

Medicare Program Integrity Manual

Chapter 10 – Medicare Enrollment

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(Rev. 10138, 05-15-20)

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10.1 – Introduction to Medicare Provider Enrollment

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This chapter specifies the resources and procedures Medicare administrative contractors (MAC) must use to establish and maintain provider and supplier enrollment in the Medicare program. These procedures apply to the MACs and the National Supplier Clearinghouse (NSC), unless contract specifications state otherwise.

10.1.1 – Definitions

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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 CMS-855 enrollment forms, you are adding additional enrollment information to your existing information (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).

Administrative Location means a physical location associated with a Medicare Diabetes Prevention Program (MDPP) supplier’s operations, from where coaches are dispatched or based, and where 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 receive a Medicare billing number and be granted Medicare billing privileges.

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.

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 100-04, chapter 1, section 30.2.4.)

Change - For purposes of completing the CMS-855 or CMS-20134 enrollment forms, 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) during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA'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 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 most recent change in majority 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 specified.

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 their 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 CMS-855 enrollment forms, 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 receive Medicare billing privileges.

Effective Date: 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 ordering or certifying Medicare-covered items and services. This is not the same as a reactivation effective date. A provider or supplier (with the exclusion of DMEPOS suppliers) may challenge an 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 CMS-855 or CMS-20134 enrollment application or the equivalent electronic enrollment process approved by the Office of Management and Budget (OMB).

Final adverse legal action means one or more of the following actions:

Convictions (as defined in 42 C.F.R. section 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 (i.e. Civil Monetary Penalties (CMP)).
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.

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, Form CMS-20134, 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 that 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.

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).

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.

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 Publication 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.

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 424.521(a).

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

Supplier is defined in 42 CFR § 400.202 and means a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare.

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.

10.2 – Provider and Supplier Types/Services

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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 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

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A. Community Mental Health Centers (CMHCs)

1. General Background Information

A community mental health center (CMHC) is a facility that provides mental health services. A CMHC must perform certain “core services.” These are:

*a. **Outpatient services** (This includes services for (1) children, (2) the elderly, (3) persons who are chronically mentally ill, and (4) certain persons who have been discharged from a mental health facility for inpatient treatment.)*

*b. **24-hour-a-day emergency psychiatric services;***

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

*d. **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 regional office (RO). (See Pub. 100-07, State Operations Manual (SOM), 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. A CMHC (or CMHC site) that operates outside of this specific community must – unless the RO holds otherwise - have a separate provider agreement/number and enrollment, and must individually meet all Medicare requirements.

2. For more information on CMHCs, refer to:

- *Section 1861(ff) of the Social Security Act*
- *42 CFR Sections 410.2, 410.43, and 410.110*
- *Pub. 100-07, chapter 2, sections 2250 – 2252P*

See sections 10.2.1(A)(3)(a) through 10.2.1(A)(3)(b) of this chapter for additional information on CMHC site visits.

3. Initial Enrollment and Certification

a. CMHC Conditions of Participation: Federal Regulations That Apply Beginning October 29, 2014

Effective October 29, 2014, CMHCs will be 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, will therefore be required to undergo a State survey as part of the certification and enrollment process. The RO will no longer be performing the site visit discussed in section (B)(1) nor will the above-referenced attestation statement be required. 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.

b. Site Visit - Initials Post Tie In

The contractor shall order a site visit of the CMHC through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the CMHC. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

i. Practice Locations/Alternative Sites

A CMHC must list in Section 4 of its Form CMS-855A all alternative sites where core services are provided (i.e., proposed alternative sites for initial applicants and actual alternative sites for those CMHCs already participating in Medicare). The RO will decide whether the site in question: (1) can be part of the CMHC's enrollment (i.e., a practice location), or (2) should be enrolled as a separate CMHC with a separate provider agreement. The practice location could be out-of-state if the RO determines that the location services the same "defined geographic area" as the main location. In all cases, the RO makes the final determination as to whether a particular practice location qualifies as an alternative site or whether a separate enrollment, provider agreement, etc., is required. If the contractor is unsure as to whether the

location requires a separate enrollment and provider agreement, it may contact the RO for clarification.

If a CMHC 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 after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

The contractor may refer to Pub. 100-07, SOM, chapter 2, section 2252, for additional information on CMHC alternative sites. Particular attention should be paid to the following provisions in section 2252I, regarding alternative sites:

- If a CMHC operates a CMS-approved alternative site, the site is not required to provide all of the core services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC.*
- RO approvals of such alternative sites should be very limited because (1) CMHCs must serve a distinct and definable community, and (2) CMS has not limited the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities.*
- The RO will inform the CMHC if it determines that the proposed alternative site must be separately approved because it is not a part of the community where the CMHC is located.*

ii. Changes of Information that Require Site Visits

If the CMHC submits a Form CMS-855A change application, the contractor shall order a site visit through PECOS for changes of address. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

iii. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

4. CMHC 40 Percent Rule

a. Background

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, as 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 contractor shall abide by the following:

i. 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 Pub. 100-08, Chapter 15, Section 15.8.2.

ii. 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(A). 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.

Sections (B)(1) and (2) above do not apply if the contractor determines that the Form CMS-855 can be returned under Pub. 100-08, Chapter 15, Section 15.8.1.

If the contractor exceeds applicable timeliness standards due to the instructions in this section 10.2.1(A), the contractor shall accordingly document the provider file consistent with section 15.23 of Pub. 100-08, Chapter 15.

iii. Special Guidelines

The following guidelines apply:

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.

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

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.

B. Comprehensive Outpatient Rehabilitation Facilities (CORFs)

1. 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 regional office (RO) 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, State Operations Manual (SOM), 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 (OPT/SLP) 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.*

2. Enrollment Information

a. Offsite Locations

Notwithstanding the “single fixed location” language cited in subsection A above, there may be isolated cases where the RO 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 Form CMS-855A application.

b. Site Visits

- Initial application – If a CORF submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing*

privileges to the CMHC. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

ii. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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 - 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 after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

3. 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, sections 2360 – 2366 (SOM)*
- *Pub. 100-07, chapter 3, section 3224 (SOM)*
- *Pub. 100-07, Appendix K (SOM)*
- *Pub. 100-02, chapter 12 (Benefit Policy Manual)*

See also Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional CORF site visit information.

C. End-Stage Renal Disease Facilities (ESRDs)

1. General Background Information

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

As ESRD facilities are technically “suppliers,” they sign a supplier agreement rather than a provider agreement. Even if the ESRD facility is a hospital unit, it signs an agreement that is separate and distinct from the hospital’s agreement.

ESRDs entities/facilities cannot be mobile.

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). (§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. (There are currently 18 Network organizations.) The organizations oversee the care that ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

2. For further information on ESRD facilities, refer to:

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

3. Types of ESRD Facilities

There are several types of ESRD facilities:

a. Renal Transplantation Center (RTC)

An RTC is a hospital unit approved to furnish – directly - transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. An RTC must be a member of the Organ Procurement and Transplantation Network (OPTN).

b. Renal Dialysis Center (RDC)

An RDC is a hospital unit approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement and outpatient dialysis). Also:

- *The RDC need not furnish transplantation services.*
- *An RTC can also be an RDC.*
- *The RDC must be hospital-owned and operated, and the hospital must be enrolled in Medicare.*

A separate, independent dialysis unit located in a Medicare-approved hospital cannot be approved as an RTC or RDC. (See Pub. 100-07, State Operations Manual, chapter 2, section 2280.1.)

c. Renal Dialysis Facility (RDF)

This is a unit (but not necessarily a hospital unit) approved to furnish dialysis services directly to ESRD patients. A hospital (whether enrolled or not) can be an RDF if it is an outpatient provider of dialysis services that will not be furnishing inpatient dialysis services. A hospital-based RDF “satellite” is one that is hospital-owned and administered but is not located on the hospital’s premises. A hospital can have multiple RDF satellites.

d. Self-Dialysis Unit (SDU)

An SDU is a unit of an approved RTC, RDC or RDF that provides self-dialysis services.

e. Special Purpose Renal Dialysis Facility (SPRDF)

SPRDFs are entities that perform ESRD services on a short-term basis in special situations for patients who cannot otherwise receive treatment in the geographical area. SPRDFs can be approved to serve vacation areas and in emergency situations. (See Pub. 100-07, State Operations Manual, chapter 2, section 2280D for more information on SPRDFs.) Like RTCs, RDCs, RDFs, and SDUs, SPRDFs must submit a Form CMS-855A to the contractor.

4. ESRD Enrollment

Each type of ESRD facility must enroll as an ESRD facility via the Form CMS-855A. Since the Form CMS-855A does not distinguish between the different types of ESRD facilities, the following principles apply:

a. If an enrolled RTC also wants to become an RDC, the provider must submit a new, complete Form CMS-855A for the RDC. For enrollment purposes, the RTC and the RDC will be treated as two separate ESRD facilities.

b. If an enrolled ESRD wants to change to another type of ESRD, the provider need not submit a Form CMS-855A change of information (assuming that this is the only change to the provider's enrollment data).

c. ESRD facilities can have multiple practice locations if the RO approves it, though this typically only occurs with RDFs.

5. ESRD Survey and Certification

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. Part I of this form must be completed, as must the Form CMS-855A, when the ESRD is initially enrolling, changing or adding a location, or undergoing a change of ownership (CHOW). Part I must also be completed for: (1) a change in service and (2) an expansion or addition of ESRD stations. However, the Form CMS-855A need not be furnished in these two latter instances (e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A), though the RO may issue a tie-in notice or approval letter to the contractor as notification of the change. Also, because the "End-Stage Renal Disease Facility" category on the Form CMS-855A encompasses all five ESRD categories, it is not necessary for the facility to submit a Form CMS-855A if it is changing from one ESRD type to another, though it must complete the Form CMS-3427. (See Pub. 100-07, State Operations Manual, chapter 2, sections 2274 – 2276 and 2278 – 227, for more information on the Form CMS-3427 requirement.)

If the RO approves the station/service change or addition, it may send a tie-in notice or approval letter to the contractor updating the number of stations or types of services.

6. Site Visits

Site visits for ESRDs are performed during the survey and certification process by the state agency.

D. Federally Qualified Health Centers (FQHCs)

1. General Background Information

FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, and clinical social workers. This also includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See CMS Publication 100-02, chapter 13, for more information). Even though they complete the Form CMS-855A application, FQHCs are considered Part B certified suppliers.

FQHCs are not required to obtain a State survey; there is no State agency involvement with FQHCs. As such, the contractor will either deny the application or make a recommendation for approval and forward it directly to the RO. The RO will then make the final decision as to whether the entity qualifies as a FQHC.

