS_RO10_CEB@cms.hhs.gov Seattle_LTC@cms.hhs.gov

10.7.5.1.1 – Additional Certified Provider and Certified Supplier Letters

(Rev. 11574; Issued: 08-25-22; Effective: 6-24-22; Implementation: 09-27-22)

This section 10.7.5.1.1 contains additional letters that contractors shall use in certain special situations involving certified providers and suppliers. They take precedence over all other letters in this chapter potentially pertaining to the situations described in this section

A. Denials Based on Survey Failure for Transitioned Certified Providers/suppliers

(This letter does not apply to non-transitioned certified providers/suppliers.)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier]:

We regret to inform you that (Provider/Supplier] does not meet the requirements for participation in the Medicare program (Title XVIII of the Social Security Act).

In order to participate in the Health Insurance for the Aged and Disabled Program, a [list the provider/supplier type] must be in compliance with all applicable Conditions of [Participation or Coverage, as applicable] established by the Secretary of Health and Human Services. Based on

the [list date survey occurred] survey conducted by [list the state agency or accrediting organization name], CMS has determined that your facility does not qualify. The deficiencies that the [list the state agency or accrediting organization name] found are listed on the Survey Report. Your facility is not in compliance with the following Conditions of [Participation or Coverage]:

§ [List regulatory cite (e.g., 42 CFR § 418.56) and the specific provision in question (e.g.,: Interdisciplinary Group, Care Planning, and Coordination of Services]

You may take steps to correct the deficiencies and reapply to establish eligibility. However, current survey funding levels (as appropriated by Congress) may not allow for a resurvey. CMS' priority for use of the limited funds available are to ensure the health and safety of Medicare beneficiaries at currently participating facilities. Contact [list the state survey agency or accrediting organization that performed the initial survey] for the status of initial surveys of non-participating facilities.

Please note that you may submit no more than two reapplications for certification in connection with one enrollment application, and no more than six months may elapse between the date of the first survey denial notification and the CMS Survey & Certification Group's receipt of the second reapplication for certification. Applicants who reapply for certification must undergo and pass a subsequent survey. (Note that a reapplication for certification is different from the submission of a [Form CMS-855A or Form CMS-855B, as applicable to the provider/supplier type] Medicare enrollment application. At this time, you need not submit a [Form CMS-855A or Form CMS-855B, as applicable] to request another survey per the previous paragraph.)

If you believe that this decision is not correct, you may request that this decision be reconsidered. The request must be submitted in writing to [list applicable SOG Location] within 60 days of the date you receive this notice. You may submit with your request any additional information which you feel may have a bearing on this decision. If you have any questions, please contact [list appropriate SOG Location contact person] at xxxxxx@cms.hhs.gov.

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

10.7.6 – Part B Non-Certified Provider and Supplier Approval Letter Templates

(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)

A. Approval – Change of Information (Part B Sole Proprietor)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

You must include your NPI, as the billing and rendering provider, on all Medicare claim submissions.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

B. Approval – Change of Information (Part B Physician Assistant)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	Physician Assistant
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Individual PTAN Effective Date	
Employer Legal Business Name (LBN)	
Employer National Provider Identifier (NPI)	
Employer Provider Transaction Access Number (PTAN)	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

You must include your NPI, as the rendering provider, on all Medicare claims submissions.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

C. Approval – Change of Information (Part B Org or Part B Sole Owner)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR §424.516 or 42 CFR§424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

D. Approval – Change of Information (Part B Reassignment for Existing Physician or Non-Physician Practitioner)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Group Legal Business Name (LBN)	
Group NPI	
Group PTAN	
Reassignment Effective Date	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

You must include your NPI, as the rendering provider, on all Medicare claim submissions.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

E. Approval – Change of Information (Part B Reassignment to CAH)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Provider/Supplier Legal Business Name (LBN)	
Provider/Supplier Type	Critical Access Hospital (CAH)
Provider/Supplier NPI	
Provider/Supplier PTAN	
Reassignment Effective Date	
Changed Information	

This action establishes a relationship between the above named individual and the Critical Access Hospital (CAH) facility, in PECOS, for enrollment purposes only. This does not constitute approval of the election of this facility or individual for Method II Billing, as identified in Section 1834(g)(2) of the Act.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

F. Approval – Initial/Reactivation Reassignment (Part B CAH)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Provider/Supplier Legal Business Name (LBN)	
Provider/Supplier Type	Critical Access Hospital (CAH)
Provider/Supplier NPI	
Provider/Supplier PTAN	
Reassignment Effective Date	

This action establishes a relationship between the above named individual and the Critical Access Hospital (CAH) facility, in PECOS, for enrollment purposes only. This does not constitute approval of the election of this facility or individual for Method II Billing, as identified in Section 1834(g)(2) of the Act.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

G. Approval – Initial/Reactivation (Part B Order and Certify)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application to solely order and certify items and services for Medicare beneficiaries. You may not send billed services claims to [Insert Contractor].

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Effective Date	

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

H. Approval – Change of Information (Part B Order and Certify)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Changed Information	

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

I. Approval – Initial/Reactivation (Part B Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR §424.516 or 42 CFR§424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your

request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.

- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]		[Centers for Medicare & Medicaid Services]
[Address]		[Center for Program Integrity]
[City], ST [Zip]	or	[Provider Enrollment & Oversight Group]
		[ATTN: Division of Provider Enrollment Appeals]
		[7500 Security Blvd.]
		[Mailstop: AR-19-51]
		[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address]	or	[ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

J. Approval – Initial/Reactivation (Part B Physician Assistant)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	Physician Assistant
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Individual PTAN Effective Date	
Employer Legal Business Name (LBN)	
Employer National Provider Identifier (NPI)	
Employer Provider Transaction Access Number (PTAN)	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

K. Approval – Initial/Reactivation (Part B Sole Owner)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Individual PTAN Effective Date	
Group Legal Business Name (LBN)	
Group Specialty	
Group NPI	
Group PTAN	
Group PTAN Effective Date	
Participation Status	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

You must include the individual provider's NPI as the rendering provider and the organizational provider's NPI as the billing provider on all Medicare claim submissions.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during

the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

L. Approval – Initial/Reactivation (Part B Sole Proprietor)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	

Individual Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

You must include your NPI, as the billing and rendering provider, on all Medicare claim submissions.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

M. Approval – Initial/Reactivation with Reassignment (Part B Ind)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your [initial or reactivation] enrollment and reassignment application(s).

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Group Legal Business Name (LBN)	
Group NPI	
Group PTAN	
Reassignment Effective Date	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.
You must include your NPI, as the billing and rendering provider, on all Medicare claim submissions.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]

[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

N. Approval – Revalidation (Part B Ind with Reassignment)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your revalidation application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Group Legal Business Name (LBN)	
Group NPI	
Group PTAN	
PTAN Effective Date	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

O. Approval – Revalidation (Part B Sole Proprietor)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your revalidation enrollment application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your

request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

P. Approval – Revalidation (Part B Physician Assistant)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your revalidation application.

Medicare Enrollment Information

Individual Name	
Individual Specialty	Physician Assistant
Individual National Provider Identifier (NPI)	

Individual Provider Transaction Access Number (PTAN)	
Individual PTAN Effective Date	
Employer Legal Business Name (LBN)	
Employer National Provider Identifier (NPI)	
Employer Provider Transaction Access Number (PTAN)	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the

provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

[Name of MAC]
[Address]
[City], ST [Zip]

Or emailed to:

[Insert MAC email address]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

Q. Approval – Revalidation (Part B Non-Certified Org or Part B Sole Owner)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your revalidation application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
Provider/Supplier National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR §424.516 or 42 CFR§424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]		[Centers for Medicare & Medicaid Services]
[Address]		[Center for Program Integrity]
[City], ST [Zip]	or	[Provider Enrollment & Oversight Group]
		[ATTN: Division of Provider Enrollment Appeals]
		[7500 Security Blvd.]
		[Mailstop: AR-19-51]
		[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

[Title]
[Company]

R. Approval – Voluntary Termination (Part B Sole Proprietor)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to disenroll from the Medicare program.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Effective Date of Termination	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

S. Approval – Voluntary Termination (Part B Physician Assistant)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to disenroll from the Medicare program.

Medicare Enrollment Information

Individual Name	
Individual Specialty	Physician Assistant
Individual National Provider Identifier (NPI)	
Individual Provider Transaction Access Number (PTAN)	
Employer Name	
Employer National Provider Identifier (NPI)	
Employer Provider Transaction Access Number (PTAN)	
Effective Date of Termination	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

T. Approval – Termination of Reassignment (Part B Ind)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to disenroll from the Medicare program.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	

Individual Provider Transaction Access Number (PTAN)	
Group Name	
Group National Provider Identifier (NPI)	
Group Provider Transaction Access Number (PTAN)	
Effective Date of Termination	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

U. Approval – Termination of Reassignment (Part B CAH)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to disenroll from the Medicare program.

Medicare Enrollment Information

Individual Name	
Individual Specialty	
Individual National Provider Identifier (NPI)	
Provider/Supplier Legal Business Name (LBN)	
Provider/Supplier Type	Critical Access Hospital (CAH)
Provider/Supplier NPI	
Provider/Supplier PTAN	
Effective Date of Termination	

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

V. Approval – Voluntary Termination (Part B Non-Certified Org or Part B Sole Owner)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to disenroll from the Medicare program.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Termination	

Reassignments and any physician assistant employment arrangements are also deactivated.

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

10.7.7 – Application Return and Rejection Model Letters
(Rev. 11859; Issued: 02-16-23; Effective: 03-17-23; Implementation: 03-17-23)

A. Returned Application Letter

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

Your Medicare enrollment application(s) was received on [date]. We are closing this request and returning your application(s) for the following reason(s):

[List all reasons for return]

If you would like to resubmit an application, you must complete a new Medicare enrollment application(s). Please address the above issues as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers can apply to enroll in the Medicare program using one of the following two methods:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). Go to: https://pecos.cms.hhs.gov/pecos/login.do.

2. Paper application process: Download and complete the Medicare enrollment application(s) at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

Please return the completed application(s) to:

[Name of MAC]
[Address]
[City], ST [Zip]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

B. Model Rejection Letter

[month] [day], [year]

[Provider/Supplier Name]

[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

We received your Medicare enrollment application(s) on [Receipt Date]. We are rejecting your application(s) for the following reason(s):

[List all reasons for rejection]

If you would like to resubmit an application, you must complete a new Medicare enrollment application(s). Please address the above issues as well as sign and date the new certification statement page on your resubmitted application(s).

In compliance with Federal regulations found at 42 CFR §424.525, providers and suppliers are required to submit complete application(s) and all supporting documentation within 30 calendar days from the postmark date of the contractor request for missing/incomplete information.

Providers and suppliers can apply to enroll in the Medicare program using one of the following two methods:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). Go to: https://pecos.cms.hhs.gov/pecos/login.do.

2. Paper application process: Download and complete the Medicare enrollment application(s) at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

Please return the completed application(s) to:

[Name of MAC]
[Address]
[City], ST [Zip]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

C. Rejection Letter for Locations That Do Not Meet the Distance Requirements

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

We received your Medicare enrollment application(s) to add a new provider-based location to your Critical Access Hospital enrollment on [date]. We are rejecting your application because the [enter the office that made the decision] has found that your new location does not meet distance requirements found in 42 CFR § 485.610(e)(2).

Please refer to communications from the [enter the office that made the decision] for instructions for your next steps regarding the new provider-based location.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

10.7.8 – Denial Model Letters

(Rev. 12209; Issued: 08-17-23; Effective: 09-18-23; Implementation: 09-18-23)

A. Denial Letter Guidance

The contractor must submit one or more of the denial citations as found in Section 10.4.2 et seq. of this chapter into the appropriate section on the Model Denial Letter. Only the CFR citation and a short heading shall be cited for the primary denial reason.

- The contractor may submit one or more denial reason, as appropriate. The denial reason(s) should state sufficient details so it is clear as to why the provider or supplier is being denied.

- Specific Denial Reasons may contain one or more of the following items:

- A specific regulatory (CFR) citation.
- Dates (of actions, suspensions, convictions, receipt of documents, etc.)
- Pertinent details of action(s)

DMEPOS supplier-only language. All denial letters for DMEPOS suppliers shall replace the 1st paragraph of the model denial letter with the following text:

Your application to enroll in Medicare is denied. After reviewing your submitted application document(s), it was determined that per 42 CFR § 405.800, 42 CFR § 424.57, and 42 CFR § 498.22, that you do not meet the conditions of enrollment or meet the requirements to qualify as a Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provider or supplier for the following reason(s):

(Exclusions and sanctions – the following two sentences should be REMOVED for all denial letters that DO NOT involve an exclusion or sanction action:

You may not appeal through this process the merits of any exclusion by another federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the federal agency that took the action.)

For IDTF, DMEPOS, and MDPP providers and suppliers, each regulatory citation needs to be listed along with the specific regulatory language. For IDTF, the standards are found in 42 CFR § 410.33(g). For DMEPOS providers and suppliers, the standards are found in 42 CFR § 424.57(c)(1) through (30). For MDPP suppliers, the standards are found in 42 CFR § 424.205(d).

If a provider is being added to the CMS Preclusion List, the following should be inserted to the denial letter (should PEOG instruct the contractor to do so:

> The Centers for Medicare & Medicaid Services (CMS) has been made aware of [Provider Name]'s [Date], felony conviction, as defined in 42 C.F.R. § 1001.2, for [reason] in violation of [Code] in the Court Name]. After reviewing the specific facts and circumstances surrounding [Jane Doe]'s felony conviction, CMS has determined that [Provider Name]'s felony conviction is detrimental to the best interests of the Medicare program and its beneficiaries.
>
> Additionally, [Provider Name] will be placed on the CMS Preclusion List because [he/she] has been convicted of a felony, as described above, under Federal or State law, within the previous 10 years, that CMS deems detrimental to the best interests of the Medicare program. CMS may take this action regardless of whether you are or were enrolled in the Medicare program. This action is being taken pursuant to 42 C.F.R. §§ 422.2, 422.222, 423.100, and 423.120(c)(6).
>
> The effective date of your inclusion on the Preclusion List is dependent upon the submission or non-submission of a reconsideration request (see below). If you do submit a reconsideration request and your inclusion on the Preclusion List is upheld, you will be added to the Preclusion List on the date of the reconsideration decision. If you do not

submit a reconsideration request, you will be included on the Preclusion List 65 days after the date of this letter.

During the time period that your name will be included on the Preclusion List as listed above, any claims you submit for health care items or services furnished under a Medicare Advantage (MA) benefit may be denied. Additionally, any pharmacy claims submitted for Medicare Part D drugs that you prescribe may be rejected or denied. This means that your patients may not be able to receive coverage of their prescriptions using their Part D benefit at the pharmacy.

The below appeal rights apply to both your denial and preclusion. If you choose to appeal, you **must** file an appeal to the denial and preclusion jointly.

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination.

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.

- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

B. Model Denial Letter

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your application to enroll in Medicare is denied for the following reason(s):

xx CFR §xxx.(x) [heading]
[Specific reason]

xx CFR §xxx.(x) [heading]
[Specific reason]

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]) The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], ST [Zip]

or

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Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
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    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

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7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

C. Denial Example Letters

Note that each example contains appeal rights for both CMS and the MAC, regardless of the example reason, so that the contractors may include the appropriate appeal address based on the provider or supplier type that has been denied.

1. Discipline Not Eligible Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your application to enroll in Medicare is denied for the following reason(s):

42 CFR §424.530(a)(1) – Not in Compliance with Medicare Requirements
There is no statutory or regulatory basis which permits a Marriage and Family Therapist to enroll or receive payment in the Medicare Program.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]) The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
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    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], ST [Zip]

or

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Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
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Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further

permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

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Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]
[Company]

2. Criteria for Eligible Discipline Not Met Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your application to enroll in Medicare is denied for the following reason(s):

42 CFR §424.530(a)(1) - Not in Compliance with Medicare Requirements

Per 42 CFR §410.75(b)(1)(i), the provider or supplier is not certified by a recognized national certifying body that has established standards for nurse practitioners.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]) The CAP must--

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    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

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[Address]
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7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through

this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]
[Company]

3. Provider Standards Not Met Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear IDTF Services, Inc.:

Your application to enroll in Medicare is denied for the following reason(s):

42 CFR §424.530(a)(5) - On-site Review - Requirements Not Met

Specifically, the following standards were not met:

42 CFR §410.33(g) 4 - Have all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. A catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, must be maintained at the physical site. In addition, portable diagnostic testing equipment must be available for inspection within two business days of a CMS inspection request. The IDTF must maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

42 CFR §410.33(g) 9 - Openly post these [IDTF] standards for review by patients and the public

42 CFR §410.33(g) 11 - Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

42 CFR §410.33(g) 12 - Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
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    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address]or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
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Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]

[Company]

4. Business Type Not Met Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:
Your application to enroll in Medicare is denied for the following reason(s):

42 CFR §424.530(a)(1) - Not in Compliance with Medicare Requirements
42 CFR §410.62(c)(ii) states that speech language pathologists in private practice must be engaged in one of the following practice types if allowed by State and local law: (A) An unincorporated solo practice; (B) An unincorporated partnership or unincorporated group practice; (C) An employee in an unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated speech-language pathology practice; (D) An employee of a physician group (includes certain Non-Physician Practitioners [NPPs], as appropriate); or (E) An employee of a group that is not a professional corporation.

Your current private practice status is an incorporated solo practice; therefore, you do not qualify as a Medicare provider or supplier.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

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Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

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Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]
[Company]

5. Existing or Delinquent Overpayments Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your application to enroll in Medicare is denied for the following reason(s):

42 CFR §424.530(a)(6) – Existing Overpayment at Time of Application

The current owner (as defined in § 424.502), physician or non-physician practitioner has an existing overpayment at the time of filing an enrollment application.

Dates: (enter date of existing or delinquent overpayment period)

Pertinent details of action(s) (Whether the person or entity is on a Medicare-approved plan of repayment of payments are currently being offset: Whether the overpayment is currently being appealed; the reason for the overpayment)

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or

emailed to the address below.

- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51

Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]
[Company]

6. MDPP Supplier Standards Not Met – Ineligible Coach Example

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your application to enroll in Medicare is denied for the following reason(s):
42 CFR §424.530(a)(1) - Not in Compliance with Medicare Requirements

Specifically, the following standards were not met:

42 CFR §424.205(d)(3) - The MDPP supplier must not include on the roster of coaches nor permit MDPP services to be furnished by any individual coach who meets any of ineligibility criteria.
42 CFR §424.205(e)(v)(a) specifies that an individual with a state or federal felony conviction in the previous 10 years of any crime against persons, such as murder, rape, assault, and other similar crimes, would not meet the eligibility criteria to be an MDPP coach.

