CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13415	**Date: September 18, 2025**
	Change Request 14109

SUBJECT: Provider Enrollment Updates to Chapter 10 of CMS Publication (Pub.) 100-08, Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to-- (1) Formally incorporate within Chapter 10 of the PIM certain existing provider enrollment procedures; and (2) Make minor technical edits.

EFFECTIVE DATE: October 20, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 20, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.2/10.2.1.4/Federally Qualified Health Centers (FQHCs)
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.2.10/Suppliers of Ambulance Services
R	10/10.2/10.2.3.15/Speech Language Pathologists in Private Practice
R	10/10.4/10.4.1.4.2/Returns
R	10/10.4/10.4.1.4.3/Rejections
R	10/10.4/10.4.2.1/Denials – General Principles
R	10/10.4/10.4.2.2/Denial Reasons
R	10/10.4/10.4.2.3/Additional Denial Policies
R	10/10.4/10.4.7.1/Revocations – Background and General Requirements
R	10/10.4/10.4.7.3/Revocation Reasons
R	10/10.4/10.4.7.4/Reenrollment Bar
R	10/10.4/10.4.7.5/Additional Revocation Policies
R	10/10.4/10.4.8/Deactivations
R	10/10.5/Timeliness and Accuracy Standards
R	10/10.6/10.6.1.2/Changes of Information – Transitioned Certified Providers and Suppliers
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.6/10.6.15/Risk-Based Screening
R	10/10.6/10.6.21.1/Additional Miscellaneous Enrollment Topics
R	10/10.6/10.6.23/Special Instructions for Electronic Funds Transfer (EFT) Accounts and Special Payment Addresses

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 13415	Date: September 18, 2025	Change Request: 14109

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II. GENERAL INFORMATION

A. Background: The CMS Pub. 100-08, Chapter 10, outlines Medicare provider enrollment procedures and instructions. This CR has several objectives. First, it will formally add to Chapter 10 a number of existing operational procedures that have already been issued via other CRs and CMS directives. Second, it will make minor technical edits for purposes of clarity. No new procedures or practices will be established.

B. Policy: This CR does not involve any legislative or regulatory policies.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14109.1	The contractor shall observe the additions and technical edits to Chapter 10 of CMS Pub. 100-08.	X	X	X						NPEAST, NPWEST

IV. PROVIDER EDUCATION

None

Impacted Contractors: None

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Program Integrity Manual

Chapter 10 – Medicare Enrollment

Table of Contents

(Rev. 13415; Issued: 09-18-25)

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Statutory Background

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

B. Requirements

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

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

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

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

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

C. Initial FQHC Applications

1. Contractor Review and Required Documents

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

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

- Exhibit 177 (Attestation Statement) signed and dated by an authorized official (as defined in 424.502). To attest to being in compliance, the facility must be open and operating when the attestation is signed. Since FQHCs must sign an agreement stipulating that they will comply with § 1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC benefit (or provider/supplier) agreement when it is also signed and dated by PEOG. (See Pub. 100-07, chapter 2, section 2826B.)
- HRSA Notice of Grant Award (NOA) or FQHC Look-Alike Designation that: (1) includes an address for the site of the applicant which matches the practice location reported on the Form CMS-855A; and (2) has valid project period and budget period dates (designation period and annual certification period dates for the FQHC Look-Alike document). A Notice of Grant Award by HRSA verifies that the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies look-alike status.
- Form CMS-588; Electronic Funds Transfer (EFT) Authorization Agreement.
- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostics test. Pub. 100-07, chapter 6, section 6002 provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the FQHC's responsibility to review the CLIA requirements and obtain a CLIA certificate if needed. Neither the contractor nor CMS determines whether the FQHC needs to obtain and submit a CLIA certificate.
- Copy of state license (if applicable). The state license must be effective and cannot have expired. The facility name and address must be listed on the license.

2. General Processing Concepts

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

(B) Date on the NOA - The project period (Line 26 of the NOA) and budget period (Line 19 of the NOA) must be valid through the date on which the FQHC's application was complete (as determined by the contractor). For the HRSA Look-Alike document, the designation period (Line 6) and Annual

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

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

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

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

(F) Date Application Complete - When reviewing an initial FQHC application, the contractor shall determine the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing, so the contractor requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its approval letter as the CCN/PTAN effective date of the FQHC. The CCN/PTAN effective date cannot be made retroactive (see section 10.6.2).

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

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

- The applicable Indian Health Service (IHS) web link at https://www.ihs.gov/locations/. The contractor can search for the facility by clicking on the "Find Health Care" sub-link https://www.ihs.gov/findhealthcare/?CFID=15011511&CFTOKEN=36378825 or downloading

the Excel complete listing of IHS facilities. (These are the highly recommended means of verification.)