Generally, in order to so qualify, the facility must be receiving, or be eligible to receive, the following types of Federal grants

- Is receiving a grant under Section 330 of the Public Health Service (PHS) Act;*
- Is receiving funding under a contract with the recipient of a Section 330 grant, and meets the requirements to receive a grant under §330 of the PHS Act;*
- Is an FQHC “Look-Alike,” i.e., the Health Resources and Services Administration (HRSA), has notified the facility it has been determined to meet the requirements for receiving a Section 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.*

The Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (DHHS) may assist the RO in determining whether a particular supplier meets FQHC standards, since HRSA maintains a list of suppliers that met certain grant requirements. (See CMS Pub. 100-07, chapter 2, sections 2825-2826D for more information.)

When sending a recommendation for approval letter to the RO for an initial FQHC application, the contractor shall indicate in the letter 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; the contractor thus requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its letter as the date the application was complete.

2. Additional information about FQHCs:

a. As stated above, there is no State agency involvement with FQHCs. However, FQHCs still must meet all applicable State and local requirements and submit all applicable licenses. Typically, HRSA will verify such State/local compliance by asking the FQHC to attest that it meets all State/local laws.

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

c. To qualify as an FQHC, the facility must, among other things, either (1) furnish services to a medically underserved population or (2) be located in a medically underserved area.

d. The FQHC must submit a signed and dated Attestation Statement for Federally Qualified Health Centers (Exhibit 177). This attestation serves as the Medicare FQHC benefit (or provider/supplier) agreement. (See Pub. 100-07, chapter 2, section 2826B.) The FQHC must also submit, as indicated above, a HRSA “Notice of Grant Award” or Look-Alike Status. A completed FQHC crucial data extract sheet (Exhibit 178), however, is no longer required.

e. The contractor shall ensure that the attestation statement (Exhibit 177) contains the same legal business 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.

f. An FQHC cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own CMS Certification Number.

3. Site Visits

Site visits for FQHCs are performed by the Health Resources and Services Administration (HRSA) prior to enrollment.

4. 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 405.2400*
- *Pub. 100-07, chapter 2, sections 2825 – 2826H*
- *Pub. 100-07, Exhibit 179*
- *Pub. 100-04, chapter 9 (Claims Processing Manual)*
- *Pub. 100-02, chapter 13 (Benefit Policy Manual)*

For information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see:

- *Pub. 100-04, chapter 1, section 20*
- *Pub. 100-04, chapter 9, section 10.3*

E. Histocompatibility Laboratories

1. General Background Information

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 493¹ (see 42 CFR §493.1 in particular) and undergo a State survey.

2. Additional Information

For information on the appropriate contractor jurisdiction for incoming histocompatibility lab applications, see CMS Pub. 100-04, chapter 1, section 20.

F. Home Health Agencies (HHAs)

1. General Background 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. All HHA services, moreover, must be part of a plan of care established by a physician, accompanied by a certification from the physician that the patient needs home health services. HHA services can be covered even if the patient lives with someone who might ordinarily be able to perform such services himself/herself.

2. Site Visit Requirements

See Pub. 100-08, Chapter 15, Section 15.19.2.2 for more information on HHA site visit requirements.

3. HHA Components

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 is a location or site that services patients in the same geographic area as the parent and shares administration with the parent on a daily basis. Branches need not enroll separately. They can 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 number.

See Pub. 100-07, chapter 2, section 2182, for more information on branches.

4. Out-of-State HHA Branches

¹ Clinical laboratory certification is handled by the Food and Drug Administration

In general, an HHA can only have a branch in another State (and treat it as a branch, rather than a separate HHA) if there is a reciprocity agreement between the two States. If none exists, the out-of-state location must enroll as a new provider by submitting a new Form CMS-855A and signing a separate provider agreement. It cannot be treated as a branch/practice location of the main HHA. (See Pub. 100-07, chapter 2, section 2184 for specific provisions regarding HHAs that cross State lines.)

5. Home Health Agency (HHA) Branches

As explained in section 10.2.1(F)(3), a branch is a location or site from which an HHA provides services within a portion of the total geographic area that the parent company serves. The branch is part of the HHA and is located sufficiently close to the parent agency such that it shares administration, supervision, and services with the parent. If an existing HHA wants to add a branch, it is considered a change of information on the Form CMS-855A.

If the contractor makes a recommendation for approval of the provider's request to add an HHA branch, the contractor shall forward the package to the State agency as described in this chapter. However, the contractor shall emphasize to the provider that a recommendation for approval of the branch addition does not signify CMS's approval of the new location. Only the RO can approve the addition.

With respect to the PECOS, the contractor does not need to create a separate enrollment record for each HHA branch. These locations can simply be listed on the main provider's enrollment record.

6. Verification of HHA Sites

HHAs are not permitted to share a practice location address. If the contractor receives an application from an HHA that has the same general practice location address as another enrolled (or enrolling) HHA and the contractor has reason to suspect that the HHAs may be concurrently operating out of the same suite or office, the contractor shall notify the National Site Visit Contractor of this at the time the contractor orders the required site visit through PECOS. If the site visit uncovers two HHAs operating within the same practice location address, the contractor shall deny/reject the application for enrollment.

7. 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.)

8. HHA Ownership Changes

Background

Effective January 1, 2011, and in accordance with 42 CFR §424.550(b)(1) - if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's 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 must instead:

- *Enroll in the Medicare program as a new (initial) HHA 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 during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA'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 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 most recent change in majority ownership.

a. Exceptions

There are several exceptions to §424.550(b)(1). Specifically, the requirements of §424.550(b)(1) do not apply if:

- *The HHA has submitted 2 consecutive years of full cost reports. (For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.)*
- *The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.*
- *The HHA 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.*
- *An individual owner of the HHA dies.*

In addition, §424.550(b)(1) does not apply to “indirect” ownership changes.

b. Applicability

As indicated earlier, the provisions of 42 CFR §424.550(b)(1) and (2) as enacted in “CMS-6010-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule” – are effective January 1, 2011. This means that these provisions impact only those HHA ownership transactions whose effective date is on or after January 1, 2011. However, the provisions can apply irrespective of when the HHA first enrolled in Medicare. Consider the following illustrations:

- Example 1 – Smith HHA initially enrolls in Medicare effective July 1, 2009. Smith undergoes a change in majority ownership effective September 1, 2011. 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 HHA initially enrolls in Medicare effective July 1, 2007. Jones undergoes a change in majority ownership effective February 1, 2011. 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, 2012. Section 424.550(b)(1) would apply to this transaction because it took place within 36 months after Jones’s most recent change in majority ownership (i.e., on February 1, 2011).*
- Example 3- Johnson HHA initially enrolls in Medicare effective July 1, 2006. It undergoes a change in majority ownership effective October 1, 2010. This transaction is not affected by §424.550(b)(1) – as enacted in CMS-6010-F – because: (1) its effective date was prior to January 1, 2011, and (2) it occurred more than 36 months after the effective date of Johnson’s initial enrollment. Johnson undergoes another change in majority ownership effective October 1, 2012. This change would be affected by §424.550(b)(1) because it occurred within 36 months of the HHA’s most recent change in majority ownership (i.e., on October 1, 2010).*
- Example 4 – Davis HHA initially enrolls in Medicare effective July 1, 1999. It undergoes its first change in majority ownership effective February 1, 2011. This change is not affected by §424.550(b)(1) because it occurred more than 36 months after Davis’s initial enrollment. Davis undergoes another change in majority ownership effective July 1, 2014. This change, too, would be unaffected by §424.550(b)(1), as it occurred more than 36 months after the HHA’s most recent change in majority ownership (i.e., on February 1, 2011). Davis undergoes another majority ownership change on July 1, 2016. This change would be 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 July 1, 2014).*

c. Section 424.550(b)(1)'s Applicability (36-Month Rule)

If the contractor receives a Form CMS-855A application reporting an HHA 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.*

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, this would constitute a change in majority ownership. This is consistent with the verbiage in the aforementioned 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. 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: (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 – regarding the

effective date of the HHA'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. If the transfer's effective date falls within one of these 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 also determine whether any of the exceptions in §424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

i. The HHA 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. As stated in CMS Pub. 15-2, Provider Reimbursement Manual, Part 2, section 3204, please refer to 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 parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

iii. The HHA 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 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 Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance.

B. For the exemption to apply, the owners must remain the same.

iv. An individual owner of the HHA dies – regardless of the percentage of ownership the person had in the HHA.

d. 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. If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor take action against the HHA without the prior approval of PEOG. If PEOG agrees with the contractor's determination, the contractor shall send a letter to the HHA notifying it that, as a result of §424.550(b)(1), the HHA must:

- Enroll as an initial applicant; and
- Obtain a new state survey or accreditation after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the State/RO.

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. The effective date of the deactivation shall be the date the HHA is notified that it must enroll as an initial applicant. If the sale has not occurred, the contractor shall alert the HHA that it must 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.

e. Additional Notes

The contractor is advised of the following:

- If the contractor learns of an HHA ownership change by means other than the submission of a CMS-855A application, it shall notify its PEOG BFL immediately.*
- If the contractor determines, under Step 3 above, that one of the §424.550(b)(2) exceptions applies, 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 undergoes 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 undergoes another change in majority ownership that did not qualify for an exception. The HHA must 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).*

9. Capitalization

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 as a result of a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds, which we term 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 Medicare billing privileges are conveyed by the Medicare contractor (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:

- Prior to making its recommendation for approval;*
- After a recommendation for approval is made but before the RO review process is completed;*
- After the RO review process is completed but before the contractor conveys Medicare billing privileges to the HHA; and*
- 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 or reactivation applications.) The contractor may request from the provider any and all documentation deemed necessary to perform this task.

The HHA must submit proof of capitalization within 30 calendar days of being requested to do so by the contractor. 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 believe it is 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 RO review process – the contractor shall seek approval from its DPSE liaison.

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 3 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 using reported cost and visit data from submitted cost reports for the first full year of operation from at least 3 HHAs that the contractor serves that are comparable to the HHA that is 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 determination of 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

The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, must include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA.

In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, 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 in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section 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 another attestation from the financial institution that the funds remain available, or, if applicable, 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

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, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by 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, including furnishing an attestation from a financial institution or other source, as may be appropriate, and 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.

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 provider:*
- A document outlining the provider'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)*
- *Letter from 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 CMS-855A is provided.

10. Additional Home Health Agency (HHA) Review Activities:

As stated in section 10.2.1(F)(9) of this chapter, the contractor must verify that a newly enrolling HHA has the required amount of capitalization after the regional office (RO) review process is completed but before the contractor conveys Medicare billing privileges to the HHA. Accordingly, the HHA must submit proof of capitalization during this “post-RO review” period.