The following coach included on Section 7 of your Form CMS-20134 or its electronic equivalent meets this ineligibility criteria:

John B. Doe | DOB: June 19, 1991 | NPI: 1234567

Please see attached documentation of the felony conviction.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if denied under 42 C.F.R. § 424.530(a)(1))

You may submit a corrective action plan (CAP) in response to the denial of an enrollment application under 42 C.F.R. § 424.530(a)(1). You may also request a reconsideration (described below). If your enrollment application was denied under authorities other than 42 C.F.R. § 424.530(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If denied under 42 C.F.R. § 424.530(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], ST [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Name]

[Title]
[Company]

10.7.9 – Revocation Letters

(Rev.: 12796; Issued: 08-15-24; Effective: 09-16-24; Implementation: 09-16-24)

A. Revocation Letter Guidance

The contractor--

- Must submit one or more of the Primary Revocation Reasons as found in section 10.4.7.3 into the appropriate section on the specific Revocation Letter. Only the CFR citation and a short heading shall be cited for the primary revocation reason.

- Shall include sufficient details to support the reason for the provider or supplier's revocation;

- Shall issue all revocation letters via certified letter, per regulations found in 42 CFR 405.800(b)(1); and

- Shall issue two revocation letters to any solely owned organizations, one for the individual and the other for the organization.

B. Model Revocation Letters

1. Revocation Example - Letter for DMEPOS Suppliers

[month] [day], [year]

[Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Certified mail number: [number]
Returned receipt requested

Dear [Supplier Name]:

The purpose of this letter is to inform you that pursuant to 42 CFR §§ 405.800, 424.57(x), 424.535(g), and 424.535(a)[(x)], your Medicare supplier number [xxxxxxxxxx], Medicare enrollment, and Medicare billing privileges for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS),

[will be revoked effective 30 days from the postmarked date of this letter]

[are revoked. The effective date of this revocation has been made retroactive to [month] [day], [year], which is the date [revocation reason]]

[The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [date]. This letter allowed you to demonstrate your full compliance with the DMEPOS supplier standards and/or to correct the deficient compliance requirement(s).]

[The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [date]. This letter allowed you to demonstrate your full compliance with the DMEPOS supplier standards and/or to correct the deficient compliance requirement(s)]

[[Contractor Name] has not received a response to the developmental letter sent to you on [date] informing you that the request for a hardship exception for the required application fee was denied. The notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application and an appeal period which you did not select.]

[[Contractor Name] has not received a response to the developmental letter sent to you on [date] informing you that the application fee was not paid at the time you filed the Form CMS-855S

enrollment application. The 30-day notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application]

We have determined that you are not in compliance with the supplier standards noted below:

42 CFR §424.57(c) [1-30] [Insert the specific performance standard not met]

Section 1834(j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834 (a)(A)(ii) of the Social Security Act and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under 1834 (j) (4) and 1879(h) of the Social Security Act, you may be liable for civil money penalties.

Pursuant to 42 CFR § 424.535(c), you are barred from reenrolling in the Medicare program for a period of [number of years] year(s) from the effective date of the revocation. To reenroll after the reenrollment bar has expired, you must meet all requirements for your supplier type. In addition, if submitting a Form CMS-855S application after the reenrollment bar's expiration, 42 C.F.R. § 424.57(d)(3)(ii) states that suppliers are required to maintain an elevated surety bond amount of $50,000 for each final adverse action (which includes a Medicare revocation) imposed. Therefore, if you do not request a reconsideration of this revocation decision or receive an unfavorable decision through the administrative review process, you must submit an elevated surety bond with any application to reenroll in Medicare. Please note that this amount is in addition to, and not in lieu of, the base $50,000 amount that must be maintained.

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to an enrollment revocation under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your enrollment was revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those revocation bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached]

coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

Chags Health Information
Technology LLC
P.O. Box 45266
Jacksonville, FL 32232

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[PEARC@c-hit.com] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.

- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether C-HIT or CMS is responsible for handling the reconsideration.

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[PEARC@c-hit.com] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

2. Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers

[Month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your Medicare enrollment and Medicare billing privileges are being revoked effective [Date of revocation] for the following reasons:

xx CFR §xxx.(x) [heading]
[Specific reason]

xx CFR §xxx.(x) [heading]
[Specific reason]

(For certified providers and certified suppliers only: Pursuant to 42 CFR §424.535(b), this action will also terminate your corresponding (provider or supplier) agreement.)

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re-enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to the revocation of Medicare billing

privileges under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your Medicare billing privileges were revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those revocation bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to maintain enrollment in the Medicare program. (Optional Coversheet sentence [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed or emailed to the address below;

- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

The CAP should be sent to:

[Name of MAC]
[Address]
[City], [ST] [Zip]

Or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC] [Address] [City], [ST] [Zip]	or	Centers for Medicare & Medicaid Services Center for Program Integrity Provider Enrollment & Oversight Group Attn: Division of Provider Enrollment Appeals 7500 Security Boulevard Mailstop AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

C. Revocation Letter Examples

Note that each example contains instructions to send appeals to both CMS and the contractor, regardless of the example reason, so that the contractors may include the appropriate appeal address based on the provider or supplier type that has been revoked. In addition, note that the section advising the provider/supplier of their right to submit a CAP are only included in the examples of revocations based on 42 C.F.R. § 424.535(a)(1).

1. Abuse of Billing Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City, State & ZIP Code]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

Your Medicare enrollment and Medicare billing privileges are being revoked effective June 16, 2022 for the following reasons:

Revocation reason: 42 CFR § 424.535(a)(8)

Specifically, you submitted 186 claims to Medicare for services provided after the date of death of 15 beneficiaries.

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re- enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.

- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

2. DMEPOS Supplier Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City], [ST] [Zip]

Reference #: [PTAN #, Enrollment #, Case #, etc.]
NPI: [xxxxxxxxxx]

Dear [Supplier Name]:

The purpose of this letter is to inform you that pursuant to 42 C.F.R. § 405.800, 42 C.F.R. §424.57(e), and 42 C.F.R. § 424.535(a)(5), your Medicare supplier number [xxxxxxxxxx], Medicare enrollment, and Medicare billing privileges for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) issued by [Contractor name) is revoked. The effective date of this revocation has been made retroactive to April 26, 2012, which is the date the Centers for Medicare & Medicaid Services (CMS) determined that your practice location is not operational.

We have determined that you are not in compliance with the supplier standards noted below:

42 C.F.R. § 424.57(c)(7) Maintain a physical facility on an appropriate site, accessible to the public and staffed during posted hours of business with visible signage.

Recently a representative of [Contractor name] attempted to conduct a visit of your facility on April 26, 2012. However, the visit was unsuccessful because your facility was closed, locked, and vacant. There was a "For Rent" sign on the window along with a sign directing customers to a nearby Rite Aid Pharmacy. Because we could not complete an inspection of your facility, we could not verify your compliance with the supplier standards. Based on a review of the facts, we have determined that your facility is not operational to furnish Medicare covered items and services. Thus, you are in violation of 42 CFR § 424.535(a)(5).

42 C.F.R. § 424.57(c)(26) must meet the surety bond requirements specified in 42 C.F.R. § 424.57(d).

We received a cancellation notice from Cook, Books & Hyde Surety indicating that the surety bond on file with the billing number 99999999 has been cancelled effective January 19, 2012. You failed to maintain a valid surety bond as required by law.

Section 1834 (j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834(a)(18)(ii) of the Social Security Act and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under sections 1834(j)(4) and 1879(h) of the Social Security Act, you may be liable for Civil Monetary penalties.

(Delete the following paragraph if no reenrollment bar established.)[Pursuant to 42 C.F.R. § 424.535(c), CMS is establishing a reenrollment bar for a period of [Insert amount of time] that

shall begin 30 days after the postmark date of this letter. This reenrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to reenroll, you must meet all requirements for your provider or supplier type.]

In addition, if submitting a Form CMS-855S application after the reenrollment bar's expiration, 42 C.F.R. § 424.57(d)(3)(ii) states that suppliers are required to maintain an elevated surety bond amount of $50,000 for each final adverse action (which includes a Medicare revocation) imposed. Therefore, if you do not request a reconsideration of this revocation decision or receive an unfavorable decision through the administrative review process, you must submit an elevated surety bond with any application to reenroll in Medicare. Please note that this amount is in addition to, and not in lieu of, the base $50,000 amount that must be maintained.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during

the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the C-HIT or CMS is responsible for handling the reconsideration.

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[PEARC@c-hit.com] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you choose not to request a reconsideration of this decision, or you do not receive a favorable decision through the administrative review process, you must wait [insert number] years before resubmitting your CMS-855S application, per the re-enrollment bar cited above. Applications received by [Contractor name] prior to this timeframe will be returned.

If you have any questions, please contact our office at [Contractor call center phone number] between the hours of [x:00 AM/PM ET/CT/PT/MT] and [x:00 AM/PM ET/CT/PT/MT].

Sincerely,

[Name]
[Title]
[Company]

3. MDPP Supplier Use of an Ineligible Coach Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City, State & ZIP Code]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [MDPP Supplier Name]:

Your Medicare enrollment and Medicare billing privileges are being revoked effective June 16, 2018 for the following reasons:

Revocation reason: 42 CFR §424.535(a)(1) – Not in Compliance with Medicare Requirements

Per 42 CFR §424.205(d)(3), MDPP suppliers must only use eligible coaches.

Revocation reason: 42 CFR §424.205(h)(v) – Use of an Ineligible coach

Specifically, you were notified on April 1, 2018 that John Doe was ineligible to serve as an MDPP coach due to an assault conviction in June 2015. On April 15, 2018, you submitted a corrective action plan (CAP), which removed John Doe from Section 7 of your Form CMS-20134. On June 1, 2018, you submitted a claim with the NPI of John Doe for services rendered May 1st, after he was removed from your coach roster. This indicates knowingly use of an ineligible MDPP coach.

Revocations under 42 CFR §424.205(h)(v) are not eligible for CAP submission. The revocation becomes effective 30 days after the date of this notice.

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re- enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to the revocation of Medicare billing privileges under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your Medicare billing privileges were revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those revocation bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to maintain enrollment in the Medicare program. (Optional Coversheet sentence [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]) The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed or emailed to the address below;

- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she

has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

10.7.10 – Corrective Action Plan (CAP) Model Letters

(Rev. 10611; Issued: 03-19-21; Effective:11-19-20; Implementation: 11-19-20)

A. CAP Withdrawn Acknowledgement Template

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

1. Email Template

To: [Email address provided by the person who submitted the CAP]

Subject: Medicare Provider Enrollment CAP re: [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the CAP]:

We are in receipt of your written withdrawal request in regard to your corrective action plan (CAP) received on [Month] [DD], [YYYY]. [MAC Name] has not yet issued a decision regarding your CAP. Therefore, [MAC Name] considers your CAP dated [Month] [DD], [YYYY] to be withdrawn. As a result, a decision will not be issued in response to your CAP.

If you have not yet filed a reconsideration request, please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]

[MAC Name]

2. Hard-Copy Letter Template

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

We are in receipt of your written withdrawal request in regard to your corrective action plan (CAP) received on [Month] [DD], [YYYY]. [MAC Name] has not yet issued a decision regarding your CAP. Therefore, [MAC Name] considers your CAP dated [Month] [DD], [YYYY] to be withdrawn. As a result, a decision will not be issued in response to your CAP.

If you have not yet filed a reconsideration request, please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

B. CAP Receipt Acknowledgement Email Template to Provider/Supplier/ Representative

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

1. Email Template

To: [Email address provided by the person who submitted the CAP]

Subject: Medicare Provider Enrollment CAP re: [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the CAP]:

We are in receipt of your corrective action plan (CAP) on behalf of [Provider/Supplier Name]. Please be advised that [MAC Name] has 60 calendar days to review your CAP and render a decision.

If you have additional information that you would like a hearing officer to consider during the CAP review you must submit that information prior to a decision being issued.

Please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely

,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

2. Hard-Copy Letter Template

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]

Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

We are in receipt of your corrective action plan (CAP) on behalf of [Provider/Supplier Name]. Please be advised that [MAC Name] has 60 calendar days to review your CAP and render a decision.

If you have additional information that you would like a hearing officer to consider during the CAP review you must submit that information prior to a decision being issued.

Please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

C. CAP Decision Email Template to Provider/Supplier/Representative

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

To: [Email address provided by the person who submitted the CAP]

Subject: Medicare Provider Enrollment CAP re: [Provider/Supplier Name]

(Be sure to attach a copy of the final decision[s] in PDF format.)

Dear [Name of the person(s) who submitted the CAP]:

Please see the attached decision regarding your Medicare Provider Enrollment CAP.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

D. CAP Not Actionable (Moot) Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the CAP received by [MAC Name] based on the initial determination letter, dated [Month] [DD], [YYYY].

In correspondence dated [Month] [DD], [YYYY], the initial determination letter, dated [Month] [DD], [YYYY] informing you of the [denial of your Medicare enrollment application or revocation of your Medicare billing privileges] was [insert description] (describe action taken in regards to the initial determination, i.e. rescission of denial or revocation). For your convenience, a copy of the initial determination is included. Therefore, the issue set forth in the CAP is no longer actionable. This issue is moot, and we are unable to render a decision on the matter.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

E. Untimely CAP Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the CAP received by [MAC Name] based on the initial determination letter, dated [Month] [DD], [YYYY].

[MAC Name] is unable to accept your CAP as it was not timely submitted. The initial determination letter was dated [Month] [DD], [YYYY]. A CAP must be received within 35 calendar days of the date of the initial determination letter. Your CAP was not received until [Month] [DD], [YYYY], which is beyond the applicable submission time frame. [Provider/Supplier/Representative] failed to show good cause for its late request. Therefore, [MAC Name] is unable to render a decision in this matter.

Please refer to the initial determination letter, dated [Month] [DD], [YYYY], for instructions on how to properly file a reconsideration request. If you have already submitted a reconsideration request, you will receive further communication related to that submission. Failure to timely file a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

F. Improperly Signed CAP Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on the initial determination letter, dated [Month] [DD], [YYYY].

[MAC Name] is unable to accept your CAP as it was not signed by an authorized or delegated official currently on file in your Medicare enrollment record, the individual provider or supplier, or a properly appointed representative. The signature requirement was stated in the initial determination letter, dated [Month] [DD], [YYYY], as well as in Chapter 10 of the Medicare Program Integrity Manual.

Please refer to the initial determination letter, dated [Month] [DD], [YYYY], for instructions on how to properly file a reconsideration request. If you have already submitted a reconsideration request, you will receive further communication related to that submission. Failure to timely file a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

G. No CAP Rights Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on the initial determination letter, dated [Month] [DD], [YYYY].

[MAC Name] is unable to accept your CAP. A provider or supplier may only submit a CAP if there has been a denial of enrollment in the Medicare program under 42 C.F.R § 424.530(a)(1) or the revocation of Medicare billing privileges under 42 C.F.R. § 424.535(a)(1). Your enrollment was not denied or revoked under one of the aforementioned authorities. Therefore, a CAP decision cannot be rendered based on this submission.

Please refer to the initial determination letter, dated [Month] [DD], [YYYY], for instructions on how to properly file a reconsideration request. If you have already submitted a reconsideration request, you will receive further communication related

to that submission. Please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

H. Not Eligible to Submit CAP Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the [corrective action plan (CAP)] received by [MAC Name], based on the [Month] [DD], [YYYY] initial determination.

[MAC Name] is unable to accept your [CAP] submission because the action taken in regards to your Medicare enrollment is not an initial determination subject to administrative review. More specifically, an initial determination has not been made as described in 42 C.F.R. § 498.3(b). Under 42 C.F.R. § 498.5(l), appeal rights extend only to initial determinations related to the denial or revocation of Medicare billing privileges.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

I. CAP Signature Development Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

We are in receipt of your CAP submission, received on [Month] [DD], [YYYY].

(If the submission is not properly signed, use the following.) [Your submission is not appropriately signed, as stated in the initial determination letter and in the Medicare Program Integrity Manual, Ch. 10, Section 10.6.18. [MAC Name] is requesting that you submit a CAP that is properly signed by the individual provider, supplier, the authorized or delegated official, or a properly appointed representative. Your properly signed submission must be received within 15 calendar days of the date of this notice. If you do not timely respond to this request, your CAP submission may be dismissed.]

(If the submission is missing a statement by the attorney, use the following.) [Your submission is missing an attorney statement that he or she has the authority to represent the provider or supplier. [MAC Name] is requesting that you submit a CAP that includes an attorney statement that he or she has the authority to represent the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, your CAP submission may be dismissed.]

(If the submission is missing a signed written notice from the provider/supplier authorizing the representative to act on his/her/its behalf, use the following.) [Your submission is missing a written notice of the appointment of a representative signed by the provider or supplier. [MAC Name] is requesting that you submit written notice of the appointment of a representative that is signed by the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, your CAP submission may be dismissed.]

Your submission should be sent to [MAC Appeal Receipt Email Address] or mailed to the following address:

[MAC Appeal Receipt Address] [MAC Fax number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

J. Favorable CAP Model Letter in Response to an Enrollment Denial

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]

Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on an enrollment denial. The initial determination letter was dated [Month] [DD], [YYYY] and the CAP was received on [Month] [DD], [YYYY]; therefore, this CAP is considered timely. (if the CAP is untimely, but good cause has been found to accept the CAP, use the following [This CAP was not timely submitted, but a good cause waiver has been granted.) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DENIAL REASON:

- 42 C.F.R. § 424.530(a)(1)

OTHER APPLICABLE AUTHORITIES:

- (Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

- Exhibit 1: (Ex.: CAP, signed by Jane Doe, dated [Month] [DD], [YYYY].)
- Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies and program instructions.

(Summarize the facts underlying the case which led up to the submission of the CAP.)

CORRECTIVE ACTION PLAN ANALYSIS:

[A [Provider/Supplier Name] may only submit a corrective action plan for noncompliance under 42 C.F.R. § 424.530(a)(1). If the initial determination was

based on any other denial reasons other than 42 C.F.R. § 424.530(a)(1), this decision will not review those authorities.]

(A CAP is an opportunity to correct the deficiencies identified in the initial determination. This section should include: A clear explanation of why the denial was overturned in sufficient detail for the provider or supplier to understand the decision and; if applicable: the nature of the provider or supplier's deficiencies, the regulatory or other policy basis to support each reason for the denial, and an explanation of how the provider or supplier now meets the enrollment criteria or requirements. This section shall not reference a CAP decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement. Approval date should be based on the date the provider or supplier came into compliance with all applicable Medicare requirements.)

(Ex: On [Month] [DD], [YYYY], Jane Doe's medical license expired. However, on [Month] [DD], [YYYY] John Smith submitted a copy of his renewed medical license, which was reinstated back to the date of expiration by the Wisconsin Medical Board. As a result, [MAC Name] finds that Jane Doe came into compliance with the applicable Medicare requirements on [Month] [DD], [YYYY]. Therefore, [MAC Name] overturns the denial of Jane Doe's Medicare enrollment application as it relates to 42 C.F.R. § 424.530(a)(1).