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

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

3. Determination

a. Approval

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

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

b. Denial

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

4. Post-PEOG Review and Response to Contractor

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

- Assign the CCN, which will be part of the 1000-1199 or 1800-1989 series

- Assign the effective date, which will be the date the FQHC application was considered complete by the contractor

- Make any necessary revisions to the draft approval letter

- Sign and date the attestation using the completion date, which is also the effective date (Exhibit 177)

- E-mail all of the foregoing documents and data to the contractor, at which point the aforementioned processing time clock resumes.

5. Post-Approval Contractor Action

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

D. Changes of Information

1. Location Changes

a. Verification

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

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

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

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

In all cases, the new address listed on the *NOA or NLD*, IHS website, etc., must match that listed on the Form CMS-855A change request. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter.

In addition, both the budget *period* date*s* and the project *period* date*s* on the *current official* NOA (or *the* designation period and annual certification period on the NLD) must be valid through the date on which the FQHC's change request application was complete (as determined by the contractor). The contractor shall develop for correct NOA dates if the project period *dates* and/or budget period *dates (*or the designation period and/or annual certification period *for an NLD)* do not meet the above-mentioned requirement.

If the new address is not on the current official NOA or NLD, either: (a) an expired NOA or NLD that has the new address in the terms and conditions, or (b) a Self-Update print-out listing the new address, can be referenced alongside the current official NOA or NLD as supporting documentation.

If the FQHC submits a Self-Update print-out alongside the current official NOA or NLD, the award number, project period, and budget period on the Self-Update print-out must match the current official NOA or NLD and must say ACTIVE. The Self-Update print-out by itself is not acceptable in lieu of the current official NOA or NLD.

b. Approval

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

c. Denial

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

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

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

3. All Other Change Requests

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

E. Changes of Ownership (CHOWs)

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

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

- The "provider agreement" for FQHCs is the Exhibit 177.
- No recommendations to the state or SOG Location are involved. The contractor and PEOG alone will handle the transaction. In particular, the contractor---in lieu of making a recommendation to the state/SOG Location---will send its "final analysis" to PEOG. PEOG will then: (i) review the

transaction; (ii) determine whether the CHOW should be approved; (iii) as needed, update ASPEN and perform any other related tasks; and (iv) notify the contractor of the results of its review and provide any required direction. The above-described process, in effect, combines a recommendation to the state/SOG Location and the contractor's post-recommendation e-mail to PEOG (described in section 10.6.1.1.3.3(B)) into a single step. For purposes of this section 10.2.1.4(E), the term "final analysis" (in the context of FQHC CHOWs) is roughly the equivalent of a recommendation to the state. Accordingly, when sending its "final analysis" to PEOG as described above, the contractor may—but is not required to—change the application's status in PECOS to "approval recommended."

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

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

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

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

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

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

1. Special Processing Steps

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

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

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

- Exhibit 177 containing the new owner's information.

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

b. Old and New Owner Applications

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

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

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

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

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

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

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

d. Intervening Change of Ownership

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

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

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

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

- Return the CHOW application.

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

- Request via letter that the FQHC submit a new initial Form CMS-855 application containing the new owner's information within 30 days of the date of the letter. If the FQHC fails to do so, the contractor shall return the originally submitted initial application and notify the FQHC accordingly. If the FQHC submits the requested application, the contractor shall process it consistent with the instructions in this chapter; the originally submitted initial application becomes moot. If the newly submitted/second initial application is denied, however, the first submitted application is denied as well; the contractor shall notify the FQHC accordingly.

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

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

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

2. Post-Initial Review Actions and Scenarios

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

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

copy of the CMS-countersigned Exhibit 177 to the FQHC; and (2) switch the PECOS record to "approved" consistent with existing instructions.

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

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

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

F. Timeframes and Alternatives

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

G. Supporting Documentation

1. Revalidations

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

2. Initial Applications, CHOWs, and Location Changes

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

H. Revocations and Other Transactions

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

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

I. Complaint Investigations

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

J. FQHC DPV Errors

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

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

K. Enrollment as Clinic Via Form CMS-855B

FQHCs that are enrolled via the Form CMS-855A may occasionally also be enrolled as a group practice or clinic via the Form CMS-855B. In this scenario, the entity need not establish separate locations, suites, etc. – one for the FQHC enrollment and another for the group enrollment. This is because it is same organization; it is simply billing Medicare via different enrollments.