To confirm that the HHA is still in compliance with Medicare enrollment requirements prior to the issuance of a provider agreement, the contractor shall also – during the post-RO review period 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) (formerly the General Services Administration (GSA) Access Management System). This activity applies: (1) regardless of whether the HHA is provider-based or freestanding, and (2) only to initial enrollments.

The capitalization and MED/SAM re-reviews described above shall be performed once the RO notifies the contractor via e-mail that the RO’s review is complete. (Per sections 10.2.1(F)(6) and Pub. 100-08, Chapter 15, Section 15.19.2.2, a site visit will be performed after the contractor receives the tie-in/approval notice from the RO but before the contractor conveys Medicare billing privileges to the HHA.) If:

a. The HHA is still in compliance (e.g., no owners or managing employees are excluded, capitalization is met):

i. The contractor shall notify the RO of this via e-mail. The notice shall specify the date on which the contractor completed the aforementioned reviews.

ii. The RO will: (1) issue a CMS Certification Number (CCN), (2) sign a provider agreement, and (3) send a tie-in notice or approval letter to the contractor. Per section 15.7.4 of Pub. 100-08, Chapter 15, the contractor

shall complete its processing of the tie-in notice/approval letter within 45 calendar days of receipt (during which time a site visit will be performed).

iii. Upon receipt of RO's notification, contractor will perform capitalization reviews discussed in section 10.2.1(F)(9) and OIG/SAM reviews discussed in Section 10.2.1(F)(10) of this chapter.

b. The HHA is not in compliance (e.g., capitalization is not met):

i. The contractor shall deny the application in accordance with the instructions in this chapter and issue appeal rights. (The denial date shall be the date on which the contractor completed its follow-up capitalization and OIG/SAM reviews.)

ii. Notify the RO of the denial via e-mail. (PEOG, not the RO, will handle any CAP or appeal related to the contractor's denial.)

iii. Upon receipt of RO's notification, contractor will perform capitalization reviews discussed in section 10.2.1(F)(9) and OIG/SAM reviews discussed in section 10.2.1(F)(10) of this chapter.

11. 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/RO 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.

12. 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, sections 2180 – 2198C (State Operations Manual)*
- Pub. 100-04, chapter 10 (Claims Processing Manual)*
- Pub. 100-02, chapter 7 (Benefit Policy Manual)*

G. Hospices

1. 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 the a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

2. Enrollment Information

a. Multiple Practice Locations

Hospices are not precluded from having multiple practice locations if permitted by the regional office (RO). If the RO 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, State Operations Manual (SOM), chapter 2, section 2081, for the policies regarding multiple hospice locations.)

b. Site Visits

i. Initial application – If a hospice submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the hospice. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

ii. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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 - 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 after the contractor receives notice of approval from the RO but before the contractor switches the provider's enrollment record to "Approved." 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

3. 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 – 2087 (SOM)*
- *Pub. 100-04, chapter 11 (Claims Processing Manual)*
- *Pub. 100-02, chapter 9 (Benefit Policy Manual)*

See Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional hospice site visit information.

H. Hospitals and Hospital Units

1. General Background Information

Hospitals and hospital units are a provider type that enrolls via the form CMS-855A, except 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 enrollment application is required*
- *Enrollment Form CMS-855B is the required application form*

2. Enrollment Information

a. 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 CMS Certification Number (CCN) to bill for swing-bed services. (The third digit of the CCN will be the letter U, W, Y or Z.)

As stated in 42 CFR §482.66, in order to obtain swing-bed status the hospital – among other things – must: (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. 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, State Operations Manual, chapter 7, sections 2036 – 2040.

b. 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.

c. Multi-Campus Hospitals

A multi-campus hospital (MCH) has two or more hospital campuses operating under one CCN number. The MCH would report its various units/campuses as practice locations on the Form CMS-855A. A hospital that has its own main campus but also occupies space in another hospital has a "satellite facility" in that other hospital.

For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

d. Physician-Owned Hospitals

A physician-owned hospital 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, Physician Owned Hospitals (POHs) are not required to submit a completed CMS-855POH or a completed Attachment 1 of the 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.

e. Critical Access Hospitals

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

f. 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.

g. Transplant Centers

For purposes of Medicare enrollment, a hospital transplant center is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant center, it must check the "other" box in section 2A2 of the CMS-855A, write "transplant center" on the space provided, and follow the standard instructions for adding a sub-unit. Unless CMS indicates otherwise, the contractor shall process the application in the same manner it would the addition of a hospital sub-unit; however, no separate enrollment in PECOS need be created for the transplant center.

3. Other Enrollment Procedures

*Regarding Section 4 of the Form CMS-855A, a hospital or other provider 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 provider'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 - for purposes of entry into the Provider Enrollment, Chain and Ownership System (PECOS). **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 a rehabilitation, psychiatric, or swing-bed unit, it should submit a Form CMS-855 change of information request and not an initial enrollment application. With respect to the Provider Enrollment, Chain and Ownership System, the contractor shall create a separate enrollment record for the hospital unit.

4. 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.

5. Form CMS-855B Applications Submitted by Hospitals

a. 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), it is not necessary for the contractor to wait until the provider agreement is issued before conveying billing privileges to the group.

b. Individual Billings

Assume an individual physician works for a hospital and will be billing 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).

I. Indian Health Services (IHS) Facilities

1. 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 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 it is dealing with an IHS facility.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, skilled nursing facilities (SNFs), critical access hospitals, or end-stage renal disease 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 CCN numbers, 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.

2. 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*

In Section 2 of the Form CMS-855A and Form CMS-855B applications, the provider or supplier must identify whether it is an Indian Health Facility enrolling with Novitas.

3. 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 (IHCIA) to provide as follows:

Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, 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, 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 CMS 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 sections 10.2.3(A) through 10.2.3(N) of this chapter.

4. Additional Information

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

J. Organ Procurement Organizations (OPOs)

1. 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. There are three general steps involved in becoming a Medicare OPO: enrollment, certification and designation.

Certification means that CMS has determined that an OPO meets the requirements for certification at 42 CFR §486.303. It does not mean, however, that the OPO can begin billing for services. CMS must first assign (or “designate”) a geographic service area to the OPO. (The provider must also complete the Form CMS-576, Request for OPO Designation.) In practical terms, “designation” means that CMS has approved the OPO for coverage of services to transplant centers and that the OPO can begin submitting claims to Medicare.

There can be only one designated OPO per geographic service area. When an OPO is de-certified and its service area is opened for competition, the applicable CMS regional office publishes a notice in local newspapers. CMS then selects an OPO to take over the service area, using the process at 42 CFR §486.316. The OPO that CMS selects must first have been certified by CMS and must meet the qualifications for designation at 42 CFR §486.304. The OPO must also sign a 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.) Note that OPOs do not receive a State survey.

2. Additional Information

For more information on OPOs, refer to:

- *Section 1138 of the Social Security Act*
- *42 CFR §486.301 - §486.348*

- *Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).*

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. However, the hospital's Medicare contractor will service the OPO, and the OPO will not receive its own CMS Certification Number.

K. Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)

1. 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.

2. Enrollment Information

a. Providers of OPT/OSP Services

There are three types of certified providers of OPT/OSP services:

- ***Rehabilitation Agencies*** – *These facilities furnish services in a team environment and in accordance with a “multidisciplinary” program to assist handicapped and disabled individuals. They provide not only OPT/OSP services, but social or vocational adjustment services as well. (See CMS Pub. 100-07, chapter 2, section 2292A.) The overwhelming majority of Part A OPT/OSP providers are rehabilitation agencies.*
- ***Clinics*** – *A clinic is created primarily for the provision of outpatient physician services. The entity's services must be furnished by a group of at least three physicians practicing medicine together, and at least one physician must be present in the clinic at all times to perform medical services.*
- ***Public Health Agency*** – *This is an agency created by a State or local government. Its primary purpose is to furnish environmental health services, preventive medical services and, in some instances, therapeutic services, as a means of sustaining the health of the general population.*

Note that:

- *If an OPT/OSP provider elects to convert to a comprehensive outpatient rehabilitation facility (CORF), it must meet the CORF conditions of coverage and participation. An initial Form CMS-855A enrollment application, State survey, and CMS regional office approval are also required.*

- *Only those clinics (as listed above) that provide OPT/OSP services 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 provider or 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.)*

b. Extension Locations

As discussed in Pub. 100-07, chapter 2, section 2298A, an OPT/OSP provider can furnish services from locations other than its primary site. (The provider must designate one location as its primary location, however.) These sites are called extension locations. They may include freestanding offices, suites in an office or medical building, or even space in an existing Medicare provider, such as a skilled nursing facility or hospital. Yet the separate area of the host provider or facility must be set aside for the provision of OPT/OSP services during the hours of the OPT/OSP provider’s operations. (The area/room/unit would be considered the extension location.)

An OPT/OSP provider may also furnish therapy services in a patient’s home or in a patient’s room in a SNF. Because they 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.)

For an OPT/OSP provider to establish an extension location in an adjoining State, the two States involved must have a signed reciprocity agreement with each other allowing approval of the extension location. An extension location situated in a different State will bill under the primary site’s provider number. (See Pub. 100-07, chapter 2, section 2302.)

If an OPT/OSP provider wants to add an extension site, a change of information request should be submitted.

With respect to the Provider Enrollment, Chain and Ownership System, a separate enrollment record for each OPT/OSP extension site is not required. These locations can simply be listed on the main provider’s enrollment record.

c. 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 – 2306 (State Operations Manual)*

- *Pub. 100-07, Appendix E*

L. Religious Non-Medical Health Care Institutions (RNHCIs)

1. 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 by nonmedical nursing personnel and include activities such as assistance in moving, comfort and support measures, and general assistance in performing day-to-day activities. (The nonmedical nursing personnel must be experienced in caring for the physical needs of nonmedical patients.) 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 CMS Pub. 100-07, chapter 2, section 2054.1B.)

CMS’s Boston regional 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 outlined in 42 CFR §403.730 through 403.746. 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).*

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

2. Additional Information

For more information on RNHCIs, 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, 20541A and 2054.1 (State Operations Manual)*
- *Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual)*
- *Pub. 100-02, chapter 1, sections 130 – 130.4.2 (Benefit Policy Manual)*

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

M. Rural Health Clinics (RHCs)

1. General Background Information

Rural health clinics (RHCs):

- *Are considered to be Part B certified suppliers, even though they enroll in Medicare via the Form CMS-855A.*
- *Must be primarily engaged in furnishing outpatient services. However, the services can, in certain instances, be performed in locations outside of the four walls of the clinic. (See CMS Pub. 100-02, chapter 13 for more information.)*
- *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).*
- *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.*
- *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:*
- *Unlike FQHCs, which can service rural or urban regions, an RHC may only service an area that: (1) is rural, and (2) contains a shortage of health services or qualified medical personnel (otherwise known as a “shortage area”). (See Pub. 100-02, chapter 13, section 10, which states that RHCs are clinics located in areas that are designated by (1) the Bureau of the Census as rural, and (2) the*

Secretary of the Department of Health and Human Services or the State as medically underserved.)