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] will continue processing the enrollment application.

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed from the provider or supplier in this CAP decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]

[MAC Name]

K. Favorable CAP Model Letter for Revocation Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on a revocation of Medicare billing privileges. The initial determination letter was dated [Month] [DD], [YYYY] and the CAP was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the CAP is untimely, but good cause has been found to accept the CAP, use the following [This CAP was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, evidence in the file, and any information received before this decision was rendered.

REVOCATION REASON:

- 42 C.F.R. § 424.535(a)(1)

OTHER APPLICABLE AUTHORITIES:

- (Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

- Exhibit 1: (Ex.: CAP, signed by Jane Doe, dated [Month] [DD], [YYYY].)
- Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the CAP.)

CORRECTIVE ACTION PLAN ANALYSIS:

[A [Provider/Supplier Name] may only submit a corrective action plan for noncompliance. If the initial determination was based on revocation reasons other than 42 C.F.R. § 424.535(a)(1), this decision will not review those authorities.]

(A CAP is an opportunity to correct the deficiencies identified in the initial determination. This section should include: A clear explanation of why the revocation is being upheld or overturned in sufficient detail for the provider or supplier to understand the decision and; if applicable: the nature of the provider or supplier's deficiencies, the regulatory basis to support the revocation for noncompliance, and an explanation of how the provider or supplier now meets the enrollment compliance criteria or requirements. This section shall not reference a CAP decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(Ex: On [Month] [DD], [YYYY], Jane Doe's medical license was suspended. However, as part of her CAP, Jane Doe submitted a revised order from the Wisconsin Medical Board, which reinstated her medical back license back to the date of suspension. As a result, [MAC Name] finds that Jane Doe came into compliance with the applicable Medicare requirements on [Month] [DD], [YYYY]. Therefore, [MAC Name] overturns the revocation of Jane Doe's Medicare billing privileges as it relates to 42 C.F.R. § 424.535(a)(1).

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] [will reinstate/has reinstated] your Medicare billing privileges, effective [Month] [DD], [YYYY].

(The reinstatement date is based on chapter 10 of the MPIM and the date of the provider's or supplier's revocation or the date the provider's or supplier's license was reinstated if the revocation involves a licensure issue.)

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed from the provider or supplier in this CAP decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

L. Unfavorable CAP Model Letter in Response to an Enrollment Denial

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on an enrollment denial. The initial determination letter was dated

[Month] [DD], [YYYY] and the CAP was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the CAP is untimely, but good cause has been found to accept the CAP, use the following [This CAP was not timely submitted, but a good cause waiver has been granted.])The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DENIAL REASON:

- 42 C.F.R. § 424.530(a)(1)

OTHER APPLICABLE AUTHORITIES:

- (Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

- Exhibit 1: (Ex.: (Ex.: CAP, signed by Jane Doe, dated [Month] [DD], [YYYY].)
- Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the CAP).

CORRECTIVE ACTION PLAN ANALYSIS:

[A [Provider/Supplier Name] may only submit a corrective action plan for noncompliance under 42 C.F.R. § 424.530(a)(1). If the initial determination was based on any other denial reasons other than 42 C.F.R. § 424.530(a)(1), this decision will not review those authorities.]

(A CAP is an opportunity to correct the deficiencies identified in the initial determination. This section should include: A clear explanation of why the denial is

being upheld in sufficient detail for the provider or supplier to understand the decision and; if applicable: the nature of the provider or supplier's deficiencies, the regulatory or other policy basis to support each reason for the denial, and an explanation of how the provider or supplier now meets the enrollment criteria or requirements. This section shall not reference a CAP decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], Jane Doe's medical license was suspended by the Wisconsin Medical Board. [MAC Name] has confirmed that Jane Doe's medical license remains suspended. As a result, [MAC Name] upholds the denial of Jane Doe's Medicare enrollment application under 42 C.F.R. § 424.530(a)(1).)

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that the CAP does not correct the deficiencies that led to the denial of your Medicare enrollment. As a result, the denial of your Medicare enrollment is upheld.

Failure to timely file a reconsideration request is deemed a waiver of all further administrative review. However, if you have submitted a reconsideration request, a separate decision is forthcoming.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

M. Unfavorable CAP Model Letter for Revocation Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP]

[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: Corrective Action Plan Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the CAP]:

This letter is in response to the corrective action plan (CAP) received by [MAC Name] based on a revocation of Medicare billing privileges. The initial determination letter was dated [Month] [DD], [YYYY] and the CAP was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the CAP is untimely, but good cause has been found to accept the CAP, use the following [This CAP was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

REVOCATION REASON:

- 42 C.F.R. § 424.535(a)(1)

OTHER APPLICABLE AUTHORITIES:

- (Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

- Exhibit 1: (Ex.: (Ex.: CAP, signed by Jane Doe, dated [Month] [DD], [YYYY].)
- Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the CAP.)

CORRECTIVE ACTION PLAN ANALYSIS:

[A [Provider/Supplier Name] may only submit a corrective action plan for noncompliance. If the initial determination was based on revocation reasons other than 42 C.F.R. § 424.535(a)(1), this decision will not review those authorities.]

(A CAP is an opportunity to correct the deficiencies identified in the initial determination. This section should include: A clear explanation of why the revocation is being upheld in sufficient detail for the provider or supplier to understand the decision and; if applicable: the nature of the provider or supplier's deficiencies, the regulatory or other policy basis to support compliance and how the provider or supplier now meets the enrollment criteria or requirements. This section shall not reference a CAP decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], Jane Doe's medical license was suspended by the Wisconsin Medical Board. Jane Doe has not submitted evidence to demonstrate that her medical license has been reinstated. In addition, [MAC Name] has confirmed that Jane Doe's medical license remains suspended. As a result, [MAC Name] upholds the revocation of Jane Doe's Medicare billing privileges under 42 C.F.R. § 424.535(a)(1).)

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that the CAP did not correct the deficiencies noted in the implementation of the revocation. As a result, the revocation of your Medicare billing privileges is upheld.

Failure to timely file a reconsideration request is deemed a waiver of all further administrative review. However, if you have submitted a reconsideration request, a separate decision is forthcoming.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

N. CAP Further Information Required for Development Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

To: [Email address provided by the person who submitted the CAP.]

Subject: Medicare Provider Enrollment CAP re: [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the CAP]

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of CAP] (If submitted on behalf of an organization or group)
[Address] (Address from which the CAP was sent)
[City], [State] [Zip Code]

Re: CAP Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (Internal Tracking)

Dear [Name of the person(s) who submitted the CAP]:

On [Month] [DD]. [YYYY], [MAC Name] issued a CAP decision. As stated in the [Month] [DD], [YYYY] CAP decision letter, the approval of [Provider/Supplier Name]'s Medicare enrollment is contingent upon the submission of [list required documentation]. Please send the required documentation within 30 calendar days to:
[MAC CAP Receipt Address]

[MAC CAP Receipt Email Address] [MAC CAP Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

10.7.11 – Reconsideration Request Model Letters

(Rev. 10611; Issued: 03-19-21; Effective:11-19-20; Implementation: 11-19-20)

A. Reconsideration Request Withdrawn Acknowledgement Template

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

1. Email Template

To: [Email address provided by the person who submitted the reconsideration request]

Subject: Medicare Provider Enrollment Reconsideration Request re: [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the reconsideration request]:

We are in receipt of your written withdrawal request in regard to your reconsideration request received on [Month] [DD], [YYYY]. [MAC Name] has not yet issued a reconsidered decision, and therefore, [MAC Name] considers your reconsideration request to be withdrawn. As a result, a decision will not be issued in response to your reconsideration request.

Please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]

[MAC Name]

2. Hard-Copy Letter Template

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the reconsideration request]:

We are in receipt of your written withdrawal request in regard to your reconsideration request received on [Month] [DD], [YYYY]. [MAC Name] has not yet issued a reconsidered decision, and therefore, [MAC Name] considers your reconsideration request to be withdrawn. As a result, a decision will not be issued in response to your reconsideration request.

Please be advised that failure to timely submit a reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

B. Reconsideration Request Receipt Acknowledgement Template to Provider/Supplier/Representative

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

1. Email Template

To: [Email address provided by the person who submitted the reconsideration request]

Subject: Medicare Provider Enrollment Reconsideration Request re**:** [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the reconsideration request]:

We are in receipt of your reconsideration request on behalf of [Provider/Supplier Name]. Please be advised that [MAC Name] has 90 calendar days to review your reconsideration request and render a decision.

If you have additional information that you would like a hearing officer to consider during the reconsideration or, if necessary, an administrative law judge (ALJ) to consider during a hearing, you must submit that information to the hearing office before a decision is rendered. This is your only opportunity to submit information during the administrative appeals process; you will not have another opportunity to do so unless an ALJ specifically allows you to do so under 42 C.F.R. §498.56(e).

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

2. Hard-Copy Letter Template

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)

NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the reconsideration request]:

We are in receipt of your reconsideration request on behalf of [Provider/Supplier Name]. Please be advised that [MAC Name] has 90 calendar days to review your reconsideration request and render a decision.

If you have additional information that you would like a hearing officer to consider during the reconsideration or, if necessary, an administrative law judge (ALJ) to consider during a hearing, you must submit that information to the hearing office before a decision is rendered. This is your only opportunity to submit information during the administrative appeals process; you will not have another opportunity to do so unless an ALJ specifically allows you to do so under 42 C.F.R. §498.56(e).

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

C. Reconsideration Request Decision Email Template to Provider/Supplier/Representative

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

To: [Email address provided by the person who submitted the Reconsideration Request]

Subject: Medicare Provider Enrollment Reconsideration Request re**:** [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the reconsideration]

(Be sure to attach a copy of the final decision[s] in PDF format.)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

Please see the attached decision regarding your Medicare Provider Enrollment Reconsideration Request.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

D. Reconsideration Request Not Actionable (Moot) Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the reconsideration request]:

This letter is in response to the reconsideration request received by [MAC Name] based on the initial determination letter, dated [Month] [DD], [YYYY].

In correspondence dated [Month] [DD], [YYYY], the initial determination letter, dated [Month] [DD], [YYYY] informing you of the [denial of your Medicare enrollment application or revocation of your Medicare billing privileges] was [insert description] (describe action taken in regards to the initial determination, i.e. rescission of the denial or revocation). For your convenience, a copy of the

initial determination is included. Therefore, the issue set forth in the reconsideration request is no longer actionable. This issue is moot, and we are unable to render a decision on the matter.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

E. Untimely Reconsideration Request Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the reconsideration request]:

This letter is in response to the reconsideration request received by [MAC Name], based on the initial determination letter dated [Month] [DD], [YYYY].

[MAC Name] is unable to accept your reconsideration request as it was not timely submitted. The initial determination letter was dated [Month] [DD], [YYYY]. A reconsideration request must be received within 65 calendar days of the date of the initial determination letter. Your reconsideration request was not received by [MAC Name] until [Month] [DD], [YYYY], which is beyond the applicable submission time frame. You have failed to show good cause for your late request. Therefore, [MAC Name] is unable to render a decision in this matter.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

F. Improperly Signed Reconsideration Request Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the reconsideration request]:

This letter is in response to the reconsideration request received by [MAC Name], based on the [Month] [DD], [YYYY] initial determination letter.

[MAC Name] is unable to accept your reconsideration request as it was not signed by an authorized or delegated official currently on file in your Medicare enrollment record, the individual provider or supplier, or a properly appointed representative. The signature requirement is stated in the [Month] [DD], [YYYY] initial determination letter, as well as in Chapter 10 of the Medicare Program Integrity Manual.

Please be advised that failure to timely submit a proper reconsideration request is deemed a waiver of all further administrative review.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

G. Not Eligible to Submit Reconsideration Request Dismissal Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

This letter is in response to the [reconsideration request] received by [MAC Name], based on the [Month] [DD], [YYYY] initial determination.

[MAC Name] is unable to accept your [reconsideration request] submission because the action taken in regards to your Medicare enrollment is not an initial determination subject to administrative review. More specifically, an initial determination has not been made as described in 42 C.F.R. § 498.3(b). Under 42 C.F.R. § 498.5(l), appeal rights related to provider enrollment extend only from initial determinations.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address] [Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

H. Reconsideration Request Signature Development Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

We are in receipt of your reconsideration submission, received on [Month] [DD], [YYYY]. (If the submission is not properly signed, use the following.) [Your submission is not appropriately signed, as required in the Medicare Program Integrity Manual, Ch. 10, Section 10.6.18. [MAC Name] is requesting that you submit a reconsideration request that is properly signed by the individual provider, supplier, the authorized or delegated official, or a representative. Your properly signed submission must be received within 15 calendar days of the date of this notice. If you do not timely respond to this request, your reconsideration submission may be dismissed.]

(If the submission is missing a statement by the attorney, use the following.) [Your submission is missing an attorney statement that he or she has the authority to represent the provider or supplier. [MAC Name] is requesting that you submit a rebuttal that includes an attorney statement that he or she has the authority to represent the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, your reconsideration submission may be dismissed.]

(If the submission is missing a signed written notice from the provider/supplier authorizing the representative to act on his/her/its behalf, use the following.) [Your submission is missing a written notice of the appointment of a representative

signed by the provider or supplier. [MAC Name] is requesting that you submit written notice of the appointment of a representative that is signed by the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, your reconsideration submission may be dismissed.]

Your submission should be sent to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[MAC Fax number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

I. Favorable Reconsideration Request Model Letter in Response to an Enrollment Denial

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the Person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] based on an enrollment denial. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this reconsideration request is considered

timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DENIAL REASON(S):

- 42 C.F.R. § 424.530(a)(denial reason 1-14)
- 42 C.F.R. § 424.530(a)(denial reason 1-14)

OTHER APPLICABLE AUTHORITIES:

- 42 C.F.R. §
- (Ex: Medicare Program Integrity Manual (MPIM) chapter 10, section 10.XX)

EXHIBITS:

- Exhibit 1: (Ex.: Reconsideration request, signed by Jane Doe, dated [Month] [DD] [YYYY].)
- Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(The hearing officer needs to check to determine if a CAP was also submitted and approved for this provider or supplier. If so, the reconsideration decision should only address the remaining authorities and use the following sentence, "[MAC Name] has approved the CAP submitted on [Month] [DD], [YYYY] in a decision dated [Month] [DD], [YYYY]. Therefore, this decision will only address the remaining denial reason(s) 42 C.F.R. § 424.530(a)(denial reason 1-14).)

(If the CAP resolves the denial in its entirety, the applicable moot model letter should be issued in response to the reconsideration request instead of this decision template.)

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations, MPIM. This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(Ex: On [Month] [DD], [YYYY], a disciplinary hearing was held regarding the medical license of Jane Doe. However, on [Month] [DD], [YYYY], the Wisconsin Medical Board declined to take disciplinary action against Jane Doe's medical license. As a result, [MAC Name] overturns the denial of Jane Doe's Medicare enrollment application as it relates to 42 C.F.R. § 424.530(a)(1).

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] will continue processing the enrollment application.

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed from the provider or supplier in this reconsideration decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

J. Favorable Reconsideration Request Model Letter in Response to a Reactivation Effective Date Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] related to a reactivation effective date determination. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this reconsideration request is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

EFFECTIVE DATE REGULATION(S):

42 C.F.R. § 424.520(a-d) (Other effective date regulations may be included)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. § 424.540 (Other applicable regulations for MPIM sections may be included)
(Ex: Medicare Program Integrity Manual (MPIM) chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: CMS-855I Medicare enrollment application, signed and certified by John Smith on [Month] [DD], [YYYY].)
Exhibit 2: (Ex: Copy of an email chain between John Smith and Jane Doe, dated

[Month] [DD], [YYYY], requesting additional informed needed to process the revalidation application to completion for John Smith to Jane Doe.

(In this section list each document submitted by the provider or supplier. Each exhibit shall include the date, if provided, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations, MPIM. This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(Ex.: On [Month] [DD], [YYYY], John Smith's revalidation application was approved with a gap in his billing privileges from [Month] [DD], [YYYY] to [Month] [DD], [YYYY]. However, as indicated above, [MAC Name] has determined that the reactivation effective should be [Month] [DD], [YYYY]. As a result of the change in the reactivation effective date, the gap in John Smith's Medicare billing privileges has been eliminated.)

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] [will modify/has modified] the reactivation effective date for [Provider/Supplier Name].

You must resubmit any claims that were denied or not previously submitted due to the former gap in your Medicare billing privileges.

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed

from the provider or supplier in this reconsideration decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and

conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

K. Favorable Reconsideration Request Model Letter in Response to an Effective Date of Participation Determination (Non-Revalidation)

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] in response to a determination of the effective date of participation in the Medicare program. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this reconsideration request is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS

manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

EFFECTIVE DATE REGULATION(S):

42 C.F.R. § 424.520(a-d)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. §
(Ex: Medicare Program Integrity Manual (MPIM) chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: CMS-855I Medicare enrollment application, signed and certified by John Smith on [Month] [DD], [YYYY].)
Exhibit 2: (Ex: Copy of an email chain between John Smith and Jane Doe, dated [Month] [DD], [YYYY], submitting the requested development documentation for John Smith to Jane Doe.

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the determination of the effective date.)

RECONSIDERATION ANALYSIS:

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations, MPIM. This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], John Smith submitted an initial enrollment application, which was subsequently rejected for failure to timely respond to a development request for additional information/documentation. As part of his reconsideration request, John Smith submitted an email receipt showing that he timely responded to the development request. As a result, [MAC Name] will modify John Smith's Medicare effective date to [Month] [DD], [YYYY].)

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] [will modify/has modified] the enrollment effective date to [Month] [DD], [YYYY].

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed from the provider or supplier in this reconsideration decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen;

and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
  - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
  - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by

clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]
Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

L. Favorable Reconsideration Request Model Letter for Revocation Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] based on a revocation of Medicare billing privileges. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

REVOCATION REASON(S):

42 C.F.R. § 424.535(a)(revocation reason 1-22)
42 C.F.R. § 424.535(a)(revocation reason 1-22)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. §
(Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: Reconsideration request, signed by Jane Doe, dated [Month] [DD] [YYYY].)
Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)
(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(The hearing officer needs to check to determine if a CAP was also submitted and approved for this provider or supplier. If so, the reconsideration decision should

only address the remaining authorities and use the following sentence, "[MAC Name] has reviewed and/or approved the CAP submitted on [Month] [DD], [YYYY] in a decision dated [Month] [DD], [YYYY].
Therefore, this decision will only address the remaining revocation reason(s) 42 C.F.R. § 424.535(a)(revocation reason 1- 22).)