L. Additional Data

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Act
- 42 CFR Part 491 and 42 CFR Part 405, subpart X
- Pub. 100-07, chapter 2, sections 2825 – 2826H
- Pub. 100-07, chapter 9, exhibits 177 and 179

- Admin Info 21 06-ALL – Transitioning FQHC Certification Enrollment Performed by the CMS SOG (Standard Operating Procedures attached)
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

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

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

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

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

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

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

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

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

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

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

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

iii. Synopsis

In sum:

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

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

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

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

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

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

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

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

B. IDTF Standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations. (§ 410.33(g)(6))

7. Agree not to directly solicit patients; this includes - but is not limited to - a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician who: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem; and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in § 410.32(a)(3). (§ 410.33(g)(7))

- By the signature of the authorized official in Section 15 of the Form CMS-855B, the IDTF agrees to comply with 42 CFR § 410.33(g)(7).

- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.

- There is no prohibition on television, radio, or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. (§ 410.33(g)(8))

9. Openly post these standards for review by patients and the public. (§ 410.33(g)(9))

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change. (§ 410.33(g)(10))

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards. (§ 410.33(g)(11))

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable federal or state licenses or certifications of the individuals performing these services. (§ 410.33(g)(12))

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days. (§ 410.33(g)(13))

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours. (§ 410.33(g)(14))

15. With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (§ 410.33(g)(15))

16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed-base location. (§ 410.33(g)(16))

17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act (§ 410.33(g)(17)) (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as an agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

If the IDTF claims that it is furnishing services under arrangement as described in section 1861(w)(1), the IDTF must provide documentation of such with its initial or revalidation Form CMS-855 application.

The IDTF must meet all of the standards in 42 CFR § 410.33 – as well as all other federal and state statutory and regulatory requirements – in order to be enrolled in, and to maintain its enrollment in, the Medicare program. Failure to meet any standard in 42 CFR § 410.33 or any other applicable requirement will result in the denial of the supplier's Form CMS-855 application or, if the supplier is already enrolled in Medicare, the revocation of its Medicare billing privileges.

C. Leasing and Staffing

For purposes of the provisions in 42 CFR § 410.33, a "mobile IDTF" does not include entities that lease or contract with a Medicare enrolled provider or supplier to provide: (1) diagnostic testing equipment; (2) non-physician personnel described in 42 CFR § 410.33(c); or (3) diagnostic testing equipment and non-physician personnel described in 42 CFR § 410.33(c). This is because the provider/supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

An IDTF is not required to report equipment that the IDTF is leasing for a period less than 90 days unless the IDTF is leasing equipment for services that they have not already reported on a Form CMS-855B IDTF Attachment. For all new services being provided, IDTFs would need to complete a change of information to include the equipment and CPT/HCPCS codes that will be billed. Any accreditation for the services provided would need to be obtained by the IDTF.

D. Sharing of Space and Equipment

As previously noted, the standard in § 410.33(g)(15) states that, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF cannot: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

If the contractor determines that an IDTF is violating at least one of the three prohibitions in § 410.33(g)(15), the contractor shall revoke the supplier's Medicare billing privileges.

E. Multi-State IDTFs

As stated in 42 CFR § 410.33(e)(1), an IDTF that operates across state boundaries must:

a. Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the states in which it operates; and

b. Operate in compliance with all applicable federal, state, and local licensure and regulatory requirements with regard to the health and safety of patients.

Under § 410.33(e)(2), the point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's

location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

F. One Enrollment per Practice Location

An IDTF must separately enroll each of its practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that an enrolling IDTF can only have one practice location on its Form CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete Form CMS-855B application for that location and have that location undergo a separate site visit. Also, each of the IDTF's mobile units must enroll separately; if a fixed IDTF site also contains a mobile unit, the mobile unit must therefore enroll separately from the fixed location.

Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location's failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

If an IDTF adds equipment for diagnostic testing that is mobile in nature but is fixed permanently to the IDTF's physical location (i.e., a CT scanner that is mounted in a bus or trailer but is parked at the IDTF's site for use by the IDTF), a second enrollment is not necessary. This equipment can be listed in the Form CMS-855B along with the services performed on the equipment. In these cases, the contractor shall indicate the use of a fixed mobile unit is in use at the IDTF's site in the site visit request so the site inspector will know to view the fixed mobile equipment as part of the IDTF.

G. Interpreting Physicians

1. Reporting Interpreting Physicians on the Form CMS-855B

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who will provide interpretations subject to the anti-markup payment limitation as detailed in CMS Pub. 100-04, chapter 1, § 30.2.9 - whether the service is provided to the IDTF on a contract basis or is reassigned.

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare.

- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so.

- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The contractor may need to contact another contractor to obtain this information.) If the applicant does not list any interpreting physicians, the contractor need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

If an interpreting physician has been recently added or changed, the new interpreting physician must have met all of the interpreting physician requirements at the time any tests were performed.

A Form CMS-855R need not accompany a Form CMS-855B application submitted by an IDTF that employs or contracts with an interpreting physician.

2. Changes of Interpreting Physicians

If an interpreting physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. To perform services as an interpreting physician, the new interpreting physician must have met all requirements at the time any tests were performed.

If the contractor receives notification from an interpreting physician that the latter is no longer interpreting tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information to end date the interpreting physician from the enrollment.

H. Effective Date of IDTF Billing Privileges

As stated in 42 CFR § 410.33(i), the filing date of an IDTF Medicare enrollment application is the date the contractor receives a signed application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by the contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

A newly-enrolled IDTF, therefore, may not receive reimbursement for services furnished before the effective date of billing privileges.

The contractor shall note that if it rejects an IDTF application under 42 CFR § 424.525 and a new application is later submitted, the date of filing is the date the contractor receives the new enrollment application.

If an IDTF undergoes an ownership change that results in a new enrollment (e.g., a new federal tax information number (TIN) results from this change), the contractor should use the transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

I. IDTF Technicians Must Be Listed on the Form CMS-855B

Each non-physician who performs IDTF diagnostic tests must be listed. These persons are often referred to as technicians.

J. IDTF Technician Licensure and Certification Requirements

All technicians must meet state licensure or state certification standards at the time of the IDTF's enrollment. The contractor may not grant temporary exemptions from such requirements.

In lieu of requiring a copy of the technician's certification card, the contractor may validate a technician's credentials online via organizations such as the American Registry for Diagnostic Medical Sonography (ARDMS), the American Registry of Radiology Technologists (ARRT), and the Nuclear Medicine Technology Certification Board (NMTCB). If online verification is not available or cannot be made, the contractor shall request a copy of the technician's certification card.

K. IDTF - Changes of Technicians

If a technician is being added or changed, the updated information must be reported via a Form CMS-855B change request. The new technician must have met all of the necessary credentialing requirements at the time any tests were performed.

If the contractor receives notification from a technician that the latter is no longer performing tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the supplier did not have another technician qualified to perform the tests listed on the current application, the supplier must submit significant documentation in the form of payroll records, etc. to substantiate the performance of the test by a properly qualified technician after the date the original technician was no longer performing procedures at the IDTF.

L. IDTF Supervising Physicians – General Principles

An IDTF must have one or more supervising physicians who are responsible for:

- The direct and ongoing oversight of the quality of the testing performed;
- The proper operation and calibration of equipment used to perform tests; and
- The qualifications of non-physician IDTF personnel who use the equipment.

Not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

Under 42 CFR § 410.33(b)(1), each supervising physician must be limited to providing general supervision at no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

M. IDTF - Information about Supervising Physicians

The contractor shall ensure and document in PECOS that each supervising physician is: (1) licensed to practice in the state(s) where the diagnostic tests the physician 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 the physician's role as a supervising physician (i.e., the physician need not have a medical practice separate from the IDTF). If the physician is enrolled in another state or with another contractor, however, the contractor shall ensure that the physician is appropriately licensed in that state.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.

- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.

- If the contractor knows that a reported supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether the latter 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 the physician's role as a supervising physician: (1) the contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a PTAN; (2) the physician shall list the IDTF's address as a practice location; and (3) the space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

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

The contractor shall: (a) be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR § 410.32(b)(3); and (b) ensure that the applicant has checked the highest required level of supervision for the tests being performed.

Each box that begins with "Assumes responsibility" must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

O. IDTF - Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervising physician listed. If Question E2 is not completed, the contractor may assume – unless it has reason to suspect otherwise - that the supervising physician in question supervises for all codes listed in Section 2 of the IDTF attachment. If Question E2 is completed, the contractor shall ensure that all codes listed in Section 2 are covered through the use of multiple supervising physicians.

The contractor no longer needs to contact each supervisory physician by telephone or otherwise to verify that the physician: (1) actually exists (e.g., is not using a false or inactive physician number); (2) indeed signed the attestation; and (3) is aware of the physician's responsibilities.

If the physician is enrolled with a different contractor, the contractor shall contact the latter contractor and obtain the listed telephone number of the physician.

P. IDTF - Changes of Supervising Physicians

If a supervising physician is being added or changed, the updated information must be reported via a Form CMS-855B change request. To perform services as a supervising physician, the new supervising physician must have met all requirements at the time any tests were performed.