- *FQHCs furnish preventive services. RHCs do not.*
- *RHCs are surveyed by the State. FQHCs are not.*

2. 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 (State Operations Manual)*
- *Pub. 100-04, chapter 9 (Claims Processing Manual)*
- *Pub. 100-02, chapter 13 (Benefit Policy Manual)*

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, refer to:

- *Pub. 100-04, chapter 1, section 20*
- *Pub. 100-04, chapter 9, section 10.3*

N. Skilled Nursing Facilities (SNFs)

1. General Background Information

As stated in CMS Pub. 100-07, State Operations Manual, chapter 7, section 7004B, 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 and is not primarily for the care and treatment of mental diseases;*
- *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.*

The transfer agreement mentioned above need not be submitted with the SNF's Form CMS-855A enrollment application; the State and/or CMS regional office (RO) will verify that the agreement exists.

Like other certified providers, SNFs receive a State survey and sign a provider agreement. SNFs cannot have multiple practice locations.

2. 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 CMS Certification Number (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.)

3. Additional Information

For more information on SNFs, refer to:

- *Section 1819 of the Social Security Act*
- *Pub. 100-07, State Operations Manual, chapter 7*
- *Pub. 100-02, Benefit Policy Manual, chapter 8*

10.2.2 – Suppliers That Enroll Via the Form CMS-855B

(Rev. 10138; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

A. Ambulatory Surgical Centers (ASCs)

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

1. General Background Information

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.)

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 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, a state survey will be performed.

Note: ASCs can be fixed locations or mobile in nature.

2. Additional Enrollment Information

The contractor shall include any licenses, certifications, and accreditations submitted by ASCs in the enrollment package that is forwarded to the state and/or RO.

Once the contractor receives the approval letter or tie-in notice from the RO for an ASC supplier, the contractor is encouraged, but not required, to contact the RO, state agency, or supplier for the applicable licensing and/or certification data and to enter it into PECOS.

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 that the address and telephone number 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.

3. Ambulatory Surgical Centers (ASCs) and Reassignment

Physicians and non-physician practitioners who meet the reassignment exceptions in 42 CFR §424.80, and Pub. 100-04, chapter 1, sections 30.2.6 and 30.2.7, may reassign their benefits to an ASC.

If a physician or non-physician practitioner wishes to reassign its benefits to an existing (that is, a currently-enrolled) ASC, both the individual and the entity must sign the CMS-855R. However, it is not necessary for the ASC to separately enroll as a group practice in order to receive benefits. It can accept reassignment as an ASC.

4. Ambulatory Surgical Centers (ASCs) - Initial Enrollment

Unlike other supplier types that enroll via the Form CMS-855B, ASCs must receive a State survey and RO approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the State. The contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the RO.

When enrolling the ASC, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. See section 15.7.8.4 of Pub. 100-08, Chapter 15 for more information on ASC tie-in notices/approval letters.

5. Ambulatory Surgical Centers (ASCs) Changes of Ownership (CHOWs)

Though ASCs are not mentioned in 42 CFR § 489.18, CMS generally applies the change of ownership (CHOW) provisions of § 489.18 to them. CHOWs involving ASCs are thus handled in accordance with the principles in §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the RO – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated).

As discussed in section 10.2.2(A)(5) of this chapter, an ASC must sign a supplier agreement with Medicare prior to enrollment.

6. ASCs and CHOWs

If – pursuant to the CHOW – the seller submits a Form CMS-855B voluntary termination application, the contractor shall contact and explain to the seller that the ambulatory surgical center will not receive any payments until the RO approves the CHOW. (This is because payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process it; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective.

7. Additional Information

For more information on ASCs, refer to:

- *42 CFR Part 416*
- *Pub. 100-07, State Operations Manual, chapter 2, section 2210 and Appendix L*
- *Pub. 100-02, Benefit Policy Manual, chapter 15, sections 260 – 260.5.3*
- *Pub. 100-04, Claims Processing Manual, chapter 14*
- *Also, see Pub. 100-07, State Operations Manual, chapter 2, section 2210, for information regarding the sharing of space between ASCs and other providers.*

8. ASCs and Hospitals

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

- *Pub. 100-04, Claims Processing Manual, chapter 14, section 10.1*
- *Pub. 100-02, Benefit Policy Manual, chapter 15, section 260.1*

B. CLIA Labs

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

1. General Background Information

As explained in Pub. 100-07, State Operations Manual, chapter 6, sections 6000 and 6002, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 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. CLIA mandates that virtually all laboratories, including physician office laboratories, 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 that perform 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*
- *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*
- *Be located in a State with a CMS approved State laboratory licensure program, be licensed or approved in accordance with state requirements.*

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 licensed 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.

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 do not report patient specific results (although they test human specimens) for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individuals;*
- *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. (See [§6022](#) for discussions on Federal laboratories.);*
- *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;*

- *Laboratories licensed in a state whose 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 testing for drugs of abuse for employment purposes.*

2. Certificates

See Pub. 100-07, State Operations Manual, chapter 6, sections 6006 through 6006.7 for information regarding the various types of CLIA certificates.

3. CLIA Enrollment

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

- *Each practice location at which laboratory tests are performed must submit to the contractor a separate CLIA certificate for that location. The only exceptions to this rule are:*
 - *Laboratories within a hospital that are located at contiguous buildings, on the same campus, and under common direction;*
 - *Non-profit or governmental laboratories that engage in limited public health testing;*
 - *Laboratories that are not at a fixed location (i.e., are mobile)*
- *(See Pub. 100-07, State Operations Manual, chapter 6, sections 6008, 6026, and 6034 through 6036.3 for more information, including guidance relating to home health agencies and hospices.)*
- *The laboratory must submit to the contractor a separate certificate for each state in which testing is performed.*
- *If a lab is under the same ownership and at the same location as the “main provider,” it generally does not need to enroll separately. The enrolling*

provider will simply furnish its CLIA number in the practice location section. Conversely, if a lab is an “independent CLIA lab,” it must enroll separately.

- *A separate enrollment record need not be created for each CLIA number. For instance, suppose a physician is enrolling in Medicare and has a CLIA number. The contractor need only create a single enrollment record that will encompass the Medicare number and the CLIA number.*

4. Procedure to Update CLIA Certificate for an Enrolled CLIA lab

A Medicare-enrolled CLIA lab shall submit the updated CLIA Certificate to its contractor with a CMS-855. The MAC shall update PECOS accordingly, regardless if the provider or supplier is in PECOS.

5. Site Visits of Independent CLIA Labs

a. Initial application – If an independent CLIA lab submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (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 Pub. 100-08, Chapter 15, Section 15.19.2.2. The National Site Visit Contractor (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.

b. Revalidation – If an independent CLIA lab 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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. 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 before the contractor switches the supplier’s enrollment record to “Approved.” 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

6. Integrated CLIA 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 shall identify the lab as a practice location in section 4 of its Form CMS-855.

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.

Labs that do not plan to participate in the Medicare program must be directed to the applicable CLIA office.

7. Additional Information

For additional data on CLIA laboratories, refer to:

- *42 CFR Part 493*
- *Publication 100-07, State Operations Manual, chapter 6 (in full)*
- *Publication 100-04, Claims Processing Manual, chapter 16*
- *Form CMS-116 (CLIA Application for Certification)*

C. Mammography Screening Centers

Mammography Screening Centers are a certified supplier type that enroll via the Form CMS-855B.

1. 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).”

2. Enrollment of Mammography Screening Centers

To enroll in Medicare, a mammography screening center 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. (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 supplier 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 follow the rejection instructions within Pub. 100-08, Chapter 15, Section 15.8.2.

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of mammography screening centers:

- *42 CFR § 410.34 (in full)*
- *Pub. 100-04, Claims Processing Manual, chapter 18, sections 20 through 20.1.2*
- *Pub. 100-02, Benefit Policy Manual, chapter 15, section 280.3*

D. Pharmacies

Pharmacies are a supplier type that enroll via the Form CMS-855B

1. General Background Information

Pharmacies typically enroll with the National Supplier Clearinghouse 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 MAC, meaning that the pharmacy must enroll with the Part A/B MAC via the Form CMS-855B.

2. Additional Information

For more information on the billing and coverage policies for Part B drugs, see:

- *Pub. 100-04, Claims Processing Manual, chapter 17*
- *Pub. 100-02, Benefit Policy Manual, chapter 15, sections 50 through 50.6*

E. Portable X-Ray Suppliers (PXRSSs)

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

1. General Background Information

To qualify as a portable x-ray supplier (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 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.

2. Enrollment of PXRSs

a. Initial application

Unlike other supplier types that enroll via the Form CMS-855B, PXRSs must receive a State survey and RO approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the State. The contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the RO and a follow-up site visit is performed per section 10.2.2(E)(3) of this chapter.

When enrolling the PXRS, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. See section 15.7.8.4 of Pub. 100-08, Chapter 15 for more information on PXRS tie-in notices/approval letters.

b. Practice Location Information

- *In order to enroll as a PXRS, a supplier must complete a Form CMS-855B, undergo a State survey, and obtain RO approval. 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.” The former term typically describes a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile homes or trailers. A “portable unit” exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.*
 - *A PXRS can be either a mobile facility or portable unit, although it usually is the latter. A mobile IDTF, on the other hand, while it too can be either, is typically a mobile facility.*
 - *Its base of operations. This is where personnel are dispatched from 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. Copies of all licenses and registrations must be submitted as well, unless stated otherwise in this chapter or in another CMS directive.*

3. Site Visits

If a PXRS submits an initial application, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (PECOS) after the contractor receives the tie-in notice (or approval letter) from the RO but before the contractor conveys Medicare billing privileges to the PXRS. 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. The National Site Visit Contractor (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.

a. 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 after the contractor receives notice of approval from the RO but before the contractor switches the supplier's enrollment record to "Approved." 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.

b. Revalidation

If a PXRS 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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. Reassignment

PXRSs may receive reassigned benefits. A PXRS need not separately enroll as a group practice in order to receive them.

4. Additional Enrollment Information

The contractor shall include any licenses, certifications, and accreditations submitted by portable x-ray suppliers in the enrollment package that is forwarded to the state and/or RO.

Once the contractor receives the approval letter or tie-in notice from the RO for a portable x-ray supplier, the contractor is encouraged, but not required, to contact the RO, state agency, or supplier for the applicable licensing and/or certification data and to enter it into PECOS.

If the portable x-ray supplier'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 that the address and telephone number 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.

See also Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional PXRS site visit information.