(If the CAP resolves the revocation in its entirety, the applicable moot model letter should be issued in response to the reconsideration request instead of this decision template.)

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the provider or supplier arguments based on the applicable regulations and sub-regulations (MPIM). This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(Ex: On [Month] [DD], [YYYY], Jane Doe's medical license was temporarily suspended by the Wisconsin medical board based on allegations of malpractice. However, on [Month] [DD] [YYYY], the Wisconsin medical board issued an order reversing the license suspension back to its implementation date based on the outcome of a hearing. As a result, [MAC Name] is overturning the revocation of Jane Doe's Medicare billing privileges as it relates to 42 C.F.R. § 424.535(a)(1).

This decision is a **FAVORABLE DECISION**. To effectuate this decision, [MAC name] [will reinstate/has reinstated] your Medicare billing privileges, effective [Month] [DD], [YYYY].

(The reinstatement date is based on chapter 10 of the MPIM and the date of the provider's or supplier's revocation or the date the provider's or supplier's license was reinstated if the revocation involves a licensure issue.)

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the MAC shall state what information is needed from the provider or supplier in this reconsideration decision. MACs shall state that the requested information/documentation must be received within 30 calendar days of the date of this decision letter.)

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you

believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing

requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

M. Unfavorable Reconsideration Request Model Letter in Response to an Enrollment Denial

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] based on an enrollment denial. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DENIAL REASON(S):

42 C.F.R. § 424.530(a)(denial reason 1-14)
42 C.F.R. § 424.530(a)(denial reason 1-14)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. §
(Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: Reconsideration request, signed by Jane Doe, dated [Month] [DD] [YYYY].)
Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board, effective [Month] [DD], [YYYY].)
(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

[Summarize the facts underlying the case which led up to the submission of the reconsideration request.]

RECONSIDERATION ANALYSIS:

(The hearing officer needs to check to determine if a CAP was also submitted and approved for this provider or supplier. If so, the reconsideration decision should only address the remaining authorities and use the following sentence, "[MAC Name] has approved the CAP submitted on [Month] [DD], [YYYY] in a decision dated [Month] [DD], [YYYY]. Therefore, this decision will only address the remaining denial reason(s) 42 C.F.R. § 424.530(a)(denial reason 1-14).)

(If the CAP resolves the denial in its entirety, the applicable moot model letter should be issued in response to the reconsideration request instead of this decision template.)

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations (MPIM). This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(Ex: On [Month] [DD], [YYYY], Jane Doe's medical license was temporarily suspended by the Wisconsin medical board based on allegations of malpractice. Jane Doe did not submit any documentation to demonstrate that her medical license was not suspended. In addition, [MAC Name] has confirmed that Jane Doe's medical license remains suspended. As a result, [MAC Name] upholds the denial of Jane Doe's Medicare enrollment application as it relates to 42 C.F.R. § 424.530(a)(1).)

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that there was no error made in the denial of your Medicare enrollment. As a result, the denial of your Medicare enrollment is upheld.

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by

clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

N. Unfavorable Reconsideration Request Model Letter in Response to a Reactivation Effective Date Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] in response to a reactivation effective date determination. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

EFFECTIVE DATE REGULATION(S):

42 C.F.R. § 424.520(a-d) (Other effective date regulations may be included)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. § 424.540 (Other applicable regulations for MPIM sections may be included)
(Ex: Medicare Program Integrity Manual (MPIM) chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: CMS-855I Medicare enrollment application, signed and certified by John Smith on [Month] [DD], [YYYY].)
Exhibit 2: (Ex: Copy of an email chain between John Smith and Jane Doe, dated [Month] [DD], [YYYY], submitting the requested development documentation for John Smith to Jane Doe.)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations, MPIM. This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], John Smith's Medicare enrollment was deactivated for failing to timely respond to a revalidation request. On [Month] [DD], [YYYY], John Smith submitted a revalidation application, which was processed and approved. Per the MPIM, Ch. 10, Section 10.4(K), John Smith's Medicare enrollment was reactivated, but with a gap in his Medicare billing privileges from [Month] [DD], [YYYY] to [Month] [DD], [YYYY]. John Smith's reconsideration request did not demonstrate an error in the determination of his reactivation effective date.)

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that no error was made in the determination of a reactivation effective date resulting in a gap in your Medicare billing privileges. As a result, your reactivation effective date will remain [Month] [DD] [YYYY].

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents

that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

O. Unfavorable Reconsideration Request Model Letter in Response to an Effective Date of Participation Determination (Non-Revalidation)

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] based on an effective date of enrollment determination. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

EFFECTIVE DATE REGULATION(S):

42 C.F.R. § 424.520(a-d)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. §
(Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: CMS-855I Medicare enrollment application, signed and certified by John Smith on [Month] [DD], [YYYY].)
Exhibit 2: (Ex: Copy of an email chain between John Smith and Jane Doe, dated [Month] [DD], [YYYY], submitting the requested development documentation for John Smith to Jane Doe.)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations (MPIM). This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], John Smith submitted an initial Medicare enrollment application. On [Month] [DD], [YYYY], [MAC Name] sent a development request to John Smith for additional documentation/information to continue processing his enrollment application.

However, John Smith did not submit the requested documentation within 30 days. As a result, [MAC Name] properly rejected John Smith's Medicare enrollment application received on [Month] [DD] [YYYY]. On [Month] [DD] [YYYY], John Smith submitted another Medicare enrollment application, which was processed and subsequently approved with an effective date of [Month] [DD], [YYYY] in accordance with 42 C.F.R. § 424.520.

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that no error was made in the determination of your effective date of participation in the Medicare program. As a result, the effective date of participation will remain the same.

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:
    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and
    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)

- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

P. Unfavorable Reconsideration Request Model Letter for Revocation Determination

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

[Month] [Day], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration Request]
[Address] (Address from which the Reconsideration Request was sent)
[City], [State] [Zip Code]

Re: Reconsideration Request Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the Reconsideration Request]:

This letter is in response to the reconsideration request received by [MAC Name] based on a revocation of Medicare billing privileges. The initial determination letter was dated [Month] [DD], [YYYY] and the reconsideration request was received by [MAC Name] on [Month] [DD], [YYYY]; therefore, this appeal is considered timely. (if the reconsideration request is untimely, but good cause has been found to accept the reconsideration request, use the following [This reconsideration request was not timely submitted, but a good cause waiver has been granted.]) The following decision is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

REVOCATION REASON(S):

42 C.F.R. § 424.535(a)(revocation reason 1-22)
42 C.F.R. § 424.535(a)(revocation reason 1-22)

OTHER APPLICABLE AUTHORITIES:

42 C.F.R. §
(Ex: Medicare Program Integrity Manual chapter 10, section 10.XX)

EXHIBITS:

Exhibit 1: (Ex.: Reconsideration request, signed by Jane Doe, dated [Month] [DD] [YYYY].)
Exhibit 2: (Ex: Copy of a medical license for Jane Doe from the Wisconsin Medical Board,

effective [Month] [DD], [YYYY].)

(In this section list each document submitted by the provider or supplier. Each exhibit should include the date, as well as a brief description of the document. You shall also include all other documentation not submitted by the provider that the hearing officer reviewed in making the decision, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

The documentation related to the matter for [Provider/Supplier Name] has been reviewed and the decision has been made in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the reconsideration request.)

RECONSIDERATION ANALYSIS:

(The hearing officer needs to check to determine if a CAP was also submitted and approved for this provider or supplier. If so, the reconsideration decision should only address the remaining authorities and use the following sentence, "[MAC Name] has denied or approved the CAP submitted on [Month] [DD], [YYYY] in a decision dated [Month] [DD], [YYYY]. Therefore, this decision will only address the remaining revocation reason(s) 42 C.F.R. § 424.535(a)(revocation reason 1-22).)

(If the CAP resolves the revocation in its entirety, the applicable moot model letter should be issued in response to the reconsideration request instead of this decision template.)

(A reconsideration request reviews whether or not an error was made at the time the initial determination was implemented. This section should summarize the statements made by the provider or supplier in its reconsideration request. Then conduct analysis of the arguments based on the applicable regulations and sub-regulations (MPIM). This section shall not reference a reconsideration decision without explaining how and why you came to that decision.)

DECISION:

(A short conclusory restatement.)

(On [Month] [DD], [YYYY], Jane Doe's medical license was suspended by the Wisconsin Medical Board. Jane Doe has not submitted evidence to demonstrate that the suspension of her medical license was rescinded. In addition, [MAC Name] has confirmed that Jane Doe's medical license remains suspended. As a result, [MAC Name] upholds the revocation of Jane Doe's Medicare enrollment application under 42 C.F.R. § 424.535(a)(1).)

This decision is an **UNFAVORABLE DECISION**. [MAC name] concludes that there was no error made in the implementation of a revocation. As a result, the revocation of your Medicare billing privileges is upheld.

FURTHER APPEAL RIGHTS - ADMINISTRATIVE LAW JUDGE (ALJ):

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request ALJ review for the reconsideration portion of this decision letter. To request ALJ review, you must file your appeal with the Civil Remedies Division of the Departmental Appeals Board within 60 calendar days after the date of receipt of this decision.

How to file a hearing request

You can file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov/.

To file a new appeal using DAB E-File, you first need to register a new account by:

1. Clicking Register on the DAB E-File home page;
2. Entering the information requested on the "Register New Account" form; and
3. Clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative.

Once registered, you may file your appeal by logging in and:

- Clicking the File New Appeal link on the Manage Existing Appeals screen, and then clicking Civil Remedies Division on the File New Appeal screen; and

- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in PDF form.

What you must include in a hearing request for ALJ review

At minimum, the Civil Remedies Division (CRD) requires a party to file the following:

- A signed request for hearing that:

    - Identifies the specific issues and the findings of fact and conclusions of law with which the party disagrees; and

    - Specifies the basis for contending that the findings and conclusions are incorrect;
- The underlying notice letter from CMS that sets forth the action taken and the party's appeal rights.

In addition, the following identifying information is required with all ALJ hearing requests:

- Your legal business name
- Your Medicare PTAN (if applicable)
- Tax Identification Number (TIN) or Employer Identification Number (EIN)
- A copy of the Hearing Officer or the CMS Regional Office (RO) decision

The procedures for ALJ review can be found at Title 42 of the Code of Federal Regulations, sections 498.40 – 498.79.

Guidelines for Using DAB E-file

- Any document, including a request for hearing, will be deemed to have been filed on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day.

- A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service.

- Parties are responsible for ensuring that DAB E-file email notifications do not go to their spam folders and that any spam filtering software they may have does not restrict their ability to receive emails from the system.

- More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E- File Procedures link on the File New Appeal Screen for CRD appeals.

If you are unable to use DAB E-file

Parties are required to use DAB E-file unless they receive a waiver. If you cannot file your appeal electronically, you may mail your hearing request, along with a request for waiver of the electronic filing requirement and an explanation of why you cannot use DAB E-file, to: Department of Health and Human Services, Departmental Appeals Board, Civil Remedies Division, Mail Stop 6132, Attn: CMS Enrollment Appeal, 330 Independence Avenue, S.W., Cohen Building, Room G-644, Washington, D.C. 20201.

Appeal rights can be found 42 C.F.R. part 498. The regulation explains the appeal

rights following the determination by the CMS as to whether such entities meet the requirements for enrollment in the Medicare program.

If you have any further questions, please forward your inquiries to [MAC Appeal Receipt Email Address] or mail it to the following address:

[MAC Appeal Receipt Address]
[Call Center Telephone Number]

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

Q. Reconsideration Further Information Required for Development Model Letter

(To be sent by hard-copy mail and email if email address is provided. Optional to send via fax if a valid fax number is available).

To: [Email address provided by the person who submitted the Reconsideration.]
Subject: Medicare Provider Enrollment Reconsideration re: [Provider/Supplier Name]

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Reconsideration] (If submitted on behalf of an organization or group)
[Address] (Address from which the Reconsideration was sent)
[City], [State] [Zip Code]

Re: Reconsideration Decision
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (Internal Tracking)

Dear [Name of the person(s) who submitted the Reconsideration]:

On [Month] [DD]. [YYYY], [MAC Name] issued a reconsideration decision. As stated in the [Month] [DD], [YYYY] reconsideration decision letter, the approval of [Provider/Supplier Name]'s Medicare enrollment is contingent upon the submission of [list required documentation]. Please send the required documentation within 30 calendar days to:

[MAC Reconsideration Receipt Address] [MAC Reconsideration Receipt Email Address] [MAC Reconsideration Receipt Fax Number]
If you have any questions, please contact our office at [phone number] between the hours of

[x:00 AM/PM] and [x:00 AM/PM].

Sincerely,
[Signature of Hearing Officer] (May be electronic) [Name of Hearing Officer]
[Position of Hearing Officer]
[MAC Name]

10.7.12 – Deactivation Model Letter

(Rev. 12393; Issued: 12-07-23; Effective: 01-01-24; Implementation: 01-02-24)

(To be sent by hard-copy mail, and via email if email address is listed in the provider/supplier correspondence mailing address on the enrollment record. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier Name] (as it appears in PECOS)
[Address]
[City], [State] [Zip Code]

Re: Deactivation of Medicare billing privileges
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (Internal Tracking)

Dear [Provider/Supplier Name]:

Your Medicare billing privileges are being deactivated effective [Month] [DD], [YYYY] pursuant to:

DEACTIVATION REASON:

- 42 C.F.R. § 424.540(a)[1-8]

[Specific reason for the deactivation of the provider/supplier's Medicare billing privileges.]

(If the deactivation is under § 424.540(a)(1), an example narrative may include:

[Contractor Name] has reviewed your Medicare billing data and found that you have not submitted any claims since January 1, 2017, which is more than 6 calendar months from the date of this letter.)

(If the deactivation is under § 424.540(a)(2), an example narrative may include:

[Contractor Name] has been informed that John Smith is deceased as of January 1, 2017. Your Medicare enrollment application, signed and certified on November 1, 2016, identifies John

Smith as a 5% or greater owner. [Contractor Name] has not received a Medicare enrollment application reporting this change in ownership.)

REBUTTAL RIGHTS:

If you believe that this determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) [Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.]

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:
[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name] [Title] [Company]

10.7.13 – Rebuttal Model Letters

(Rev. 11637; Issued: 10-07-22; Effective: 12-09-22; Implementation: 12-09-22)

Instruction

For the following model letters, all text within parentheses is intended as instruction/explanation and should be deleted before the letter is finalized and sent to the provider or supplier. All text within brackets requires the contractor to fill in the appropriate text. All letters shall be saved in PDF format.

A. Rebuttal Signature Development Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

We are in receipt of your rebuttal submission on behalf of [Provider/Supplier], received on [Month] [DD], [YYYY].

(If the submission is not properly signed, use the following.) Your submission is not appropriately signed, as required in the Medicare Program Integrity Manual, Ch. 10, Section 10.4(M). [Contractor Name] requests that you submit a rebuttal properly signed by the individual provider, supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) [Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.]

Your properly signed submission must be received within 15 calendar days of the date of this notice. If you do not timely respond to this request, [Contractor Name] may dismiss your rebuttal submission.

(If the submission is missing a statement by the attorney, use the following.) Your submission is missing an attorney statement that he or she has the authority to represent the provider or

supplier. [Contractor Name] requests that you submit a rebuttal that includes an attorney statement that he/she/they have the authority to represent the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, [Contractor Name] may dismiss your rebuttal submission.

(If the submission is missing a signed written notice from the provider/supplier authorizing the legal representative to act on his/her/their/its behalf, use the following.) Your submission is missing a written notice of the appointment of a representative signed by the provider or supplier. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf. [Contractor Name] requests that you submit written notice of the appointment of a representative that is properly signed by the provider or supplier within 15 calendar days of the date of this notice. If you do not timely respond to this request, [Contractor Name] may dismiss your rebuttal submission.

Please send the required documentation to:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
Fax: [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

B. Rebuttal Further Information Required Development Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission

Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (Optional)

Dear [Name of the person(s) who submitted the rebuttal]:

On [Month] [DD]. [YYYY], [Contractor Name] issued a favorable rebuttal determination, reversing the deactivation of [Provider/Supplier Name]'s Medicare billing privileges. As stated in the [Month] [DD], [YYYY] determination letter, the reactivation of [Provider/Supplier Name]'s Medicare enrollment is contingent upon the submission of [list required documentation]. Please send the required documentation to:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
Fax: [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

C. Rebuttal Moot Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal submission, on behalf of [Provider/Supplier], received on [Month] [DD], [YYYY]. On [Month] [DD], [YYYY], [Contractor Name] approved an application to reactivate [Provider/Supplier]'s Medicare billing privileges without a gap. Therefore, the issue set forth in the rebuttal submission is no longer actionable. As a result, this issue is moot and a determination will not be made in regards to the rebuttal submission.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

D. Rebuttal Facts or Issues and Reasons for Disagreement Development Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address] (Address from which the Rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Rebuttal]:

We are in receipt of your rebuttal submission on behalf of [Provider/Supplier Name], received on [Month] [DD], [YYYY].

As stated in the deactivation letter dated [Month] [DD], [YYYY], to be accepted and reviewed, your rebuttal must state the facts or issues identified in the deactivation letter with which you disagree and your reasons for disagreement. The rebuttal received on [Month] [DD], [YYYY] does not clearly identify the facts or issues with which you disagree and your reasons for disagreement. [Contractor Name] is granting you an additional 15 calendar days from the date of this notification

letter to submit a proper rebuttal that clearly identifies the facts or issues with which you disagree and your reasons for disagreement. This revised rebuttal submission must be received within 15 calendar days of the date of this notice. If you do not timely respond to this request, [Contractor Name] may dismiss your rebuttal submission.

Please send the required documentation to:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
Fax: [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)

[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

E. Rebuttal Withdrawn Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

We are in receipt of your written withdrawal request in regards to your rebuttal received on [Month] [DD], [YYYY], submitted on behalf of [Provider/Supplier Name]. [Contractor Name] has not yet issued a rebuttal determination. Therefore, [Contractor Name] considers the rebuttal

to be withdrawn. As a result, a determination will not be issued in response to the rebuttal and [Provider/Supplier Name]'s Medicare billing privileges will remain deactivated.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

F. Rebuttal Receipt Acknowledgement Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

We are in receipt of your rebuttal on behalf of [Provider/Supplier Name]. Please be advised that [Contractor Name] has made an interim determination to maintain the deactivation of your Medicare billing privileges. However, [Contractor Name] will further review the information and documentation submitted in the rebuttal and will render a final determination regarding the deactivation of your Medicare billing privileges within 30 days of the date of receipt.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]

[Position of Hearing Officer]
[Contractor Name]

G. Final Rebuttal Decision Email Template

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

To: [Email address provided by the person who submitted the rebuttal and email address listed in the provider/supplier correspondence mailing address on the enrollment application if different from the email address on the rebuttal submission.]