5. PXRS and CHOWs

Though PXRSs are not mentioned in 42 CFR § 489.18, CMS generally applies the change of ownership (CHOW) provisions of § 489.18 to them. CHOWs involving PXRSs are thus handled in accordance with the principles in §489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). Note that the RO – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated).

If – pursuant to the CHOW – the seller submits a Form CMS-855B voluntary termination application, the contractor shall contact and explain to the seller that the portable x-ray supplier will not receive any payments until the RO approves the CHOW. (This is because payments must be sent to the seller until the tie-in/approval letter is sent). If the seller insists that its application be processed, the contractor shall process it; however, it shall first notify the facility/new owner and explain that payments will cease once the seller's termination is effective.

6. Additional Information

For more information on PXRSs, refer to:

- *42 CFR §§ 486.100 – 486.110*
- *Pub. 100-07, State Operations Manual, chapter 2, sections 2420 – 2424B*

- *Pub. 100-02, Benefit Policy Manual, chapter 15, sections 80.4 – 80.4.4*
- *Pub. 100-04, Claims Processing Manual, chapter 13, sections 90 – 90.5*

See also Pub. 100-08, Chapter 15, Section 15.19.2.2 for additional PXRS site visit information.

F. Radiation Therapy Centers (RTCs)

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

1. 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.

2. Additional Information

For additional background on radiation therapy services, see:

- *42 CFR § 410.35*
- *Pub. 100-04, Claims Processing Manual, chapter 13*
- *Pub. 100-02, Benefit Policy Manual, chapter 15, section 90*

G. Suppliers of Ambulance Services

Suppliers of Ambulance Services are supplier types that enroll via the Form CMS-855B.

1. 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*
- *Pub. 100-02, Benefit Policy Manual, chapter 10 (in full)*
- *Pub. 100-04, Claims Processing Manual, chapter 15*

2. Types of Ambulance Services

As stated in 42 CFR § 410.40, there are several types of ambulance services covered by Medicare. They are generally defined in § 414.605 as follows:

a. 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.

b. Advanced Life Support, level 2 (ALS2) - Either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the seven ALS procedures specified in § 414.605.

c. Air Ambulance (Fixed-Wing and Rotary-Wing) (See § 414.605 for specific definitions of fixed-wing and rotary-wing).

d. 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 an individual who is qualified in accordance with state and local laws as an emergency medical technician-basic (EMT-Basic).

e. 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(c). PI typically 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(c), PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area (see § 410.40(c)(1) for more information on this requirement)*
- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:*
 - Are certified to furnish ambulance services as required under § 410.41;*
 - Furnish services only at the BLS level; and*
 - Be prohibited by state law from billing for any service*
- Be furnished by a paramedic ALS intercept supplier that meets the following conditions:*
 - Is certified to furnish ALS services as required in § 410.41(b)(2); and*

- *Bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.*

f. 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., nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.)

3. Ambulance Qualifications

a. 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.*

b. Vehicle Personnel

Per 42 CFR § 410.41(b)(1)(i) and (ii), a BLS vehicle must be staffed by at least two people, one of whom must be: (1) certified as an emergency medical technician by the state or local authority where the services are furnished, and (2) legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

An ALS vehicle, in addition to meeting the BLS vehicle staff requirements described in 42 CFR § 410.41(b)(1), 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.

4. 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.

5. Geographic Area: Single Contractor Jurisdiction

If an ambulance company will be furnishing 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 be furnishing services in more than one contractor jurisdiction, it shall follow the applicable instructions below.

6. Geographic Area: Multiple States

The applicant must list the geographic areas in which it provides services. If the supplier indicates that it provides 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 section 10.2.2(G)(6) of this chapter to determine whether a separate enrollment for the additional state is required.

7. Practice Location

For purposes of provider enrollment, 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 1 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 5 conditions described in Pub. 100-08, Chapter 15, Section 15.5.4.1.C are met. (If separate applications are not required, the contractor shall still create a separate Provider Enrollment, Chain and Ownership System (PECOS) record for each state.)

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 CMS-855B, the supplier would have to list all of the data mentioned in Example (a) above. For its Contractor Y 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.

8. 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.)*

9. Paramedic Intercept Information

Paramedic intercept services typically involves an arrangement between a basic life support (BLS) ambulance supplier and an advanced life support (ALS) ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. (See 42 CFR § 410.40 for more information.) If the applicant indicates that it has such an arrangement, it must attach a copy of the agreement/contract.

10. Air Ambulances

Air ambulance suppliers must submit the following:

1. *Proof that the air ambulance supplier 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/*
- *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.*

11. 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.

H. Intensive Cardiac Rehabilitation (ICR)

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

1. Background

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.

2. ICR Enrollment

In order to enroll as an Intensive Cardiac Rehab (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 - on its Form CMS-855B enrollment application.

The contractor shall use specialty code 31 for these enrollments.

The contractor shall only accept and process reassignments (Form CMS-855Rs) to ICR suppliers from physicians defined in section 1861(r)(1) of the Social Security Act. However, reassignments are not required.

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*
- *Publication 100-04, Medicare Claims Processing Manual, chapter 32, sections 140.2.2 – 140.2.2.6*
- *Publication 100-02, Medicare Benefit Policy Manual, chapter 15, section 232*

I. Independent Diagnostic Testing Facilities (IDTFs)

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

1. General Background Information

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 Code of Federal Regulations (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. IDTF Standards

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

- a. *Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.*
- *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.*
- b. *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.*

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).

- c. *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.)*
- *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 100-08, Chapter 15, Sections 15.5.4 and 15.5.4.2 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).*
- d. *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.*

e. *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.*

The requirements in 42 CFR §410.33(g)(5) take precedence over the guidelines in Pub. 100-08, Chapter 15, Section 15.5.4.A 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.

f. *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 must remain 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.

g. 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).

- 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.*

h. 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.*

i. Openly post these standards for review by patients and the public.

j. 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.

k. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards.

- l. 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.*
- m. 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.*
- n. 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.*
- o. 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.*
- p. 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. (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 of the standards in 42 CFR §410.33 or any other applicable requirements 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.

3. 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 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.

4. Sharing of Space and Equipment

Effective January 1, 2008, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not: (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. (See 42 CFR §410.33(g)(15).)

If the contractor determines that an IDTF is leasing or subleasing its operations to another organization or individual, the contractor shall revoke the supplier's Medicare billing privileges.

5. 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.*

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.

6. IDTF Enrollment Information

Consistent with 42 CFR §410.33(g), each IDTF must certify on its Form CMS-855B enrollment application that it meets the IDTF standards under Section 10.2.2(I)(2) of this Chapter and all other requirements.

7. 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. Consequently, if a fixed IDTF site also contains a mobile unit, the mobile unit must 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 MAC 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.

8. Interpreting Physicians

a. Listing Interpreting Physicians

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 Publication 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 independent diagnostic testing facility (IDTF) that employs or contracts with an interpreting physician.

b. 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. The new interpreting physician must have met all of the necessary requirements at the time any tests were performed to perform services as an interpreting physician.

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.

9. Effective Date of IDTF Billing Privileges

The filing date of an IDTF Medicare enrollment application is the date that the contractor receives a signed application that it is able to process to approval. (See 42 CFR §410.33(i).) 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 a MAC; 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 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 in PECOS (a new federal Tax Identification Number is a result of this change), MACs should use the transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

10. 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.

11. IDTF Technicians Licensure and Certification Requirements

All technicians must meet the standards of a state license or state certification 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.

12. 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 provider 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.

13. IDTF Supervising Physicians – General Principles

Under 42 CFR §410.33(b)(1), an independent diagnostic testing facility (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.

14. IDTF: Information about Supervising Physicians

The contractor shall ensure and document 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 listed 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:*
 - The contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a Provider Transaction Access Number*
 - The physician shall list the IDTF's address as a practice location*
 - The space-sharing prohibition in 42 CFR §410.33(g) does not apply in this particular scenario.*

IDTF: General, Direct, and Personal Supervision

Under 42 CFR §410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR §410.32(b)(3), the contractor shall ensure that the IDTF's supervising physician furnishes this level of supervision.

The contractor's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR §410.32(b)(3), and shall 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.

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 phony 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.

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. The new supervising physician must have met all of the necessary requirements at the time any tests were performed to perform services as a supervising physician.

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 MAC shall proceed with non-compliance revocation procedures as noted in Pub. 100-08, Chapter 15, Section 15.27.2.

15. Desk and Site Reviews

All initial and revalidating independent diagnostic testing facility (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 Pub. 100-08, Chapter 15, Section 15.19.2.2.*
- The IDTF meets the supplier standards in 42 CFR § 410.33.*

The contractor shall order the site visit through the Provider Enrollment, Chain and Ownership System. The National Site Visit Contractor (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.

16. Mobile Units

Mobile units are required to 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 that are 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).*

17. 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 not 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 NVSC 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 originally listed only general supervision codes, was only reviewed for only general supervision tests, and 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.

18. IDTF That Performs Diagnostic Mammography

If an independent diagnostic testing facility (IDTF) performs diagnostic mammography services, it must have a Food and Drug Administration (FDA) 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.

19. IDTF Ownership of CLIA Laboratory

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number (TIN) 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.

10.2.3 - Individual Practitioners That Enroll Via the Form CMS-855I (Rev. 10138; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

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 Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15 for specific information regarding the required qualifications of the suppliers listed in this section 10.2.3 et seq.

A. Anesthesiology Assistants

Federal regulations at 42 CFR § 410.69(b) defines 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:*
 - Is accredited by the Committee on Allied Health Education and Accreditation; and*
 - Includes approximately 2 years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.*

With respect to education and training, Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, section 140.1 further describes an anesthesiology assistant as a person who has successfully completed a 6-year program for anesthesiology assistants, of which 2 years consists of specialized academic and clinical training in anesthesia.

B. Audiologists

Section 1861(l)(3)(B) of the Social Security Act and Pub. 100-02, Medicare Benefit Policy Manual, 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 which 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.*

C. Certified Nurse-Midwives

Federal regulations at 42 CFR §410.77 list the Medicare qualifications for certified nurse-midwives (CNMs). These qualifications require that a CNM must:

- *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 College of Nurse-Midwives Certification Council.*

For more information on certified nurse midwives, refer to:

- *Section 1861(gg) of the Social Security Act;*
- *Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 180; and*
- *Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, section 130.1.*

D. Certified Registered Nurse Anesthetists (CRNAs)

Federal regulations at 42 CFR § 410.69(b) state that a 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:*
 - a. *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*
 - b. *Is a graduate of a program described in paragraph (3) and within 24 months after that graduation meets the requirements of paragraph (4)(i).*

For more information on CRNAs, refer to:

- *Section 1861(bb) of the Social Security Act*
- *Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, section 140.1*

E. Clinical Nurse Specialists

Federal regulations at 42 CFR §410.76 and in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 210 states 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, Medicare Benefit Policy Manual, Chapter 15, section 210 states that the following organizations are recognized by CMS 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; and*
- g. National Board on Certification of Hospice and Palliative Nurses.*

F. Clinical Psychologists

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.*

Clinical psychologists are authorized under the Medicare program to furnish “physician” services that fall under their state scope of practice and, have services furnished as an incident to their own personal professional services without physician supervision, involvement or oversight. Clinical psychologists can perform diagnostic psychological and neuropsychological tests without a physician or authorized non-physician practitioner’s order. Solely for purposes of diagnostic psychological and neuropsychological tests, clinical psychologists are authorized to supervise these tests in addition to physicians.