Subject: Medicare Provider Enrollment Rebuttal re: [Provider/Supplier Name]

Dear [Name of the person(s) who submitted the rebuttal]:

Please see the attached determination regarding your rebuttal, submitted on behalf of [Provider/Supplier Name].

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

H. Rebuttal Dismissal Model Letters

1. Untimely Rebuttal Dismissal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission

Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name], based on the letter deactivating [Provider/Supplier Name]'s Medicare billing privileges dated [Month] [DD], [YYYY].

[Contractor Name] is unable to accept your rebuttal as it was not timely submitted. The deactivation letter was dated [Month] [DD], [YYYY]. A rebuttal must be received within 15 calendar days of the date of the [Month] [DD], [YYYY] deactivation letter. Your rebuttal was not received until [Month] [DD], [YYYY], which is beyond the applicable submission time frame. [Provider/Supplier/Legal Representative/Representative] failed to show good cause for the late request. Therefore, [Contractor Name] is unable to render a determination in this matter and [Provider/Supplier]'s Medicare billing privileges will remain deactivated.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

2. Improper Signature Rebuttal Dismissal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address](Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name], based on the letter deactivating [Provider/Supplier Name]'s Medicare billing privileges dated [Month] [DD], [YYYY].

[Contractor Name] is unable to accept your rebuttal as it was not signed by an authorized or delegated official currently on file in your Medicare enrollment, the individual provider or supplier, a legal representative, or did not contain the required statement of representation from an attorney or signed written notice appointing a non-attorney legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf. The signature requirement is stated in the [Month] [DD], [YYYY] deactivation letter. Additionally, in a letter dated [Month] [DD], [YYYY], [Contractor Name] requested that you provide a properly signed submission and permitted an additional 15-calendar days to submit your response.

(If no response received, use this language: [To date, [Contractor Name] has not received a response. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.])

(If response received after 15 calendar days, use this language: [While [Contractor Name] received a response, it was not timely received within 15-calendar days. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.])

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/CT/MT/PT] and [x:00 a.m./p.m ET/CT/MT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

3. No Rebuttal Rights Rebuttal Dismissal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal] (If submitted on behalf of an organization or group)
[Address](Address from which the rebuttal was sent)

[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name], submitted on behalf of [Provider/Supplier Name].

[Contractor Name] is unable to accept your rebuttal submission because the action taken in regards to your Medicare billing privileges does not afford the opportunity for a rebuttal. Under 42 C.F.R. § 424.546, only a provider or supplier whose Medicare billing privileges are deactivated may file a rebuttal in accordance with 42 C.F.R. § 405.374. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

4. More than One Submission Rebuttal Dismissal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address](Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal submitted on behalf of [Provider/Supplier Name], based on the deactivation letter dated [Month] [DD], [YYYY].

[Contractor Name] previously received a rebuttal for [Provider/Supplier Name] on [Month] [DD], [YYYY]. Per Chapter 10 of the Medicare Program Integrity Manual, only one rebuttal request may be submitted per deactivation. Therefore, [Contractor Name] is unable to accept your additional rebuttal[s] received on [Month] [DD], [YYYY]. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

5. No Specification of Why the Provider/Supplier Disagrees with Enrollment Deactivation and Reasons for Disagreement Rebuttal Dismissal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address] (Address from which the Rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the Rebuttal]:

This letter is in response to the rebuttal submitted on behalf of [Provider/Supplier Name] based on the deactivation letter, dated [Month] [DD], [YYYY].

[Contractor Name] is unable to accept your rebuttal as it does not specify the facts or issues identified in the deactivation letter with which you disagree and your reasons for disagreement. The requirement to identify the facts or issues with which you disagree and your reasons for disagreement was stated in the deactivation letter, dated [Month] [DD], [YYYY], as well as in 42 C.F.R. § 424.546(b), and in Chapter 10 of the Medicare Program Integrity Manual. Additionally, in a letter dated [Month] [DD], [YYYY], [Contractor Name] requested that you identify the facts or issues identified in the deactivation letter with which you disagree and your reasons for disagreement and permitted an additional 15-calendar days to submit your response.

(If no response received, use this language: [To date, [Contractor Name] has not received a response. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.])

(If response received after 15 calendar days, use this language: [While [Contractor Name] received a response, it was not timely received within 15-calendar days. As a result, [Contractor Name] is dismissing your rebuttal and no decision will be rendered.])

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

I. Rebuttal Not Actionable Model Letter (Moot)

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address] (Address from which the rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Submission
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)

NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name], concerning the deactivation of [Provider/Supplier Name]'s Medicare billing privileges, effective [Month] [DD], [YYYY].

On [Month] [DD], [YYYY], [Contractor Name] reopened the deactivation for [Provider/Supplier Name] and issued a revised initial determination. This revised initial determination rendered the issue set forth in your rebuttal no longer actionable. For your convenience a copy of the revised initial determination is attached. Accordingly, the issue addressed in your rebuttal is now moot, and we are unable to render a determination on the matter.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

(The contractor shall include PDF copy of the letter that rendered the rebuttal moot (e.g. the revised initial determination).)

J. Favorable Rebuttal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address] (Address from which the Rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Determination
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Name of the Person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name] based on the deactivation of [Provider/Supplier Name]'s Medicare billing privileges. (If the rebuttal was timely, use the following.) [The deactivation letter was dated [Month] [DD], [YYYY] and [Contractor Name] received the rebuttal on [Month] [DD], [YYYY]; therefore, this rebuttal is considered timely.] (If the rebuttal is untimely, but good cause has been found to accept the rebuttal, use the following.) [The deactivation letter was dated [Month] [DD], [YYYY] and [Contractor Name] received the rebuttal on [Month] [DD], [YYYY]. This rebuttal was not timely submitted, but a good cause waiver has been granted.]) [Contractor Name] based the following determination on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DEACTIVATION REASON:

- 42 C.F.R. § 424.540(a)([1-8])

OTHER APPLICABLE AUTHORIT[Y/IES]: (list any authorities cited in analysis)

- 42 C.F.R. § 424.546
- Medicare Program Integrity Manual (MPIM) chapter 10.XX (If applicable).
- (Ex.: If deactivation based non-compliance, list supplier standards)
- (Ex.: If deactivation based on failure to report, list regulation that requires reporting)

EXHIBITS:

- Exhibit 1: (Example: Rebuttal letter to CMS, signed by John Smith, Administrator for Home Healthcare Services, LLC, dated January 1, 2018);
- Exhibit 2: (Example: Letter from [Contractor Name] to Home Healthcare Services, LLC, dated December 1, 2017, deactivating Home Healthcare Services, LLC's Medicare billing privileges pursuant to 42 C.F.R. § 424.540(a)(3)).

(In this section list each document submitted by the provider or supplier. Each exhibit shall include the date, as well as a brief description of the document. The contractor shall also include other documentation not submitted by the provider or supplier that the hearing officer reviewed in making the determination, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

[Contractor Name] has reviewed the documentation related to the matter for [Provider/Supplier Name] and made the determination in accordance with the applicable Medicare rules, policies and program instructions.

(Summarize the facts underlying the case which led up to the submission of the rebuttal.)

REBUTTAL ANALYSIS:

(A rebuttal reviews whether or not an error was made in the implementation of the deactivation of the provider's or supplier's Medicare billing privileges. This section shall summarize the statements made by the provider or supplier in its rebuttal, then provide an analysis of the arguments based on the applicable regulations and sub-regulations, such as the MPIM. Any regulation or sub-regulatory guidance that is referenced in this section shall also be listed in "Other Applicable Authorities." It is insufficient to state a rebuttal determination without explaining how and why the determination was made.)

DECISION:

(A short conclusory restatement.)

(Example: On [Month] [DD], [YYYY], [Contractor Name] received a revalidation application for Home Healthcare Services, LLC. On [Month] [DD], [YYYY], [Contractor Name] rejected Home Healthcare Services, LLC's revalidation application prior to 90 calendar days from the date of the revalidation request letter. As a result, [Contractor Name] finds that the deactivation of Home Healthcare Services, LLC's Medicare billing privileges was not appropriately implemented based on the information available.)

This is a **FAVORABLE DETERMINATION**. To effectuate this determination, [Contractor name] will reinstate [Provider/Supplier Name]'s Medicare billing privileges.

(If additional information is needed from the provider or supplier in order to reactivate the enrollment, the Contractor shall state what information is needed from the provider or supplier in this rebuttal determination. Contractors shall state that the requested information/documentation must be received within 30 calendar days of the date of this determination letter)

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

K. Unfavorable Rebuttal Model Letter

(To be sent by hard-copy mail, and via email if email address is provided with the rebuttal submission, and email address listed in the provider/supplier correspondence mailing address on the enrollment application or enrollment record if different from the email address on the rebuttal submission. Optional to send via fax if a valid fax number is available.)

[Month] [DD], [YYYY]

[Provider/Supplier/Attorney/Firm Name]
Attn: [Signer/Submitter of Rebuttal]
[Address] (Address from which the Rebuttal was sent)
[City], [State] [Zip Code]

Re: Rebuttal Determination
Legal Business Name: [Provider/Supplier Name] (as it appears in PECOS)
NPI: [XXXXXXXXXX]
PTAN: [XXXXX]
Reference Number: [XXXX] (optional)

Dear [Person(s) who submitted the rebuttal]:

This letter is in response to the rebuttal received by [Contractor Name] based on the deactivation of [Provider/Supplier Name]'s Medicare billing privileges. (If the rebuttal was timely, use the following.) [The deactivation letter was dated [Month] [DD], [YYYY] and [Contractor Name] received the rebuttal on [Month] [DD], [YYYY]; therefore, this rebuttal is considered timely.] (If the rebuttal is untimely, but good cause has been found to accept the rebuttal, use the following.) [The deactivation letter was dated [Month] [DD], [YYYY] and [Contractor Name] received the rebuttal on [Month] [DD], [YYYY]. This rebuttal was not timely submitted, but a good cause waiver has been granted.]) [Contractor Name] based the following determination is based on the Social Security Act (Act), Medicare regulations, the CMS manual instructions, the Medicare enrollment record, and any information received before this decision was rendered.

DEACTIVATION REASON:

- 42 C.F.R. § 424.540(a)([1-8])

OTHER APPLICABLE AUTHORIT[Y/IES]: (list any authorities cited in analysis)

- 42 C.F.R. § 424.546
- Medicare Program Integrity Manual chapter 10.XX (If applicable)
- (Ex.: If deactivation based non-compliance, list supplier standards)
- (Ex.: If deactivation based on failure to report, list regulation that requires reporting)

EXHIBITS:

- Exhibit 1: (Example: Rebuttal letter to CMS, signed by John Smith, Administrator for Home Healthcare Services, LLC, dated January 1, 2018);
- Exhibit 2: (Example: Letter from [Contractor Name] to Home Healthcare Services, LLC, dated December 1, 2017, deactivating Home Healthcare Services, LLC's Medicare billing privileges pursuant to 42 C.F.R. § 424.540(a)(3)).

(In this section list each document submitted by the provider or supplier. Each exhibit shall include the date, as well as a brief description of the document. The Contractor shall also include other documentation not submitted by the provider or supplier that the hearing officer reviewed in making the determination, e.g., enrollment applications, development letters, etc.)

BACKGROUND:

[Contractor Name] has reviewed the documentation related to the matter for [Provider/Supplier Name] and made the determination in accordance with the applicable Medicare rules, policies, and program instructions.

(Summarize the facts underlying the case which led up to the submission of the rebuttal.)

REBUTTAL ANALYSIS:

(A rebuttal reviews whether or not an error was made in the implementation of the deactivation of the provider's or supplier's Medicare billing privileges. This section shall summarize the statements made by the provider or supplier in its rebuttal, then provide an analysis of the arguments based on the applicable regulations and sub-regulations, such as the MPIM. Any regulation or sub-regulatory guidance that is referenced in this section shall also be listed in "Other Applicable Authorities." It is insufficient to state a rebuttal determination without explaining how and why the determination was made.)

DECISION:

(A short conclusory restatement.)

(Example: On [Month] [DD], [YYYY], [Contractor Name] received a revalidation application for Home Healthcare Services, LLC. On [Month] [DD], [YYYY], [Contractor Name] sent a development request to continue processing Home Healthcare Services, LLC's revalidation application. Home Healthcare Services, LLC did not timely respond to [Contractor Name]'s development request. As a result, [Contractor Name] properly rejected Home Healthcare Services, LLC's revalidation application. Therefore, [Contractor Name] finds that the deactivation of Home Healthcare Services, LLC's Medicare enrollment under 42 C.F.R. § 424.540(a)([1-8]) was appropriately implemented.)

This is an **UNFAVORABLE DETERMINATION**. [Contractor name] concludes that there was no error made in the deactivation of [Provider/Supplier Name]'s Medicare billing privileges. As a result, [Provider/Supplier Name]'s Medicare billing privileges will remain deactivated.

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

10.7.14 – Model Opt-out Letters
(Rev. 12550; Issued: 03-21-24; Effective: 04-21-24; Implementation: 04-21-24)

The Contractors shall use the model letters in this section to respond to eligible practitioners' opt-out affidavits, request additional documentation, approve opt out affidavits and acknowledge the cancelation or early termination of an opt-out. The Contractors shall not use these model letters to respond to Medicare enrollment applications or other correspondence. The Contractors may issue the Model Opt-out Development Letter via fax, e-mail or mail to the eligible practitioner.

A. Opt-out Affidavit Development Letter

MACs shall use the following letter to request missing information from an eligible practitioner that wishes to opt-out of Medicare. This letter should be sent only one time and include a request for all missing information. The MAC may select the response type, either via mail, fax or email.

[month] [day], [year]

[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner]:

[Insert MAC] requires the following information to complete the processing of your Medicare opt-out affidavit:

[Specify information needed]

Submit the requested information within 30 calendar days of the postmark date of this letter [to the address listed below, via fax to (###-###-####), or via email to (enter PE analyst's email address here)]. We may reject your opt-out affidavit if you do not furnish the requested information within this timeframe.

[Name of MAC]
[Address]
[City], [ST] [Zip]

Attach a copy of this letter with your revised opt-out affidavit.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM] .

Sincerely,

[Name]
[Title]
[Company]

B. Opt-out Rejection Letter

If an eligible practitioner does not respond timely or does not respond with needed information to complete an opt-out affidavit, the MACs shall issue this rejection letter.

[month] [day], [year]

[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear Eligible Practitioner Name:

[Insert MAC] is rejecting your Medicare opt-out affidavit, received on [insert date], for the following reason(s):

[List all reasons for rejection:]

To resubmit your opt-out affidavit include all information needed to process your opt-out request. Additional information on submitting a complete opt-out affidavit can be found at: [enter MAC website address].

Return the completed opt-out affidavit to:

[Name of MAC]
[Address]
[City], [ST] [Zip]

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

C. Opt-out Return Letters

Opt-out affidavits should only be returned for the following reasons:

1. The eligible practitioner requesting to opt-out of Medicare is not appropriately licensed by the state,
2. The practitioner is a specialty that is ineligible to opt-out (e.g., Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.),
3. The opt-out affidavit is filed with an incorrect MAC,
4. The eligible practitioner decides not to opt out of Medicare while their opt-out affidavit is still in process, but not yet approved by the MAC,
5. The eligible practitioner submits a cancellation request too late (within 30 days of the auto-renewal date or after the auto-renewal date), this return letter provides appeal rights, or
6. The eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date.

MACs shall issue the specific letter for the return reason.

1. Opt-out Return Letter – Unlicensed Eligible Practitioner

[month] [day], [year]
[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], as you are not licensed by the state for the specialty type you indicated on your opt-out affidavit.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]

[Title]
[Company]

2. Opt-out Return Letter – Ineligible Practitioner

[month] [day], [year]
[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because you indicated a specialty that is ineligible to opt-out (e.g., Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.) of Medicare.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

3. Opt-out Return Letter – Submitted to Incorrect MAC

[month] [day], [year]
[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because your opt-out affidavit was filed with an incorrect Medicare Administrative Contractor for the state that you are located in. Your affidavit should be resubmitted to the appropriate contractor for processing.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

4. Opt-out Return Letter – Withdraw of Affidavit During Processing

[month] [day], [year]

[Eligible Practitioner Name]

[Address]

[City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because you have decided to withdraw your opt-out affidavit while it is still in process.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

5. Opt-out Return Letter – Late Cancellation Request

[Month] [DD], [YYYY]
[Eligible Practitioner Name]
[Address from which opt-out was sent]

[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
NPI: [xxxxxxxxxx]

We Can't Cancel Your Medicare Opt-Out Status

Dear [Eligible Practitioner Name]:

We can't cancel the automatic renewal of your Medicare opt-out status because we didn't get your cancellation request in time. Your opt-out status automatically renewed for 2 years on [Month] [DD], [YYYY].

To properly cancel your opt-out status, you needed to submit your request by [Month] [DD], [YYYY], which was at least 30 days before your automatic opt-out renewal. [Contractor Name] is returning your written request, which they got on [Month] [DD], [YYYY].

Next Steps

If you don't request reconsideration, your next chance to cancel the automatic renewal of your Medicare opt-out status is prior to [Month] [DD], [YYYY] for the renewal that will occur on [Month] [DD], [YYYY].

If you believe you submitted a proper cancellation request before [Month] [DD], [YYYY], you can submit a reconsideration request to appeal the determination that you didn't timely or properly cancel your opt-out status. CMS (or a contractor) will review your request to see if we made an error in determining that you didn't cancel your opt-out status in a proper or timely manner. We'll base this decision on the information you include in your reconsideration request, CMS and contractor documents, and applicable regulations in 42 C.F.R. §§ 405.400-405.455. Submitting a reconsideration request doesn't allow you to submit (or allow us to accept) an untimely request to cancel your opt-out status.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.

- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]
[Address]
[City], [ST] [Zip]

(OR)

[Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850]

Or emailed to: [Contractor email] [or ProviderEnrollmentAppeals@cms.hhs.gov].

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

6. Opt-out Return Letter – Cancellation Request Submitted Too Early

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
NPI: [xxxxxxxxxx]

Dear [Eligible Practitioner Name]:

[Contractor Name] is returning your written request to cancel the automatic renewal your Medicare opt-out status, submitted on [Month] [DD], [YYYY], as it was submitted at more than 90 days prior to the end of your current opt-out period.

Please submit your cancellation request no later than 30 days prior to the end of your current opt-out period to avoid auto-renewal of your opt-out status. Your autorenewal date is: [Month] [DD], [YYYY].