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 attempt to consult with their patient’s primary care or attending physician.

For more information on clinical psychologists, refer to Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 160.

G. Clinical Social Workers

Federal regulations at 42 CFR §410.73(a) defines 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, SNF, or clinic.*

For more information on clinical social workers, refer to Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 170.

H. Nurse Practitioners

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 master's or doctoral degree is required to obtain a license as an NP in the state, then the MACs do not need to separately verify the degree or require documentation be submitted by the provider.*
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, Medicare Benefit Policy Manual, 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; and*
- *National Board on Certification of Hospice and Palliative Nurses*

I. Occupational Therapists in Private Practice

1. Private Practice

Section 42 CFR 410.59(c)(ii), (iii), and (iv) state that an occupational therapist in private practice must:

- a. Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types:

 - i. An unincorporated solo practice.*
 - ii. A partnership or unincorporated group practice.*
 - iii. An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated occupational therapy practice.*
 - iv. An employee of a physician group.*
 - v. An employee of a group that is not a professional corporation.**

AND

- b. Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home.

 - i. 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.*
 - ii. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.**

AND

- c. Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.*

2. Regulatory Definition

Section 42 CFR § 484.4 defines an occupational therapist as an individual who:

- (a) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;*
- (b) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and*
- (c) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).*

OR

On or before December 31, 2009--

- (a) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or*
- (b) When licensure or other regulation does not apply--*
 - (i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and*
 - (ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).*

OR

On or before January 1, 2008--

- (a) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and*

Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(b) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

OR

On or before December 31, 1977--

(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.

3. Occupational Therapist Educated Outside the United States

Section 42 CFR § 484.4 states that if the occupational therapist was educated outside the United States, he or she must meet all of the following:

a. Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry-level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

b. Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

c. On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

4. Occupational Therapists: Additional References

See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15:

- Section 230.2(B) for more detailed information regarding the required qualifications of occupational therapists.*

- *Section 230.4 for detailed information regarding the term “private practice.”*

5. Other Enrollment Information

All OTs in private practice must respond to the questions in section 2K of the CMS-855I. If the OT plans to provide his/her services as: (1) a member of an established OT group, (2) an employee of a physician-directed group, or (3) an employee of a non-professional corporation, and that person wishes to reassign his/her benefits to that group, this section does not apply. Such information will be captured on the group’s CMS-855B application.

If the OT 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 4B of the 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 OT services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the provider cannot furnish a copy of the lease, the contractor shall deny the application.

J. Physical Therapists in Private Practice

1. Physical Therapist in Private Practice

Section 42 CFR 410.60(c)(ii), (iii), and (iv) state that a physical therapist in private practice must:

- a. Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types:*
 - i. An unincorporated solo practice.*
 - ii. A partnership or unincorporated group practice.*
 - iii. An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated physical therapy practice.*
 - iv. An employee of a physician group.*
 - v. An employee of a group that is not a professional corporation*

AND

b. Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home.

i. 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.

ii. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

AND

c. Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

2. Regulatory Definition

Section 42 CFR § 484.4 defines a physical therapist as a person who is licensed, if applicable, by the state in which practicing (unless licensure does not apply) and who meets one of the following requirements:

(a) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR § 212.15(e) as it relates to physical therapists; and

(b) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

OR

On or before December 31, 2009--

(a) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(b) Meets both of the following:

(i) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentialed evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR § 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

OR

Before January 1, 2008--

(i) Graduated from a physical therapy curriculum approved by one of the following:

(ii) The American Physical Therapy Association.

(iii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(vi) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

OR

On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

OR

Before January 1, 1966--

*(i) Was admitted to membership by the American Physical Therapy Association;
or*

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

Has graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

OR

Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

3. Physical Therapist Trained Outside the United States

Section 42 CFR § 484.4 states that if the physical therapist was trained outside the United States before January 1, 2008, he or she must meet the following requirements:

- a. Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.*
- b. Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.*

4. Physical Therapists: Additional References

See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15:

- Section 230.2(B) for more detailed information regarding the required qualifications of physical therapists.*
- Section 230.4 for detailed information regarding the term “private practice.”*

5. Site Visits of Physical Therapists in Private Practice

(This site visit requirement is pursuant to 42 CFR § 424.518(b).)

Subject to subsection F below, site visits will be performed in accordance with the following:

- i. Initial application – If a physical therapist (PT) or PT group submits an initial application for private practice, the contractor shall order a site visit through the Provider Enrollment, Chain and Ownership System (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 Pub. 100-08, Chapter 15, Section 15.19.2.2. The National Site Visit Contractor (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 PT or PT 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 Pub. 100-08, Chapter 15, Section 15.19.2.2. 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 PT or PT 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 in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with Pub. 100-08, Chapter 15, Section 15.19.2.2. 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.*

6. Physical Therapists: Additional Site Visit Information

NOTE: *The contractor shall also view the following:*

- In section 2A 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 2A 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, 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, not a physical therapy group in private practice. However, this does not exempt the physical therapist from screening required at the "moderate" risk level.*

- *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 (Form CMS-855I and Form CMS-855R). However, a site visit is not required for an enrolled private practice physical therapist who is reassigning his or her benefits only (Form CMS-855R).*
- *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.*

7. Other Enrollment Information

All PTs in private practice must respond to the questions in section 2K of the CMS-855I. If the PT plans to provide his/her services as: (1) a member of an established PT group, (2) an employee of a physician-directed group, or (3) an employee of a non-professional corporation, and that person wishes to reassign his/her benefits to that group, this section does not apply. Such information will be captured on the group's CMS-855B application.

If the PT 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 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 PT services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the provider cannot furnish a copy of the lease, the contractor shall deny the application.

K. Physicians

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*
- *Optometry*

2. A chiropractor who meets the qualifications specified in 42 CFR § 410.22.

Refer to Pub. 100-04, Medicare Claims Processing Manual, 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.

L. Physician Assistants (PAs)

Federal regulations at 42 CFR § 410.74(c), 42 CFR § 410.150(a)(15), and Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 190 require that a physician assistant (PA) must meet the following Medicare requirements:

- Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA)); or*
- 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 physician assistant.*

As indicated in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 190(D):

- *Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself. In other words, the PA cannot individually enroll in Medicare and receive direct payment for his or her services. This also means that the PA does not reassign his or her benefits to the employer, since the employer must receive direct payment anyway.*
- *The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., limited liability company) in a state that permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a*

qualified employer is not a group of PAs that incorporate to bill for its services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as providers or suppliers of services.

- *PAs also have the option under their benefit to furnish services as an independent contractor (1099 employment arrangement) in which case the contractor serves as the PA's employer and Medicare payment is made directly to the contractor.*

1. Other Enrollment Information

As stated in the instructions on page 3 of the CMS-855I, physician assistants (PAs) who are enrolling in Medicare need only complete sections 1, 2, 3, 13, 15, and 17 of the CMS- 855I. The physician assistant must furnish his/her NPI in section 2A of the application, and must list his/her employers in section 2I.

The contractor must verify that the employers listed are: (1) enrolled in Medicare, and (2) not excluded or debarred from the Medicare program. (An employer can only receive payment for a PA's services if both are enrolled in Medicare.) All employers must also have an established record in PECOS. If an employer is excluded or debarred, the contractor shall deny the application.

Since PAs cannot reassign their benefits – even though they are reimbursed through their employer – they should not complete a CMS-855R.

M. Psychologists Practicing Independently

Pub. 100-02, Medicare Benefit Policy Manual, 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:*

- *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*
- *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 nonphysician 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.

Other Enrollment Information

The contractor shall ensure that all persons who check "Psychologist Billing Independently" in section 2D2 of the CMS-855I answer all questions in section 2J. If the supplier answers "no" to question 1, 2, 3, 4a, or 4b, the contractor shall deny the application.

N. Registered Dietitians

Federal regulations at 42 CFR § 410.134 state that a registered dietitian (or nutrition professional) is an individual who, on or after December 22, 2000:

- 1. 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;*
- 2. Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and*
- 3. 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 (1) and (2) above.*

There are two exceptions to these requirements:

- *A dietitian or nutritionist licensed or certified in a state as of December 21, 2000, is not required to meet the requirements of (1) and (2) above.*
- *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 (1) and (2) above.*

O. Speech Language Pathologists in Private Practice

Effective July 1, 2009, in order to qualify as an outpatient speech-language pathologist in private practice, an individual must meet the following requirements:

- 1. 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.*
- 2. Engage in the private practice of speech-language pathology as an individual, in one of the following practice types:*
 - a. An unincorporated solo practice*
 - b. An unincorporated partnership or unincorporated group practice*
 - c. 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*
 - e. An employee of a group that is not a professional corporation*

For more information on speech language pathologists in private practice, refer to Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 230.

P. Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC

Since Part A/B MACs make payments for implantable prosthetics and DME to hospitals, physicians or ASCs, A/B MACs shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. 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 supplier with the National Supplier Clearinghouse if it meets the definition of a supplier as well as the requirements in 42 CFR § 424.57.

10.2.4 - Other Medicare Part B Services

(Rev. 10138; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

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 may also want to 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 that 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 (DSMT)

DSMT Background

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. Currently, CMS recognizes the American Diabetes Association (ADA) and the American Association of Diabetes Educators (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 National Supplier Clearinghouse 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:

- *The effective date provision in 42 CFR § 424.520(d) does not apply to the enrollment of mass immunizers. This is because the individual/entity is not enrolling as a physician, non-physician practitioner, physician group or non-physician practitioner group.*
- *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 defines 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. In order to furnish the TC of advanced diagnostic imaging services for Medicare beneficiaries, suppliers must be accredited by January 1, 2012. The effective date of the previously named regulation is January 1, 2012.

CMS approved four national accreditation organizations (AOs) – the American College of Radiology, the Intersocietal Accreditation Commission, the Joint Commission and Rad Site - to provide accreditation services for suppliers of the TC of advanced diagnostic imaging procedures. The accreditation will apply only to the suppliers of the images, not to the physician's interpretation of the image. Also, this accreditation only applies to those who are paid under the Physician Fee Schedule. All accreditation organizations have quality standards that address the safety of the equipment as well as the safety of the patients and staff. A provider submitting claims for the TC must be accredited by January 1, 2012 to be reimbursed for the claim if the service is performed on or after that date. 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 date 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 CMS-855. Information for all ADI accredited suppliers is provided to CMS from the approved ADI Accreditation Organizations. The Medicare enrollment contractors do not need to verify ADI information sent on the application.