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

D. Opt-out Affidavit Approval Letters

The Contractors shall issue an Opt-out Affidavit Approval model letter when approving an opt-out affidavit and PECOS has been updated with the affidavit information. The approval letter shall be issued for the following reasons:

1. Approved Opt-Out, Eligible Practitioner May Order & Refer
2. Approved Opt-Out, Eligible Practitioner May Not Order & Refer (OIG Exclusion)
3. Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Ineligible Specialty)
4. Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Did Not Elect to Order & Refer)
5. Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Eligible Practitioner Does Not Have an NPI)
6. Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Eligible Practitioner has Revoked Billing Privileges)
7. Approved Opt-Out Change of Information

The Opt-out approval letter shall include:

- The eligible practitioner's personal information:
  - Name,
  - Address,
  - NPI,
  - Specialty, and
  - Eligibility to order and refer.

- The eligible practitioner's opt-out effective date.

- The date that the eligible practitioner can submit a request to cancel their opt-out affidavit (at least 30 days prior to the end-date of their current opt-out period).

- The date the eligible practitioner can terminate his/her/their opt-out early (if they are eligible to so, no later than 90 days after the effective date) of the eligible practitioner's initial 2-year opt-out period.

- Should the eligible practitioner opt-out a subsequent time after cancelling, contractors shall remove the paragraph noting "Since you are opting out for the very first time…" since this statement no longer applies.

1. Opt-out Affidavit Approval Letter – Eligible Practitioner Approved to Order & Refer

[Month] [DD], [YYYY]
[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
Dear [Eligible Practitioner Name]:

You've Successfully Opted Out of Medicare

Opt-out Affidavit Information:

Practitioner Name:	[Name]
Address:	[Address, City, State, Zip]
NPI:	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You're eligible to Order and Refer
Effective Date:	[Effective date]

[Contractor Name] approved your Medicare opt-out affidavit. **You don't need to take additional action at this time.** However, since you're opting out of Medicare for the first time, you have a one-time, 90-day period to change your mind about opting out. If you decide to terminate your opt-out status during this 90-day period, submit your written request by [Month] [DD], [YYYY]. After this 90-day period ends, you can cancel your opt-out status at the end of the 2 year opt-out period only. Your opt-out status will automatically renew every 2 years.

To cancel your opt-out status, submit written cancellation request at least 30 days before the end of the opt-out period. For example, if you decide you want to cancel your opt-out status at the end of this opt-out period, submit your cancellation request by [Month] [DD], [YYYY].

If you believe you submitted a proper termination request within 90 days of the effective date above, you can submit a reconsideration request. A reconsideration request allows you to appeal the determination that you didn't timely and properly terminate your opt-out status. CMS (or a contractor) will review your request to see if we made an error in determining that you didn't terminate your opt-out status in a proper or timely manner. We'll base this decision on the information you include in your reconsideration request, CMS and contractor documents, and applicable regulations 42 C.F.R. §§ 405.400-405.455. Submitting a reconsideration request doesn't allow you to submit (or allow us to accept) an untimely request to terminate your opt-out status. **You may submit a reconsideration request by [Month] [DD], [YYYY] (65 days after the 90-day termination period ends).).**

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must:

- Be received in writing by the date indicated above and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]
[Address]
[City], [ST] [Zip]

OR

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,
[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

2. Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Excluded by the OIG)

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] approved your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You are not eligible to Order and Refer*
Effective Date:	[Effective date]

* You have been excluded by the OIG (and even if you have or have not obtained a waiver according to 42 C.F.R. § 1001.1901(c)), you may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing, no later than [Month] [DD], [YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Right to Submit a Reconsideration Request sections below.

To cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]	OR	Centers for Medicare & Medicaid Services
[Address]		Provider Enrollment & Oversight Group

[City], [ST] [Zip]

ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

3. Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Ineligible Specialty)

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] approved your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You are not eligible to Order and Refer*
Effective Date:	[Effective date]

* You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries, as your specialty is ineligible to order and refer.

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90-day period to change your mind about opting out. If you decide to terminate during this 90-day period, you must submit your request, in writing, no later than [Month] [DD], [YYYY]. After this 90-day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90-day period ends. Please follow the

Right to Submit a Reconsideration Request section below.

To cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the

administrative appeals process unless an ALJ allows additional information to be submitted; and

- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name] [Address] [City], [ST] [Zip]	OR	Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Boulevard Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

4. Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Did Not Elect to Order and Refer)

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] approved your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You are not eligible to Order and Refer*
Effective Date:	[Effective date]

* You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries as you did not elect to be and ordering and referring practitioner on your opt-out affidavit.

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90-day period to change your mind about opting out. If you decide to terminate during this 90-day period, you must submit your request, in writing, no later than [Month] [DD], [YYYY]. After this 90-day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90-day period ends. Please follow the Right to Submit a Reconsideration Request section below.

To cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name] [Address] [City], [ST] [Zip]	OR	Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Boulevard Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

5. Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Eligible Practitioner Does Not Have an NPI)

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] approved your Medicare opt-out affidavit.

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[Not Provided]
Specialty:	[Specialty]
Ordering and Referring:	You are not eligible to Order and Refer*
Effective Date:	[Effective date]

* You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries, as you have not obtained an NPI.

Opt-out Affidavit Information:

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing, no later than [Month] [DD], [YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Right to Submit a Reconsideration Request section below.

To cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.

- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]	OR	Centers for Medicare & Medicaid Services
[Address]		Provider Enrollment & Oversight Group
[City], [ST] [Zip]		ATTN: Division of Provider Enrollment Appeals
		7500 Security Boulevard
		Mailstop: AR-19-51
		Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

6. Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Eligible Practitioner Has Revoked Billing Privileges)

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] approved your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You are not eligible to Order and Refer*
Effective Date:	[Effective date]

* Your billing privileges have been revoked, you may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing, no later than [Month] [DD], [YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Right to Submit a Reconsideration Request section below.

To cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]	OR	Centers for Medicare & Medicaid Services
[Address]		Provider Enrollment & Oversight Group
[City], [ST] [Zip]		ATTN: Division of Provider Enrollment Appeals

7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

7. Opt-out Affidavit Approval Letter – Approved Opt-Out Change of Information

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)

Dear [Eligible Practitioner Name]:

[Insert Contractor] has updated your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	[Name]
Address on File:	[Address, City, State, Zip]
National Provider Identifier (NPI):	[NPI]
Specialty:	[Specialty]
Ordering and Referring:	You [are/are not] eligible to Order and Refer[*]
Effective Date:	[Effective date]
Changed Information:	

[* You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries, as you have {enter reason for inability to order and refer}.]

As a reminder, to cancel opt-out, you must submit a cancellation request at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month] [DD], [YYYY].

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

E. Opt-out Renewal Alert Letter

The contractor shall issue the following letter to inform the eligible practitioner that the opt-out is due to be automatically renewed.

[Month] [DD], [YYYY]
[Eligible Practitioner Name]
[Address from which opt-out was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
NPI: [xxxxxxxxxx]

Action Needed to Cancel Your Medicare Opt-Out Status

Dear [Eligible Practitioner Name]:

Your Medicare opt-out status will be automatically renewed for a new 2-year opt-out period on [Month] [DD], [YYYY]. You don't need to take additional action at this time.
However, if you would like to cancel your opt-out status, submit a written cancellation request by [Month] [DD], [YYYY], which is at least 30 days before the end of your current opt-out period.

If you believe you submitted a proper cancellation request by [Month] [DD], [YYYY], you can submit a reconsideration request. A reconsideration request allows you to appeal the determination that you didn't timely and properly terminate your opt-out status. CMS (or a contractor) will review your request to see if we made an error in determining that you didn't cancel your opt-out status in a proper or timely manner. We'll base this decision on the information you include in your reconsideration request, CMS and contractor documents, and applicable regulations 42 C.F.R. §§ 405.400-405.455. Submitting a reconsideration request doesn't allow you to submit (or allow us to accept) an untimely request to cancel your opt-out status. **You may submit a reconsideration request by [Month] [DD], [YYYY] (65 days after the last day to cancel the current opt-out period).**

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing by the date indicated above and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request; and
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name]
[Address]

[City], [ST] [Zip]

OR

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

F. Opt-out Affidavit Termination Letter

If an eligible practitioner timely terminates his/her/their initial opt-out, the Contractors shall acknowledge this action by using this model letter. If the eligible practitioner requests a cancellation, the Contractors shall indicate the date of the cancellation and remove the following paragraph regarding termination. If the eligible practitioner terminates the opt-out, the Contractors shall remove the cancellation language.

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which request was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
NPI: [xxxxxxxxxx]

Dear [Eligible Practitioner Name]:

[Insert Contractor] completed your request to terminate your Medicare opt-out affidavit.

Want to enroll as a Medicare billing provider or for the sole purpose of ordering and referring? Submit the appropriate Provider Enrollment Chain and Ownership System (PECOS) application or paper CMS-855 form.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name] OR Centers for Medicare & Medicaid Services

[Address]
[City], [ST] [Zip]

Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

G. Opt-out Affidavit Cancellation Letter

If an eligible practitioner timely submits an opt-out cancellation request, the Contractors shall acknowledge this action by using this model letter.

[Month] [DD], [YYYY]

[Eligible Practitioner Name]
[Address from which request was sent]
[City], [ST] [Zip]

Reference: [Case/Control Number] (optional)
NPI: [xxxxxxxxxx]

Dear [Eligible Practitioner Name]:

[Contractor Name] completed your request to cancel your Medicare opt-out affidavit.

Your opt-out status will be canceled effective [Month] [DD], [YYYY].

Want to enroll as a Medicare billing provider or for the sole purpose of ordering of referring? Submit the appropriate Provider Enrollment Chain and Ownership System (PECOS) application or paper CMS-855 form.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the implementation of the initial determination. (Optional Coversheet sentence) [To facilitate the processing of your reconsideration request, please utilize

and include the attached coversheet [also found at [[insert web address for coversheet]] with your submission.]

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he/she/they have the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

Failure to submit a reconsideration request is deemed a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to: (Insert correct address based on whether the contractor or CMS is responsible for handling the reconsideration.)

[Contractor Name] [Address] [City], [ST] [Zip]	OR	Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Boulevard Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to: ([Contractor email] or ProviderEnrollmentAppeals@cms.hhs.gov).

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Signature of Hearing Officer] (May be electronic)
[Name of Hearing Officer]
[Position of Hearing Officer]
[Contractor Name]

10.7.15 –Revalidation Notification Letters
(Rev.: 12356; Issued: 11-09-23; Effective: 01-01-24; Implementation: 01-02-24)

A. Revalidation Letter – Non-DMEPOS Supplier

REVALIDATION

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Every five years, CMS requires you to revalidate your Medicare enrollment record. You need to update or confirm all the information in your record, including your practice locations and reassignments.

We need this from you by **[Due date, as Month dd yyyy]**. If we don't receive your response by then, we may stop your Medicare billing privileges.

If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating by [Due date, as Month dd yyyy]

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments: <Only include this title if the record has any reassignments>
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at go.cms.gov/MedicareRevalidation.

What you need to do

Revalidate your Medicare enrollment record, through https://pecos.cms.hhs.gov/pecos/login.do or [form CMS-855 or Form CMS-20134].

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484-8049.
- **Paper:** Download the right version of form [CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification. For more on fees and exceptions, search cms.gov for "CR 7350" or "Fee Matrix".

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if: (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data.
The current version of the form can be found at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS588.pdf.

If you need help

Visit go.cms.gov/MedicareRevalidation
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

B. Revalidation Letter – DMEPOS Supplier

REVALIDATION

[month] [day], [year]
[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Every three years, CMS requires you to revalidate your Medicare enrollment record. You need to update or confirm all the information in your record, including your practice location.

We need this from you by [Due date, as Month dd yyyy]. If we do not receive your response by then, we may stop your Medicare billing privileges.

If you are a non-certified provider or supplier and your enrollment is deactivated, you will maintain your original PTAN. However, you will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating by [Due date, as Month dd yyyy]
[Name] | NPI [NPI] | PTAN [PTAN]
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

The CMS lists the records that need revalidating at go.cms.gov/MedicareRevalidation.

What you need to do

Revalidate your Medicare enrollment record, through https://pecos.cms.hhs.gov/pecos/login.do or [Form CMS-855S ~~or Form CMS-20134~~].

- **Online:** PECOS is the fastest option. If you do not know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484-8049.

- **Paper:** Download the right version of form [CMS-855S] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification. For more on fees and exceptions, search cms.gov for "CR 7350" or "Fee Matrix".

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if: (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data.

The current version of the form can be found at http://www.cms.gov/Medicare/CMSForms/CMS-Forms/Downloads/CMS588.pdf.

If you need help

Visit go.cms.gov/MedicareRevalidation
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

C. Revalidation Letter – CHOW Scenario Only

[month] [day], [year]

PROVIDER/SUPPLIER NAME
ADDRESS 1, ADDRESS 2
CITY STATE ZIP CODE

NPI:
PTAN:

Dear Provider/Supplier Name:

THIS IS A PROSPECTIVE PROVIDER ENROLLMENT REVALIDATION REQUEST

IMMEDIATELY SUBMIT AN UPDATED
PROVIDER ENROLLMENT PAPER APPLICATION 855 FORM TO VALIDATE YOUR ENROLLMENT INFORMATION

In accordance with Section 6401 (a) of the Patient Protection and Affordable Care Act, all new and existing providers must be reevaluated under the new screening guidelines. Medicare requires all enrolled providers and suppliers to revalidate their enrollment information every five years (reference 42 CFR §424.515). To ensure compliance with these requirements, existing regulations at 42 CFR §424.515(d) provide that the Centers for Medicare & Medicaid Services (CMS) is permitted to conduct off-cycle revalidations for certain program integrity purposes. Upon the CMS request to revalidate its enrollment, the provider/supplier has 60 days from the post mark date of this letter to submit complete enrollment information.

You previously submitted a change of ownership (CHOW) application that is currently being reviewed by the State Agency. Since your application has not been finalized, please validate that we have the most current information on file. Any updated information received since your initial submission will be forwarded to the State Agency for their final determination.

Providers and suppliers can validate their provider enrollment information using the paper application form. To validate by paper, download the appropriate and current CMS-855 Medicare Enrollment application from the CMS Web site at https://www.cms.gov/MedicareProviderSupEnroll/. Mail your completed application and all required supporting documentation to the [insert contractor name], at the address below.

[Insert application return address]

A new Electronic Funds Transfer (EFT) Authorization Form (CMS-588) is only required to be submitted as part of your revalidation package if (1) you have no Form CMS-588 on file with Medicare at all; or (2) you are changing any of your existing Form CMS-588 data.

The current version of the form can be found at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS588.pdf.

If additional time is required to complete the validation applications, you may request one 60-day extension, which will be added onto the initial 60 days given to respond to the request. The request may be submitted in writing from the individual provider, the Authorized or Delegated Official of the organization or the contact person and addressed to the MAC(s). The request should include justification of why a 60-day extension is needed. The request may also be made by contacting your MAC(s), via phone.

Physicians, non-physician practitioners and physician and non-physician practitioner organizations must report a change of ownership, any adverse legal action, or a change of practice location to the MAC within 30 days. All other changes must be reported within 90 days. For most but not all other providers and suppliers, changes of ownership or control, including changes in authorized official(s), must be reported within 30 days; all other changes to enrollment information must be made within 90 days. For all provider and supplier types, any change of practice location (including practice location additions, deletions, and relocations) must be reported within 30 days.

Failure to submit complete enrollment application(s) and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being deactivated and your CHOW not being processed. We strongly recommend you mail your documents using a method that allows for proof of receipt.

If you have any questions regarding this letter, please call [contractor telephone number will be inserted here] between the hours of [contractor telephone hours will be inserted here] or visit our Web site at [insert Web site] for additional information regarding the enrollment process or the [insert application type].

Sincerely,
[Your Name]
[Title]

D. Large Group Revalidation Notification Letter

[month] [day], [year]

PROVIDER/SUPPLIER GROUP NAME
ADDRESS 1, ADDRESS 2
CITY STATE ZIP CODE

NPI:
PTAN:

Dear Provider/Supplier Group Name:

THIS IS **NOT** A PROVIDER ENROLLMENT REVALIDATION REQUEST

This is to inform you that a number of physicians and/or non-physician practitioners reassigning all or some of their benefits to your group have been selected for revalidation. For your convenience, a list of those individuals is attached. A revalidation notice will be sent to the physician or non-physician practitioner within the next seven months. They will need to respond by the revalidation due date provided for each provider. It is the responsibility of the physician and/or non-physician practitioner to revalidate all their Medicare enrollment information and not just that associated with the reassignment to your group practice.

In accordance with Section 6401 (a) of the Patient Protection and Affordable Care Act, all new and existing providers must be reevaluated under the new screening guidelines. Medicare requires all enrolled providers and suppliers to revalidate their enrollment information every five years (reference 42 CFR §424.515). To ensure compliance with these requirements, existing regulations at 42 CFR §424.515(d) provide that the Centers for Medicare & Medicaid Services (CMS) is permitted to conduct off-cycle revalidations for certain program integrity purposes.

Physicians and non-physician practitioners can revalidate by using either Internet-based PECOS or submitting a paper CMS-855 enrollment application. Failure to submit a complete revalidation application and all supporting documentation within 60 calendar days may result in the physician or non-physician practitioner's Medicare billing privileges being deactivated. As such, your group will no longer be reimbursed for services rendered by the physician or non-physician practitioner.

If you have any questions regarding this letter, please call [contractor telephone number will be inserted here] between the hours of [contractor telephone hours will be inserted here] or visit our Web site at [insert Web site] for additional information regarding the revalidation process.

Sincerely,

[Your Name]
[Title]

E. Revalidation Pend Letter

PAYMENT HOLD

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

We are holding all payments on your Medicare claims, because you haven't revalidated your enrollment record with us. This does not affect your Medicare participation agreement, or any of its conditions.

Every [three or five years], CMS requires you to revalidate your Medicare enrollment record information. You need to update or confirm all the information in your record, including your practice locations and reassignments.

Failure to respond to this notice will result in a possible deactivation of your Medicare enrollment. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments:
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at **go.cms.gov/MedicareRevalidation**.

How to resume your payments

Revalidate your Medicare enrollment record, through https://pecos.cms.hhs.gov/pecos/login.do or [form CMS-855 or Form CMS-20134].

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484-8049.
- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

If you need help

Visit **go.cms.gov/MedicareRevalidation**
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

F. Revalidation Deactivation Letter

STOPPING BILLING PRIVILEGES

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Your Medicare billing privileges are being deactivated effective [Month] [DD], [YYYY], pursuant to 42 C.F.R. § 424.540(a)(3) because you have not timely revalidated your enrollment record with us, or your revalidation application has been rejected because you did not timely respond to our requests for more information. We will not pay any claims after this date.

Every five years [three for DMEPOS suppliers], CMS requires you to revalidate your Medicare enrollment record.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments:
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Revalidations.html.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.546. The rebuttal must be received in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider's or supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she has the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal request.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

How to recover your billing privileges

Revalidate your Medicare enrollment record, through PECOS.cms.hhs.gov, or [Form CMS-855 or Form CMS-20134].