10.2.5 – Suppliers That Enroll Via the Form CMS-855S

(Rev. 10138; Issued: 05- 15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

A. Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

1. Special Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Instructions

Sections 10.2.5(A)(1) through 10.2.5(A)(2) instruct the National Supplier Clearinghouse on the appropriate handling of certain situations involving DMEPOS suppliers.

2. DMEPOS Supplier Accreditation

a. General Requirement

DMEPOS suppliers must be accredited prior to submitting an application to the National Supplier Clearinghouse (NSC). The NSC shall deny any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt.

The NSC shall revoke an enrolled DMEPOS supplier's billing privileges if the DMEPOS supplier fails to: (1) obtain and submit supporting documentation that the DMEPOS supplier has been accredited, or (2) maintain its required accreditation.

In the future, Medicare will deny claims for those DMEPOS suppliers who fail to maintain accreditation information on file with the NSC.

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. Special Situations

Changes of Ownership

i. Change of Ownership and Accreditation

A change of ownership application for an existing supplier location submitted by a new owner company with a new tax identification number (TIN) 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).

ii. Change of Ownership Involving More than 5 Percent of the Ownership Interest

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:

- If the change in ownership has not been reported to the NSC within the required 30-day period, the NSC shall proceed with revocation action.*
- If the change has been received within the required 30-day period and the supplier has been accredited, the NSC shall immediately notify the accreditor of the ownership change and request that the latter advise the NSC if the accreditation should still remain in effect.*

iii. 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.

d. Fraud Level Indicators for DMEPOS Suppliers - Development and Use

The National Supplier Clearinghouse (NSC) 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 NSC 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 NSC project officer.

(NOTE: These risk categories are in addition to, and not in lieu of, those specified in section 15.19.2 of Pub. 100-08, Chapter 15.)

In assessing a fraud level indicator, the NSC 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 NSC 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), a Zone Program Integrity Contractor (ZPIC), and/or a Unified Program integrity Contractor (UPIC) shall be reported to the NSC project officer. The NSC shall update the fraud level indicator based on information obtained by the OIG, CMS (including CMS satellite office), ZPIC, and/or a UPIC only after the review and concurrence of the NSC project officer.

In addition, the NSC shall monitor and assess geographic trends which indicate or demonstrate that one geographic area has a higher potential for having fraudulent suppliers.

e. 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, and not limited to 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 §424.518(c)(2). The on-site visits that the NSC 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.

f. Fraud Level Indicator Standards

The NSC shall have documented evidence that it has, at a minimum, met the following requirements:

- Assign 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.*
- Update the DMEPOS fraud level indicator for each enrolled DMEPOS supplier on an annual basis.*

g. Alert Codes for DME Suppliers

The NSC shall receive and maintain the following “alert indicators” from the DME MACs, Zone Program Integrity Contractors (ZPICs), and Unified Program Integrity Contractors (UPICs):

<i>Alert Code</i>	<i>Definition</i>
<i>A</i>	<i>Possible fraudulent or abusive claims identified</i>
<i>B</i>	<i>Overpayments</i>
<i>D</i>	<i>Violations of disclosure of ownership requirements</i>
<i>E</i>	<i>Violations of participation agreements</i>

L *Suspended by contractor outside alert code process*

M *Supplier is going through claims appeal process*

The NSC shall append the supplier file and transfer to the DME-MACs, ZPICs and/or UPICs the following alert codes in the following circumstances:

Alert Code *Definition*

C *Violations of supplier standards*

F *Excluded by the Office of Inspector General or debarred per the GSA debarment list*

H *Meets supplier standards; however, the NSC recommends increased scrutiny by the contractor (initiated by NSC-MAC only)*

N *Supplier being investigated under the "Do Not Forward" initiative (initiated by NSC 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 NSC 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 NSC. This alert code notifies the contractors that a supplier may be inclined to submit a high percentage of questionable claims.

The NSC shall share the above information with the DME MACs, ZPICs, 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 NSC also shall forward alert codes submitted by the contractors with the other contractors within 7 calendar days after receipt.

3. Surety Bonds

a. Background

Surety Bond Exemptions

All DMEPOS suppliers are subject to the surety bond requirement, except:

- *Government-operated DMEPOS suppliers are exempted if the supplier has provided CMS with a comparable surety bond under State law.*
- *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.*
- *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.*
- *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 DMEPOS supplier no longer qualifies for an exception, it must submit a surety bond to the NSC - 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 NSC with their 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 CMS-855S application submitted on or after May 4, 2009, by a supplier described in this section (2), the NSC 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 monetary penalties (CMPs), or assessments - pay CMS a total of up to the full penal amount of the bond in the following amounts:*
- The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible, and*
- 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 NSC. Moreover, the bond must be continuous.

e. 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 must provide written notice of such to the NSC 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.

If a gap in coverage exists, the NSC shall revoke the supplier's billing privileges. 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 NSC 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 NSC; the appropriate addresses can be found on the NSC's Web site at www.palmettogba.com/nsc.

g. Reenrollment and Reactivation

The supplier must furnish the paperwork described in subsection 10.2.5(A)(3)(d) above with any CMS-855S reenrollment or reactivation application it submits to the NSC unless it already has the information on file with the NSC. For example, if a supplier has submitted a continuous surety bond to the NSC prior to submission of its reenrollment application, a new copy of surety bond is not be required unless the NSC 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 NSC 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.

i. Claims against Surety Bonds

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:

i. The amount of any unpaid claim, plus accrued interest, for which the supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) is responsible.

ii. The amount of any unpaid claim, civil monetary penalty (CMP) or assessment imposed by CMS or the Office of Inspector General (OIG) on the DMEPOS supplier, plus accrued interest.

This section 10.2.5(A)(3)(i) describes the procedures involved in making a claim against a surety bond.

j. Unpaid Claims

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(A) 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 or 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.

k. Collection

i. Delinquency Period

If the Durable Medical Equipment Medicare Administrative Contractor (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 the 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.

ii. Request for Payment from Surety

If, however, the supplier has a surety bond (and subject to situations (1) through (6) 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 yet 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 (1) through (6) 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:

- 1. 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.*

2. 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.

3. 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.

4. 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.

5. 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.

l. 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.

The DME MAC may choose to aggregate debts from the same supplier into one surety letter, provided they are at least 30 days delinquent.

The surety letter shall:

- Follow the format of the applicable model letter in Section 10.7.15 through 10.7.15(E).*
- 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.*
- Be accompanied by the following documents, which constitute “sufficient evidence” for purposes of §424.57(a):*

m. Overpayment Services Report

A computer-generated “Overpayment Services Report” containing the following information:

- i. 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)*
- ii. Date on which supplier was paid*
- iii. Paid Amount*
- vi. Overpayment Amount*

(NOTE: The report shall not include HICN, or any information otherwise protected under the Privacy Act.)

n. Overpayment Determination Letter

A copy of the overpayment determination letter that was sent to the supplier.

- State that payment shall be made via check or money order and that the Payee shall be the DME MAC.*
- Identify 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.

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 in section 10.2.5(A)(3)(o)(ii) 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.

o. Verification of Payment

i. 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:

A. 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.)

B. Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the NSC 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 NSC 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 NSC.

If the NSC 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 NSC (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.*

ii. 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:

A. 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;

B. 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.

C. No later than 14 days after Step B (above) has been completed – and if full payment still has not been received -- send the letter identified in Section 10.7.15 of this chapter to the surety.

D. Include information relating to the surety's non-payment in the report identified in section 10.2.5(A)(3)(o)(ii).

iii. 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:

A. Refer the unpaid 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;

B. 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.

C. No later than 14 days after Step (ii) has been completed – and if full payment still has not been received -- send the letter identified in Section 10.7.15 of this chapter to the surety.

D. Include information relating to the surety's partial non-payment in the report identified in section 10.2.5(A)(3)(o)(iii).

E. 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 NSC 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 NSC 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 NSC.”

If the NSC 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 NSC (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.

iv. 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.

v. Summary

The following chart outlines the timeframes involved in the surety bond collection process for overpayments:

<i>Day 1</i>	<i>Initial Demand Letter Sent</i>
<i>Day 31</i>	<i>Debt is Delinquent/Interest Starts</i>
<i>Day 41</i>	<i>Recoupment Starts</i>
<i>Day 66</i>	<i>Intent to Refer Letter Sent</i>
<i>Day 115</i>	<i>Surety Bond Letter Sent</i>
<i>Day 150</i>	<i>Referral to Treasury</i>

4. Surety Bonds: Claims Pertaining to Assessments and Civil Monetary Penalties (CMPs)

a. 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 NSC and the supplier/debtor shall be copied) shall:

- Follow the format of the applicable model letter in Pub. 100-08, Chapter 15, Sections 15.21.7.1.1.A through 15.21.7.1.1.E.*
- 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.*

i. 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 in section (A)(3)(b) 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.

ii. 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:

1. *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.)*

2. Notify the applicable CMS Regional Office (RO) via letter or e-mail that payment was made.

3. If the OIG imposed the CMP or assessment, notify the OIG via letter that payment was made.

4. Send a mailed, faxed, or (preferably) e-mailed letter to the supplier (on which the NSC 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 NSC 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 NSC.”

If the NSC 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 NSC (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:

- 1. Continue collection efforts as outlined in Pub. 100-06, chapter 4;*
- 2. 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.*
- 3. No later than 14 days after Step 2 has been completed – and if full payment still has not been received -- send the letter identified in Pub. 100-08, Chapter 15, Section 15.21.7.1.1.E to the surety.*
- 4. Include information relating to the surety's non-payment in the report outlined in section 10.2.5(A)(3)(o)(ii).*

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:

- 1. Continue collection efforts as outlined in Pub. 100-06, chapter 4;*
- 2. 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.*
- 3. No later than 14 days after Step (ii) has been completed – and if full payment still has not been received -- send the letter identified in Section 10.7.15 of this chapter to the surety.*
- 4. Include information relating to the surety's partial non-payment in the report identified in 10.2.5(A)(3)(o)(iii).*
- 5. 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 NSC 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 NSC 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 NSC.”

If the NSC 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 NSC (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.

D. 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.

B. Indian Health Services (IHS) Facilities’ Enrollment as DMEPOS Suppliers

1. Background

The National Supplier Clearinghouse (NSC) 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 NSC 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 IHS, and (2) facilities owned by the IHS

but tribally operated or totally owned and operated by a tribe. CMS will provide the NSC with a list of IHS facilities that distinguishes between these two types.

On the list, the NSC shall use the column entitled, “FAC OPERATED BY”, for this purpose.

2. Enrollment

The provider/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.*

3. Supplier Standards, Exceptions and Site Visits

All IHS facilities, whether operated by the IHS or a tribe:

- Shall meet all required standards, with the exception of:*
- The comprehensive liability insurance requirements under 42 CFR 424.57(c)(10).*
- 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).*

- *Shall, like all other DMEPOS suppliers, undergo site visits in accordance with Pub. 100-08, Chapter 15, Section 15.19.2.2. (This includes all hospitals and pharmacies enrolling as DMEPOS suppliers.)*

4. Provider Education for IHS Facilities

The NSC shall ensure that its Web site includes the information contained in this section 10.2.5(B) that is specific to enrollment of IHS facilities (whether operated by the IHS or a tribe).

5. Specialty Codes

The NSC 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).

C. Pharmacies' Enrollment as DMEPOS Suppliers

Refer to 10.2.2(D) for a discussion of pharmacy enrollment via the Form CMS-855B (i.e., pharmacy not enrolling as a DMEPOS supplier).

1. Compliance Standards for Pharmacy Accreditation

The National Supplier Clearinghouse (NSC) shall not require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.

The NSC-Medicare Administrative Contractor (MAC) 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 NSC-MAC 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 NSC-MAC 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 (CMS-855S), and as described in the internet enrollment application version of the Provider Enrollment, Chain and Ownership System (PECOS). Before mailing the letters, the NSC-MAC shall obtain NSC project officer

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 NSC-MAC shall review the attestations received from pharmacies. Pharmacies that properly signed the attestation letter shall be given an accreditation status of exempt. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations. The NSC-MAC 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 NSC-MAC shall compile a sample listing of at least 10 percent of the pharmacies that have submitted an NSC accepted attestation exempting them from accreditation. The NSC-MAC 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 NSC-MAC shall obtain NSC project officer approval of the letter. Within 45 days after project officer approval of the letter the NSC-MAC shall mail a copy of the letter to the random sample of pharmacies which claimed exemption through an attestation. The NSC-MAC shall determine the acceptability of the replies received in response to the audit verification random sample mailing. The NSC shall use DMEPOS billing data for only products and services requiring accreditation to assist in the determination. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications. The NSC-MAC shall consult with the NSC project officer in cases where they are uncertain as to the acceptability of the supplier's response to the audit request. By June 30, 2011, the NSC-MAC 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 in compliance 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 NSC-MAC 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. 10138; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

A. General Background Information

The Diabetes Prevention Program (DPP) 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. The clinical intervention consists of 16 intensive “core” sessions of a curriculum in a group-based, classroom-style setting that provides practical training in long-term dietary change, increased physical activity, and behavior change strategies for weight control. After the 16 core sessions, less intensive monthly follow-up sessions help ensure that the participants maintain healthy behaviors. The primary goal of the intervention is lowering the progression to type 2 diabetes, measured using a proxy of at least 5 percent average weight loss among participants.

The Center for Medicare & Medicaid Innovation (CMMI) first tested the DPP program in the Medicare population through a Round One Health Care Innovation Award (HCIA). In March 2016, Department of Health and Human Services (HHS) announced that the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) certified the pilot DPP model as a cost savings program that reduced net Medicare spending. The Secretary then determined that the program demonstrated the ability to improve the quality of patient care without limiting coverage or benefits. Together, these determinations fulfilled CMMI’s model expansion requirements of Section 1115A of the Social Security Act.

As a result, CMMI expanded the initial HCIA model test into a national Medicare DPP (MDPP) model where organizations furnish MDPP services to beneficiaries with an indication of pre-diabetes for one year, and individuals who meet certain performance goals may continue eligibility to receive MDPP services through monthly ongoing maintenance sessions for up to an additional year.

B. MDPP Suppliers Eligibility and Enrollment Requirements

An entity or individual who wishes to furnish MDPP services –to Medicare beneficiaries must enroll as an “MDPP supplier” via the Form CMS-20134. Such suppliers must meet the following requirements:

- Have MDPP preliminary recognition, as defined at 42 CFR 424.205 or full recognition as determined by the Center for Disease Control and Prevention’s (CDC) Diabetes Prevention Recognition Program (DPRP)*
- Obtained and maintained valid TIN and NPI at the organizational level*
- Passed application screening at a high categorical risk level per § 424.518(c) upon initial enrollment and revalidate at moderate categorical risk level per § 424.518(b), and*

- *Complies with the supplier standards.*

As noted above, 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 DPP and monitors 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 into Medicare. Though an entity may furnish a select number of virtual MDPP make up sessions to a beneficiary (no more than 4 per beneficiary over the entire period of MDPP services), they would still be considered in-person MDPP suppliers.

C. MDPP Supplier Standards

All MDPP suppliers must comply with MDPP supplier standards in order to obtain and retain Medicare billing privileges. Consistent with 42 CFR §424.205(d), each MDPP Supplier must certify on its Form CMS-20134 enrollment application that it meets and will continue to meet the following standards and all other requirements:

- *Must have and maintain MDPP preliminary recognition, or full CDC DPRP recognition.*
- *Must not currently have its billing privileges terminated or be excluded by a state Medicaid agency.*
- *Must not permit MDPP services to be furnished by or include on its roster any individual coach who meets ineligibility criteria.*
- *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.*
- *Must update this enrollment application within 30 days for any changes of ownership, changes to the coach roster, and final adverse legal action history and update all other changes within 90 days.*
- *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.*
- *Must not convey or reassign a supplier billing number.*
- *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 exemptions.*
- *Must offer MDPP beneficiaries the entirety of the MDPP benefit to which they are eligible.*
- *Must not, nor may other individuals or entities performing functions or services related to MDPP 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.

- 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 the MDPP benefit, and these standards.*
- 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.*
- 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.*
- 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.*
- 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 documentation requirements.*

The CMS will notify any contractor when an MDPP supplier within their jurisdiction has moved from preliminary or full recognition down to pending, and therefore no longer maintains eligibility for 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 such standards are determined as non-compliance, and the associated enrolment denial and revocation authorities would apply.

10.2.7 - Providers/Suppliers Not Eligible to Participate

(Rev. 10138; Issued: 05-15-2020; Effective: 06-16-2020; Implementation: 06-16-2020)

Below is a list of individuals and entities that frequently attempt to enroll in Medicare, but are not eligible to do so. This list is not an all-inclusive list. If the contractor receives an enrollment application from any of these individuals or entities, 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*
- *Birth 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*
- *Marriage Family Therapist*
- *Master of Social Work*
- *Medicare Beneficiaries*
- *Mental Health Counselor*

- *National Certified Counselor*
- *Naturopath*
- *Occupational Therapist Assistant*
- *Physical Therapist Assistant*
- *Registered Nurse*
- *Speech and Hearing Center*
- *State Medicaid Agency*

State Medicaid agencies do not have a National Provider Identifier and are not eligible to enroll in the Medicare program. If a Medicaid State agency 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) (denials) and § 424.535(a)(3) (revocations) as the basis.

- *Substance Abuse Facility*

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R10138PI</u>	05/15/2020	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment)	06/16/2020	11546
<u>R434PI</u>	09/14/2012	Removal of Remaining Material from Chapter 10 of the Program Integrity Manual (PIM)	10/16/2012	8026
<u>R416PI</u>	04/13/2012	General Update to Chapter 15 of the Program Integrity Manual (PIM) –Part III	02/27/2012	7698
<u>R405PI</u>	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
<u>R386PI</u>	09/01/2011	Ordering/Referring Providers Who Are Not Enrolled in Medicare	04/19/2010	6696
<u>R363PI</u>	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
<u>R356PI</u>	09/24/2010	Manual Redesign	10/26/2010	7083
<u>R354PI</u>	08/27/2010	Manual Redesign	09/28/2010	7016
<u>R347PI</u>	07/15/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15	07/30/2010	6938
<u>R344PI</u>	06/18/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15 - Rescinded and replaced by Transmittal 347	07/05/2011	6938
<u>R339PI</u>	05/21/2010	Cardiac Rehabilitation and Intensive Cardiac Rehabilitation	10/04/2010	6850
<u>R334PI</u>	04/23/2010	Update to Site Verification Process	05/24/2010	6895
<u>R332PI</u>	03/26/2010	Reporting Changes in Surety Bonds	06/28/2010	6854
<u>R329PI</u>	03/19/2010	Change in Provider Enrollment Timeliness Standards for Certain Paper Applications	06/21/2010	6807
<u>R328PI</u>	03/19/2010	Ordering/Referring Providers Who Are Not Enrolled in Medicare – Rescinded and replaced by Transmittal 386	04/19/2010	6696
<u>R326PI</u>	03/12/2010	Revision of the Internet Only Manual to Remove References to “Purchased	06/14/2010	6627

Rev #	Issue Date	Subject	Impl Date	CR#
		Diagnostic Test” and Replace With Language Consistent With the Anti-Markup Rule		
<u>R324PI</u>	02/05/2010	Revisions to Model Approval Letters	03/08/2010	6780
<u>R323PI</u>	01/29/2010	Verification of Legal Status	03/29/2010	6748
<u>R322PI</u>	01/15/2010	Durable Medical Equipment (DME MAC) and the National Supplier Clearinghouse (NSC MAC) Procedures for Third Party Notification of Deceased Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) Supplier Associates	7/06/2010	6714
<u>R321PI</u>	12/30/2009	Verification of Legal Status Rescinded and replaced by Transmittal 323	03/29/2010	6748
<u>R320PI</u>	12/23/2009	Provider Enrollment Revisions	01/25/2010	6645
<u>R318PI</u>	12/18/2009	Implementation of Home Health Agency Program Safeguard Provisions - Rescinded	01/01/2010	6750
<u>R316PI</u>	12/04/2009	Administrative Appeals Process for Provider Enrollment	01/04/2010	6487
<u>R315PI</u>	12/04/2009	Provider Enrollment and Veteran’s Administration (VA) Hospitals	03/08/2010	6735
<u>R314PI</u>	11/27/2009	Clarification of Deactivation Instructions	12/28/2009	6734
<u>R312PI</u>	11/20/2009	Home Health Agency (HHA) Capitalization Requirements	12/21/2009	6732
<u>R307PI</u>	10/23/2009	Establishing New Practice Locations in a Different State	01/25/2010	6649
<u>R306PI</u>	10/02/2009	Site Verifications	11/02/2009	6639
<u>R304PI</u>	09/25/2009	Inter-Contractor Communication and Provider Enrollment Revocations	10/26/2009	6642
<u>R300PI</u>	09/01/2009	Compliance Standards for Consignment Closets and Stock and Bill Arrangements - Rescinded	03/01/2010	6528
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