- Online: PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484-8049.

- Paper: Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you deserve a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

If you need help Visit https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Revalidations.html.

Call [contractor telephone number] or visit [contractorsite.com] for more options.

Sincerely,

[Name]
[Title]
[Company]

G. Revalidation Past-Due Group Member Letter

REVALIDATION | Past-Due Group Member

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Every five years, CMS requires providers to revalidate their Medicare enrollment records. You have not revalidated by the requested due date of [revalidation due date].

You need to update or confirm all the information in your record, including your practice locations and reassignments. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN, however will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

If multiple records below need to be revalidated, please coordinate with the appropriate parties to provide only one response.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]
Reassignments: <Only include this title if the record has any reassignments>
[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]
<Repeat for other reassignments>

CMS lists the records that need revalidating at **go.cms.gov/MedicareRevalidation**.

What your group member needs to do

Revalidate their Medicare enrollment record, through https://pecos.cms.hhs.gov/pecos/login.do. or [form CMS-855 or Form CMS-20134].

- **Online:** PECOS is the fastest option. If they don't know their username or password, PECOS offers ways to retrieve them. Our customer service can also help by phone at 866-484-8049.

- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for their situation at cms.gov. We recommend getting proof of receipt for this mailing. Mail to [contractor address].

If your group member needs help

Visit **go.cms.gov/MedicareRevalidation**
Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

H. Model Return Revalidation Letter

RETURN REVALIDATION

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City], [State] [Zip Code]

NPI: [xxxxxxxxxx]

Dear [Provider/Supplier Name],

Your Medicare enrollment application(s) was received on [date]. We are closing this request and returning your application(s) for the following reason(s):

- The [Form CMS-855 or Form CMS-20134] application received by [PROVIDER/SUPPLIER NAME] was unsolicited.
    - An unsolicited revalidation is one that is received more than seven months prior to the provider/supplier's due date. Due dates are established around 5 years from the provider/suppliers last successful revalidation or their initial enrollment.
    - To find the provider/suppliers revalidation due date, please go to http://go.cms.gov/MedicareRevalidation.
    - If you are not due for revalidation in the current seven-month period, you will find that your due date is listed as "TBD" (or To Be Determined). This means that you do not yet have a due date for revalidation within the current seven-month period. This list with be updated monthly.

- If your intention is to change information on your Medicare enrollment file, you must complete a new Medicare enrollment application(s) and mark 'change' in section 1 of the [form CMS-855 or Form CMS-20134].

- Please address the above issues as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers can apply to enroll in the Medicare program using one of the following two methods:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). Go to: https://pecos.cms.hhs.gov/pecos/login.do.

2. Paper application process: Download and complete the Medicare enrollment application(s) at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html.

If you need help

Visit http://go.cms.gov/MedicareRevalidation, or
Call2 [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,
[Name]
[Title]
[Company]

10.7.16 – Model Letters for Claims Against Surety Bonds
(Rev. 10524; Issued: 12-17-20; Effective: 11-13-20; Implementation: 11-13-20)

When making a claim against a surety bond in accordance with section 10.2.5(A)(2)(o)(ii) of this chapter, the contractor shall use the applicable model letter below:

A. Letter for Overpayments – Supplier is Still Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Supplier Legal Business Name
Supplier DBA Name (if any)
Supplier Address
Supplier National Provider Identifier (NPI)

Dear Surety:

(Supplier legal business name) is currently enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As a condition of its Medicare enrollment, (Supplier) is required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Supplier) has a $_____ surety bond with your company.

Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS - upon receiving written notice from CMS containing "sufficient evidence" as defined in the Program Integrity Manual, CMS Pub. 100-08, §10.2.5(A)(3)(b) - the amount of any unpaid claim for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. An "unpaid claim" is defined in 42 C.F.R. §424.57(a) as an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible.

CMS has determined that (Supplier) has incurred an overpayment in the amount of (insert dollar amount) for (insert "a service" or "services", as applicable) performed on (insert date(s) of service). This determination was made based on specific information about the overpayment, which is included in the attachments to this letter.

CMS has been unable to recover the full overpayment from (Supplier) using its existing recoupment procedures. (Supplier) has repaid (insert "none" or "only $_____) of the overpayment amount. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be (insert DME MAC), which is CMS's Durable Medical Equipment Medicare Administrative Contractor for (Supplier)'s location.

Failure to make the requested payment in a timely manner may result in referrals to the United States Department of Justice for collection action, and/or the United States Department of the Treasury for revocation of [surety name's] authority to provide federal bonds.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____. (The contractor shall identify a specific individual who the surety can contact if questions arise.)

Sincerely,
(Name and title)

cc: Supplier Name

B. Letter for Overpayments - Supplier is No Longer Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Former Supplier Legal Business Name
Former Supplier DBA Name (if any)
Former Supplier Address
Former Supplier NPI

Dear Surety:

(Former Supplier legal business name) was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) until (insert effective date of termination/revocation). As a condition of its Medicare enrollment, (Former Supplier) was required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Former Supplier) obtained a $_____ surety bond with your company.

Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – upon receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any unpaid claim for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. An "unpaid claim" is defined in 42 C.F.R. §424.57(a) as an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible.

CMS has determined that (Supplier) incurred an overpayment in the amount of (insert dollar amount) for (insert "a service" or "services", as applicable) performed on (insert date(s) of service). This determination was made based on specific information about the overpayment, which is included in the attachments to this letter.

CMS has been unable to recover the full overpayment from (Former Supplier) using its existing recoupment procedures. (Former Supplier) has repaid (insert "none" or "only $_____) of the overpayment amount.

(Former Supplier's) surety bond coverage with your company ended on (insert date). However, consistent with 42 C.F.R. §424.57(d)(5)(iii), the surety is liable for unpaid claims that:

- CMS assessed against the supplier based on overpayments that took place during the term of the bond or rider, and

- Were assessed by CMS during the 2 years following the date that the supplier failed to submit a bond or required rider or the date that the supplier's Medicare enrollment was terminated, whichever is later.

The overpayment occurred on (insert date), which was within the period of (Former Supplier)'s surety bond coverage with your company. Moreover, CMS has made its overpayment determination within the 2-year period following the date of the termination of (Former

Supplier)'s Medicare enrollment. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be (insert DME MAC), which is CMS's Durable Medical Equipment Medicare Administrative Contractor for (Supplier)'s location.

Failure to make the requested payment in a timely manner may result in referrals to the United States Department of Justice for collection action, and/or the United States Department of the Treasury for revocation of [surety name's] authority to provide federal bonds.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____. (The contractor shall identify a specific individual who the surety can contact if questions arise.)

Sincerely,
(Name and title)

cc: Supplier Name

C. Letter for Civil Monetary Penalties and Assessments – Supplier is Still Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Supplier Legal Business Name
Supplier DBA Name (if any)
Supplier Address
Supplier NPI

Dear Surety:

(Supplier legal business name) is currently enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As a condition of its Medicare enrollment, (Supplier) is required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Supplier) has a $_____ surety bond with your company.

Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – upon receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any civil monetary penalty (CMP) and/or assessment for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. (Insert applicable language……..

> A CMP is defined in §424.57(a) as a sum that CMS has the authority, as implemented by 42 C.F.R. §402.1(c) (or the Department of Health and Human Services Office of Inspector General (OIG)) has the authority, under section 1128A of the Act or 42 C.F.R. Part 1003) to impose on a supplier as a penalty.
>
> OR
>
> An assessment is defined as a sum certain that CMS or the Department of Health and Human Services Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII or XXI of the Social Security Act.)

(CMS or OIG, as applicable) imposed a (CMP and/or assessment, as applicable) on (Supplier) on (date) in the amount of ($ _____). The (CMP and/or assessment) was imposed because (insert explanation, using information furnished by CMS or OIG).

Relevant documentation supporting our determination is attached to this letter. (Attach copy of notice of CMP/assessment that was sent to supplier.)

(CMS or OIG, as applicable) has attempted to recover the amount of the (CMP or assessment) from (Supplier) using its existing collection procedures. (Supplier), however, has repaid (insert "none" or "only $_____) of this amount. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be the Centers for Medicare and Medicaid Services.

Failure to make the requested payment in a timely manner may result in referrals to the United States Department of Justice for collection action, and/or the United States Department of the Treasury for revocation of [surety name's] authority to provide federal bonds.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____. (The contractor shall identify a specific individual who the surety can contact if questions arise.)

Sincerely,

(Name and title)

cc: Supplier Name

D. Letter for Civil Monetary Penalties and Assessments – Supplier is No Longer Enrolled in Medicare

Date

Surety Name
Surety Address

RE: Former Supplier Legal Business Name
Former Supplier DBA Name (if any)
Former Supplier Address
Former Supplier NPI

Dear Surety:

(Former Supplier legal business name) was enrolled in Medicare as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) until (insert effective date of termination/revocation). As a condition of its Medicare enrollment, (Former Supplier) was required – under Federal regulations at 42 C.F.R. §424.57(d) - to maintain a surety bond in an amount of no less than $50,000. In accordance with this provision, (Former Supplier) obtained a $_____ surety bond with your company.

Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), the surety must pay CMS – upon receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond – the amount of any civil monetary penalty (CMP) and/or assessment for which the DMEPOS supplier is responsible, up to the full penal amount of the bond. (Insert applicable language……..

> A CMP is defined in §424.57(a) as a sum that CMS has the authority, as implemented by 42 C.F.R. §402.1(c) (or the Department of Health and Human Services Office of Inspector General (OIG) has the authority, under section 1128A of the Act or 42 C.F.R. Part 1003)) to impose on a supplier as a penalty.
>
> OR
>
> An assessment is defined as a sum certain that CMS or the Department of Health and Human Services Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII or XXI of the Social Security Act.)

(CMS or OIG, as applicable) imposed a (CMP and/or assessment, as applicable) on (Former Supplier) on (date) in the amount of ($ _____). The (CMP and/or assessment) was imposed because (insert explanation, using information furnished by CMS or OIG).

Relevant documentation supporting our determination is attached to this letter. (Attach copy of notice of CMP/assessment that was sent to former supplier.)

(CMS or OIG, as applicable) has attempted to recover the amount of the (CMP or assessment) from (Former Supplier) using its existing collection procedures. (Former Supplier), however, has repaid (insert "none" or "only $_____) of this amount.

(Former Supplier)'s surety bond coverage with your company ended on (insert date). However, consistent with 42 C.F.R. §424.57(d)(5)(iii), the surety is liable for CMPs and/or assessments that:

- CMS or OIG imposed or asserted against the supplier during the term of the bond or rider, and

- Were imposed or assessed by CMS during the 2 years following the date that the supplier failed to submit a bond or required rider or the date that the supplier's Medicare enrollment was terminated, whichever is later.

The (CMP and/or assessment) was based on events that occurred (insert relevant date(s)), which was within the period of (Former Supplier's) surety bond coverage with your company. Moreover, CMS imposed the (CMP and/or assessment) within the 2-year period following the date of the termination of (Former Supplier)'s Medicare enrollment. Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), therefore, CMS requests that (Surety) make payment to CMS in the amount of (insert applicable amount) no later than 30 days from the date of this letter. Payment shall be made via check or money order and sent to the following address:

Contractor Name
Address
City, State and Postal ZIP Code

The payee shall be the Centers for Medicare & Medicaid Services.

Failure to make the requested payment in a timely manner may result in referrals to the United States Department of Justice for collection action, and/or the United States Department of the Treasury for revocation of [surety name's] authority to provide federal bonds.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____. (The contractor shall identify a specific individual who the surety can contact if questions arise.)

Sincerely,
(Name and title)

cc: Supplier Name

E. Surety Non-Payment Letter

Date

Surety Name
Surety Address

RE: Supplier Legal Business Name
Supplier DBA Name (if any)
Supplier Address
Supplier National Provider Identifier (NPI)

Dear Surety:

Consistent with 42 C.F.R. §424.57(d)(5)(i)(A), we sent you a letter dated (date of letter) requesting that you make payment to CMS in the amount of (insert applicable amount) no later than 45 days from the date of said letter, a copy of which is attached. (Attach a copy of the demand letter.) As payment has not been received, this matter may be referred for further action to the United States Department of Justice for collection and/or the United States Department of the Treasury for revocation of [surety name's] authority to provide federal bonds.

Should you have any questions about this letter, please do not hesitate to contact _____ at _____. (The contractor shall identify a specific individual who the surety can contact if questions arise.)

Sincerely,
(Name and title)

cc: Supplier Name

10.7.17 – Model Identity Theft Prevention Letter

(Rev. 10611; Issued: 03-19-21; Effective:11-19-20; Implementation: 11-19-20)

[month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

As a security precaution, we are writing to confirm that you submitted a Medicare enrollment application(s) to enroll in or change an existing enrollment at the following address:

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

If this application was submitted without your authorization, please contact the Medicare contractor that processes your claims immediately. The Medicare Fee-For-Service contact information can be found at www.cms.hhs.gov/MedicareProviderSupEnroll.

We will process your application(s) according to The Centers for Medicare & Medicaid (CMS) timeliness standards and will contact you if additional information is needed. We will notify you once processing is complete.

Please contact our office with any questions at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM] and refer to your application(s) reference number [Reference number]

Sincerely,

[Name]
[Title]
[Company]

10.7.18 - Model Documentation Request Letter

(Rev. 10611; Issued: 03-19-21; Effective:11-19-20; Implementation: 11-19-20)

A. Model Language for §424.516(f)(1) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in §424.516(f)(1).

"Dear Provider/Supplier:

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation for 7 years from the date of service, and

- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who

ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with §424.516(f)(1), please mail to us copies of the orders for the items or services that were furnished to the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the provider or supplier furnished the items/services in question. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10)."

Please contact our office with any questions at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM] and refer to your application(s) reference number [Reference number]

Sincerely,

[Name]
[Title]
[Company]

B. Model Language for §424.516(f)(2) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in § 424.516(f)(2).

"Dear Physician/Professional:

Under 42 CFR §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain documentation for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request. The documentation to be maintained includes written and electronic documents relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with §424.516(f)(2), please mail to us copies of the orders for items or services that you issued for the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the orders were made. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10)." (For individuals enrolled via the Form CMS-855O, the contractor shall instead use the following language: "Failure to timely submit this documentation may result in the revocation of your Form CMS-855O enrollment.")

Please contact our office with any questions at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM] and refer to your application(s) reference number [Reference number]

Sincerely,

[Name]
[Title]
[Company]

10.7.19 – ESRD Approval Letters

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

In the ESRD situations described in this section 10.7.19, the letters below shall be used as directed in section 10.2.1.3 notwithstanding any other instruction to the contrary in this chapter.

A. ESRD Service Station/Modality Changes

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your State Agency has notified [insert contractor name] [insert contractor number] that your end-stage renal disease (ESRD) facility changed [your approved service modalities and/or

number of stations.] Therefore, your facility is now approved for a total of [number of in-center hemodialysis stations] maintenance stations and the services outlined below:

Medicare Enrollment Information

Legal Business Name (LBN)
Doing Business As (DBA)
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Effective Date

CMS Certification Information

CCN
Effective Date
Changed Information
Effective Date of Change(s) (Include detailed changes or section. Select from list below.)

__In-Center Hemodialysis (HD)
__In-Center Peritoneal Dialysis (PD)
__In-Center Nocturnal HD
__Home HD Training and Support
__HD in LTC
__Home PD Training and Support
__PD in LTC
__Dialyzer Reuse

You should report to the [State Agency ([SA])] any changes in location, services, or organization which might affect your certification status or the status of your ESRD facility. In addition, providers must notify CMS when there is a change of ownership. Therefore, you must notify your Medicare Administrative Contractor (MAC) and the [SA] promptly if there is a change in the legal status of the ownership of this facility.

We look forward to continuing to work with you in the administration of the Medicare program. If you have any questions regarding this, please contact [STATE AGENCY NAME], [STATE AGENCY EMAIL ADDRESS].

[Include appropriate MAC signature]

Cc: State Agency
Accrediting Organization (if appropriate)

B. State Agency Approved Initial

[Month, Day, Year]
[Provider/Supplier Name]
[Address]

[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency [and Accrediting Organization}]. Your initial enrollment application is approved.

Your unit has been approved as a renal dialysis [facility/center]. This approval is for a total of [number] maintenance stations. Your [facility/center] is approved to provide the following services:

[List all that apply--]

__In-Center Hemodialysis (HD)
__In-Center Peritoneal Dialysis (PD)
__In-Center Nocturnal HD
__Home HD Training and Support
__HD in LTC
__Home PD Training and Support
__PD in LTC
__Dialyzer Reuse

Medicare Enrollment and Provider/Supplier Information

Medicare Enrollment Information
Legal Business Name (LBN)
Doing Business As Name
Primary Practice Location Address
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Enrollment Effective Date

Please inform the [State Survey Agency/AO] if you wish to relocate your [facility/center], change the services that you are currently providing, change the number of approved stations, or undergo a change in ownership.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.
Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

• Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
• State the issues or findings of fact with which you disagree and the reasons for disagreement.
• Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]
CC: State Agency [and AO, if applicable]

C. Change of Ownership

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Subject: ESRD Medicare Change of Ownership

Dear Administrator:

[Insert Contractor name [and Contractor number]] has received a response from the State Agency. Your change of ownership application is now approved.

[INSERT or CHECK THE APPLICABLE PARAGRAPH]:

__ [Facility status is not changing]
When an ESRD facility undergoes a change of ownership, the new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from free-standing to hospital-based]
When an ESRD facility undergoes a change of ownership and changes its status from a free-standing ESRD facility to a hospital-based ESRD center, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD center is issued a new CCN number that links it to the provider with which it is associated. The new

owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from hospital-based to free-standing]
When an ESRD center undergoes a change of ownership and changes its status from a hospital-based ESRD center to a free-standing ESRD facility, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD facility is issued a new CCN to indicate the free-standing designation. The new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner. Therefore, the CCN of [old CCN] is hereby terminated effective [Date of CHOW]. Your facility's approved CCN is provided below.

Your facility has been approved for a total of [number of in-center hemodialysis stations] maintenance stations. Also, your facility is approved to provide the following services:

[CHECK OR INSERT ALL APPLICABLE]

__In-Center Hemodialysis (HD)
__In-Center Peritoneal Dialysis (PD)
__In-Center Nocturnal HD
__Home HD Training and Support
__HD in LTC
__Home PD Training and Support
__PD in LTC
__Dialyzer Reuse

Medicare Enrollment Information

Legal Business Name (LBN)
Doing Business As Name
Primary Practice Location Address
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Effective Date of Change of Ownership

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system. Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services

Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850
Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]

[Company]
CC: State Agency [and AO, if applicable]

10.7.20 – Stay of Enrollment Letters
(Rev.:12524; Issued: 03-01-24; Effective: 04-01-24; Implementation: 06-03-24)

This section 10.7.20 contains letters that contractors shall use in stay of enrollment situations. Note that the contractor may remove language from the letter that obviously does not apply to the provider/supplier type in question (e.g., reassignment language in a letter pertaining to an HHA under a stay).

A. Imposition of Stay of Enrollment Notification Letter – Revalidation Non-Response

Stay of Enrollment

[month] [day], [year]

[Provider/Supplier
Name] [Address]
[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Pursuant to 42 CFR § 424.541, we are placing a stay on your Medicare enrollment record effective [insert day of letter's issuance] because you have not responded to our revalidation request of [date revalidation request letter sent]. Your revalidation was due on [inset date].

During this stay, claims for services and items you furnish during this period will be rejected.

H o w e v e r , this does not affect your Medicare participation agreement or any of its conditions, and you remain enrolled in the Medicare program.

Every [three or five years], CMS requires you to revalidate your Medicare enrollment record information. Failure to submit a revalidation application within 30 days of this notice may result in a deactivation of your Medicare enrollment. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN; however, you will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs revalidating

[Name] | **NPI** [NPI] | **PTAN** [PTAN]

Reassignments:

[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

<Repeat for other reassignments>

The CMS lists the records that need revalidating at:

go.cms.gov/MedicareRevalidation.

How to resume your payments:

- **Revalidate your Medicare enrollment record**, through https://pecos.cms.hhs.gov/pecos/login.do or [Form CMS-855 or Form CMS-20134].

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484- 8049.
- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the stay of enrollment as indicated in 42 C.F.R. § 424.541(b). The rebuttal must be received in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in

response to this stay of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative who is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider's or supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she has the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal request.

The provider's or supplier's failure to submit a rebuttal that is both timely and fully compliant with all of the requirements above constitutes a waiver of all rebuttal rights.
The rebuttal should be sent to the following:

[For non-DMEPOS:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

OR, as applicable

Name and address of MAC

For DMEPOS:

Chags Health Information Technology LLC
P.O. Box 45266 Jacksonville, FL 32232]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

If you need help

Visit **go.cms.gov/MedicareRevalidation**

Call [contractor phone #] or visit [contractorsite.com] for more options.

Sincerely,

[Name]
[Title]
[Company]

B. Imposition of Stay Notification Letter – All Situations Other than Section 10.7.20(A)

Stay of Enrollment

[month] [day], [year]

[Provider/Supplier
Name] [Address]

[City], [State] [Zip Code]

Dear [Provider/Supplier Name],

Pursuant to 42 CFR § 424.541, we are placing a stay on your Medicare enrollment record effective [day of letter's issuance] because [provide explanation, such as "you did not report a new managing employee within 30 days of the change as required under 42 CFR § 424.516 (or 42 CFR § 424.57(c)(2) for DMEPOS suppliers)" or "your current ownership information on file with Medicare is incorrect"].

> [Example of supporting facts and rationale: [ABC, Inc.'s Medicare 855 enrollment record reflects that Jane Doe is the owner, authorized official, director and managing employee of Argo Medical Supplies & Services, Inc. However, CMS has found information on the New York Secretary of State which reveals that John Doe is listed as manager effective October 11, 2023. A manager (which meets the definition of managing employee, per 42 C.F.R. § 424.502) is required to be reported on the 855S enrollment record.]]

During this stay, claims for services and items you furnish during this period will be rejected. H o w e v e r , this does not affect your Medicare participation agreement or any of its conditions, and you remain enrolled in the Medicare program.

[In order to maintain enrollment in the Medicare program, you must submit a CMS 855 Change of Information Application. Failure to do so by [today's date + 30] may result in a deactivation or revocation of your Medicare enrollment. If you are a non-certified provider or supplier, and your enrollment is deactivated, you will maintain your original PTAN; however, you will not be paid for services rendered during the period of deactivation. This will cause a gap in your reimbursement.

What record needs to be updated.

[Name] | **NPI** [NPI] | **PTAN** [PTAN]

[Legal Business Name] | [dba Name] | Tax ID [Tax ID, mask all but last 4 digits]

How to resume your payments:

- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484- 8049.
- **Paper:** Download the right version of [form CMS-855 or Form CMS-20134] for your situation at cms.gov. We recommend getting proof of receipt for your mailing. Mail to [contractor address].

If you have a fee due, use PECOS to pay. If you feel you qualify for a hardship waiver, mail us a request on practice letterhead with financial statements, application form, and certification.

Rebuttal Rights:

If you believe that this determination is not correct, you may rebut the stay of enrollment as indicated in 42 C.F.R. § 424.541(b). The rebuttal must be received in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this stay of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. (Delete next sentence if letter is related to a DMEPOS supplier's enrollment.) Authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider's or supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she has the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal request.

The provider's or supplier's failure to submit a rebuttal that is both timely and fully compliant with all of the requirements above constitutes a waiver of all rebuttal rights.

The rebuttal should be sent to the following:

[For non-DMEPOS:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop: AR-19-51
Baltimore, MD 21244-1850

OR, as applicable

Name and address of MAC

For DMEPOS:

Chags Health Information Technology LLC
P.O. Box 45266
Jacksonville, FL 32232]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 a.m./p.m ET/MT/CT/PT] and [x:00 a.m./p.m ET/MT/CT/PT].

Sincerely,

[Name]

[Title]

[Company]

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R13062PI	03/13/2025	Sixteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication 100-08	04/11/2025	13848
R12796PI	08/15/2024	Fourteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	09/16/3024	13725
R12717PI	07/18/2024	Thirteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	08/19/2024	13683
R12639PI	05/16/2024	Twelfth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	06/17/2024	13551
R12550PI	03/21/2024	Eleventh General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	04/21/2024	13509
R12524PI	03/01/2024	Stay of Enrollment	06/03/2024	13449
R12514PI	02/22/2024	Fourth Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0	03/25/2024	13305
R12393PI	12/07/2023	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Home Health Prospective Payment System (HH PPS) Final Rule	01/02/2024	13333
R12356PI	11/09/2023	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Physician Fee Schedule (PFS) Final Rule	01/02/2024	13331
R12217PI	08/24/2023	Indian Health Service (IHS) Rural Emergency Hospital (REH) Provider Enrollment	01/02/2024	13312
R12209PI	08/17/2023	Tenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	09/17/2023	13308
R12100PI	06/29/2923	Ninth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	07/31/2023	13209
R11949PI	04/13/2023	Third Policy Change Request (CR) Regarding Implementation of the Provider Enrollment,	06/19/2023	13147

Rev #	Issue Date	Subject	Impl Date	CR#
		Chain and Ownership System (PECOS) 2.0		
R11891PI	03/09/2023	Second Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0	06/19/2023	13036
R11839PI	02/09/2023	First Policy Change Request Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0	06/19/2023	12780
R11859PI	02/16/2023	Eighth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	03/17/2023	13061
R11808PI	01/24/2023	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08	01/03/2023	12865
R11771PI	12/302022	Internet-Only Manual (IOM) Updates for Nurse Practitioners (NPs) and Clinical Nurse Specialists (CNSs)	01/31/2023	13029
R11739PI	12/09/2022	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Rescinded and replaced by transmittal 11808	01/03/2023	12865
R11701PI	11/10/2022	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08- No Longer Sensitive-Rescinded and replaced by transmittal 11739	01/06/2023	12865
R11694PI	11/09/2022	Medicare Enrollment of Rural Emergency Hospitals (REHs) – No Longer Sensitive	10/28/2022	12867
R11682PI	11/04/2022	Seventh General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08	12/05/2022	12880
R11637PI	10/07/2022	Provider Enrollment Appeals and Rebuttals - Revised Instructions and Model Letters	12/09/2022	12731
	09/15/2022	Medicare Enrollment of Rural Emergency Hospitals (REHs) **SENSITIVE and CONTROVERSIAL-**Rescinded and replaced by transmittal 11649	10/28/2022	12867
	09/01/2022	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08- **SENSITIVE and CONTERVERSIAL-**Rescinded and replaced by transmittal 11701	01/06/2023	12865

Rev #	Issue Date	Subject	Impl Date	CR#
R11576PI	08/25/2022	Final Round of Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions	09/30/2022	12868
R11574PI	08/25/2022	Sixth General Update to Provider Enrollment Instructions in Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)	09/27/2022	12789
R11536PI	08/05/2022	Provider/Supplier Enrollment Adverse Legal Actions	09/06/2022	12235
R11432PI	05/26/2022	Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions	05/27/2022	12749
R11307PI	03/25/2022	Fifth General Update to Provider Enrollment Instructions in Chapter 10 of Publication (Pub.) 100-08	04/25/2022	12598
R11154PI	12/10/2021	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08	01/03/2022	12502
R11142PI	12/02/2021	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08- Rescinded and replaced by transmittal 11154	01/03/2022	12502
R11139PI	11/23/2021	Revisions to Certified Provider/Supplier Model Letters and Instructions for Processing Initial Skilled Nursing Facility (SNF) Enrollment Applications	01/03/2022	12368
R11125PI	11/18/2021	Update to Enrollment Processing Requirements for Certified Provider/Supplier Change of Ownership (CHOW) and Change of Information (COI) Applications	01/03/2022	12431
R11040PI	10/14/2021	Revisions to Certified Provider/Supplier Model Letters and Instructions for Processing Initial Skilled Nursing Facility (SNF) Enrollment Applications - Rescinded and replaced by transmittal 11139	11/18/2021	12431
R11020PI	10/01/2021	Restructuring of Section 10.4 in Chapter 10 of Publication (Pub.) 100-08	10/29/2021	12412
R10975PI	09/08/2021	Changes of Information Involving Certified Providers and Certified Suppliers	10/08/2021	12386
R10909PI	08/10/2021	Fourth General Update to Chapter 10 of	09/13/2021	12330

Rev #	Issue Date	Subject	Impl Date	CR#
		Publication (Pub.) 100-08		
R10868PI	07/14/2021	Third General Update to Chapter 10 of Publication (Pub.) 100-08	08/13/2021	12284
R10828PI	06/11/2021	Provider Enrollment Rebuttal Process - Additional Instructions for Returning Applications and Deactivations	07/12/2021	12248
R10800PI	05/20/2021	Second General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual	06/22/2021	12162
R10740PI	05/07/2021	Voluntary Terminations of Enrollment Involving Certified Providers and Certified Suppliers	06/07/2021	12160
R10735PI	04/27/2021	Updates to Medicare Administrative Contractor (MAC) Appeals and Rebuttals Reporting	05/27/2021	12157
R10727PI	04/13/2021	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10 of Pub. 100-08, Modification of the Timeliness Standards	02/01/2021	11865
R10723PI	04/08/2021	Implementation of Provider Enrollment Provisions in CMS-6058-FC – Phase 1 – Continued Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08	08/10/2020	11551
R10672PI	03/18/2021	First General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)	03/18/2021	12149
R10674PI	03/19/2021	Second Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)	01/29/2021	12113
R10611PI	03/19/2021	Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08	11/19/2020	11917
R10560PI	01/20/2021	Second Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)- Rescinded and replaced by transmittal 10674	01/29/2021	12113
R10524PI	12/17/2020	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10	11/13/2020	11700
R10467PI	11/13/2020	Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers	11/01/2020	11954
R10481PI	11/18/2020	Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)	11/20/2020	12058

Rev #	Issue Date	Subject	Impl Date	CR#
R10434PI	10/30/2020	Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers – Rescinded and Replaced by Transmittal 10467	11/01/2021	11954
R10355PI	09/18/2020	Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08- Rescinded and replaced by transmittal 10611	11/19/2020	11917
R10353PI	09/11/2020	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10 of Pub. 100-08, Modification of the Timeliness Standards- Rescinded and Replaced by Transmittal 10727	02/01/2021	11865
R10345PI	09/11/2020	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10- Rescinded and replaced by transmittal 10524	11/13/2020	11700
R10239PI	07/28/2020	Implementation of Provider Enrollment Provisions in CMS-6058-FC – Phase 1 – Continued Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08- Rescinded and replaced by transmittal 10723	08/10/2020	11551
R10228PI	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08	08/27/2020	11884
	07/10/2020	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment	06/16/2020	11546
R10146PI	05/22/2020	Implementation of Provider Enrollment Provisions in CMS-6058-FC – Phase 1 – Continued Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08– Rescinded and replaced by Transmittal 10239	07/24/2020	11551
R10182PI	05/152020	Update to Chapter 10 of Publication (Pub.) 100-08 - Model Letter Templates	09/16/2020	11375
R10138PI	06/15/2020	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment)- Rescinded and replaced by Transmittal 10219	06/16/2020	11546

Rev #	Issue Date	Subject	Impl Date	CR#
R434PI	09/14/2012	Removal of Remaining Material from Chapter 10 of the Program Integrity Manual (PIM)	10/16/2012	8026
R416PI	04/13/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM) –Part III	02/27/2012	7698
R405PI	01/26/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM) –Part III – Rescinded and replaced by Transmittal 416	02/27/2012	7698
R386PI	09/01/2011	Ordering/Referring Providers Who Are Not Enrolled in Medicare	04/19/2010	6696
R363PI	01/14/2011	Clarification for Part A Contractors Including Audit and Claims Intermediaries Notifying Each Other via E-mail Upon Processing of the Initial Enrollment Application, Change of Information, Voluntary Termination, or Any Other CMS-855 Transaction	02/15/2011	7221
R356PI	09/24/2010	Manual Redesign	10/26/2010	7083
R354PI	08/27/2010	Manual Redesign	09/28/2010	7016
R347PI	07/15/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15	07/30/2010	6938
R344PI	06/18/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15 - Rescinded and replaced by Transmittal 347	07/05/2011	6938
R339PI	05/21/2010	Cardiac Rehabilitation and Intensive Cardiac Rehabilitation	10/04/2010	6850
R334PI	04/23/2010	Update to Site Verification Process	05/24/2010	6895
R332PI	03/26/2010	Reporting Changes in Surety Bonds	06/28/2010	6854
R329PI	03/19/2010	Change in Provider Enrollment Timeliness Standards for Certain Paper Applications	06/21/2010	6807
R328PI	03/19/2010	Ordering/Referring Providers Who Are Not Enrolled in Medicare – Rescinded and replaced by Transmittal 386	04/19/2010	6696
R326PI	03/12/2010	Revision of the Internet Only Manual to Remove References to “Purchased Diagnostic Test” and Replace With Language Consistent With the Anti-Markup Rule	06/14/2010	6627
R324PI	02/05/2010	Revisions to Model Approval Letters	03/08/2010	6780
R323PI	01/29/2010	Verification of Legal Status	03/29/2010	6748
R322PI	01/15/2010	Durable Medical Equipment (DME MAC) and the National Supplier Clearinghouse (NSC MAC) Procedures for Third Party Notification of	7/06/2010	6714

Rev #	Issue Date	Subject	Impl Date	CR#
		Deceased Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) Supplier Associates		
R321PI	12/30/2009	Verification of Legal Status Rescinded and replaced by Transmittal 323	03/29/2010	6748
R320PI	12/23/2009	Provider Enrollment Revisions	01/25/2010	6645
R318PI	12/18/2009	Implementation of Home Health Agency Program Safeguard Provisions - Rescinded	01/01/2010	6750
R316PI	12/04/2009	Administrative Appeals Process for Provider Enrollment	01/04/2010	6487
R315PI	12/04/2009	Provider Enrollment and Veteran's Administration (VA) Hospitals	03/08/2010	6735
R314PI	11/27/2009	Clarification of Deactivation Instructions	12/28/2009	6734
R312PI	11/20/2009	Home Health Agency (HHA) Capitalization Requirements	12/21/2009	6732
R307PI	10/23/2009	Establishing New Practice Locations in a Different State	01/25/2010	6649
R306PI	10/02/2009	Site Verifications	11/02/2009	6639
R304PI	09/25/2009	Inter-Contractor Communication and Provider Enrollment Revocations	10/26/2009	6642
R300PI	09/01/2009	Compliance Standards for Consignment Closets and Stock and Bill Arrangements - Rescinded	03/01/2010	6528
R299PI	08/28/2009	Updates to Model Rejection, Returned Application, Revalidation, Approval, Denial/Revocation Letters and Identity Theft Prevention Letter	09/28/2009	6527
R297PI	08/07/2009	Compliance Standards for Consignment Closets and Stock and Bill Arrangements - Rescinded and replaced by Transmittal 300	09/08/2009	6528
R296PI	07/10/2009	Provider Enrollment Verification Activities	08/10/2009	6499
R295PI	06/29/2009	Revision to Certain Instructions Related to Provider Enrollment Deactivations and Revocations	07/27/2009	6491
R291PI	06/12/2009	Reassignment and Ambulatory Surgical Centers (ASCs)	10/05/2009	6470
R289PI	04/15/2009	Incorporation of Physician Fee Schedule Regulatory Changes	04/01/2009	6310
R288PI	04/02/2009	Incorporation of Physician Fee Schedule Regulatory Changes - Rescinded and replaced by Transmittal 289	04/01/2009	6310

Rev #	Issue Date	Subject	Impl Date	CR#
R287PI	03/27/2009	Surety Bonds for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)	04/06/2009	6392
286PI	03/13/2009	Incorporation of Physician Fee Schedule Regulatory Changes – Rescinded and replaced by Transmittal 288	04/01/2009	6310
R284PI	02/20/2009	Model Letter Updates	03/20/2009	6244
R280PI	12/31/2008	Incorporation of Recent Regulatory Revisions Pertinent to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)	02/02/2009	6282
R277PI	12/19/2008	Additional Provider Enrollment Verification and Program Integrity Activities	01/20/2009	6097
R276PI	12/19/2008	Deceased Individuals and the Provider Enrollment Process	01/20/2009	6194
R275PI	12/12/2008	Administrative Appeals for Provider Enrollment	01/12/2009	6248
R272PI	11/07/2008	Clarification of Provider Enrollment Procedures Involving Certified Suppliers and Providers	12/08/2008	6151
R271PI	10/24/2008	Instructions for the Implementation of the Internet-Based Provider Enrollment, Chain and Ownership System (PECOS)	11/24/2008	6231
R269PI	09/19/2008	Incorporation of Recent Regulatory Revisions into Chapter 10 of the Program Integrity Manual	10/20/2008	6178
R266PI	09/05/2008	Model Letters	10/06/2008	6051
R261PI	06/27/2008	Update to Section 12 of Chapter 10 of the Program Integrity Manual	07/28/2008	6071
R260PI	06/20/2008	Clarification of Chapter 10	07/22/2008	6065
R251PI	04/11/2008	Administrative Appeals for Provider Enrollment	05/12/2008	5826
R246PI	03/14/2008	Clarification of Items in Chapter 10	04/14/2008	5952
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