If the contractor receives notification from a supervising physician that the latter is no longer supervising tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B

change of information. If the IDTF did not have another supervising physician listed on the current application, the IDTF must submit a change of information adding a new supervising physician. If the IDTF does not provide this information, the contractor shall proceed with non-compliance revocation procedures as noted in section 10.4(M) of this chapter.

Q. Desk and Site Reviews

All initial and revalidating IDTF applicants shall receive: (1) a thorough desk review; and (2) a mandatory site visit prior to the contractor's approval of the application. The general purposes of these reviews are to determine whether:

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.

- To the extent applicable, the IDTF meets the criteria outlined in sections 10.6.20(A) and 10.6.20(B) of this chapter.

- The IDTF meets the supplier standards in 42 CFR § 410.33.

The contractor shall order the site visit through PECOS. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

R. Mobile Units

Mobile units must list their geographic service areas in Section 4 of the Form CMS-855B. Based on the information furnished therein, the NSVC will generally perform the site visit via one of the following methods: (1) the mobile unit visits the office of the NSVC (or some other agreed-to location) for inspection; (2) the NSVC visits the mobile unit's base of operations to inspect the unit; or (3) the NSVC obtains an advance schedule of the locations at which the IDTF will be performing services and conducts the site visit at one of those locations.

Units performing CPT-4 or HCPCS code procedures that require direct or personal supervision mandate special attention. To this end, the contractor shall maintain a listing of all mobile IDTFs that perform procedure codes that require such levels of supervision. The contractor shall also discuss with the applicant and all supervising physicians listed:

- How they will perform these types of supervision on a mobile basis;

- What their responsibilities are; and

- That a patient's physician who is performing direct or personal supervision for the IDTF on the patient should be aware of the prohibition concerning physician self-referral for testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

S. Addition of Codes

An enrolled IDTF that wants to perform additional CPT-4 or HCPCS codes must submit a Form CMS-855B change request. If the additional procedures are of a type and supervision level similar

to those previously reported (e.g., an IDTF that performs MRIs for shoulders wants to perform MRIs for hips), a new site visit is typically not required, though the contractor reserves the right to request that the NSVC perform one.

If, however, the enrolled IDTF wants to perform additional procedures that are 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 NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

If the enrolled IDTF (1) originally listed only general supervision codes, (2) was only reviewed for general supervision tests, and (3) now wants to perform tests that require direct or personal supervision, the contractor shall promptly suspend all payments for all codes other than those requiring general supervision. The contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

In the situations described in the two previous paragraphs, the contractor shall not approve the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

T. IDTF That Performs Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration certification to perform the mammography. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography screening center.

U. IDTF Ownership of CLIA Laboratory

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number may own both an IDTF and an independent CLIA laboratory. In such a situation, they should be separately enrolled and advised to bill separately. The contractor shall also advise its claims unit to ensure that the CLIA codes are not being billed under the IDTF provider number.

V. Denials and Revocations for Non-Compliance with IDTF Supplier Standards

Pursuant to 42 CFR §§ 424.530(a)(1)/(18) and 424.535(a)(1)/(23), an IDTF's enrollment may be denied or revoked if it violates any applicable standard in *§ 410.33(g).*

10.2.2.10 – Suppliers of Ambulance Services

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

Suppliers of ambulance services are supplier types that enroll via the Form CMS-855B.

A. General Background Information

It is important that the contractor review and adhere to the following regulations and instructions regarding the required qualifications of ambulance suppliers:

- 42 CFR §§ 410.40 and 410.41
- 42 CFR Part 414, subpart H
- Pub. 100-02, chapter 10
- Pub. 100-04, chapter 15

B. Types of Ambulance Services

As stated in 42 CFR § 410.40(c), there are several levels of ambulance services covered by Medicare. They are generally defined in § 414.605 and in Pub. 100-02, chapter 10, section 30.1 as follows:

1. Advanced Life Support, level 1 (ALS1) - Transportation by ground ambulance vehicle, medically necessary supplies and services, and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

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

3. Air Ambulance (Fixed-Wing and Rotary-Wing) (See § 414.605 and Pub. 100-02, chapter 10, section 30.1.1.for specific definitions of fixed-wing and rotary-wing.)

4. Basic Life Support (BLS) - Transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished and where at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the state or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

5. Paramedic ALS Intercept Services (PI) - Per § 414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in § 410.40(d). In general, PI involves an arrangement between a BLS ambulance supplier and an ALS ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. Under § 410.40(d)(1) through (3), respectively, PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area (see § 410.40(d)(1) for more information on this requirement).

- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions: (1) are certified to furnish ambulance services as required under § 410.41; (2) furnish services only at the BLS level; and (3) be prohibited by state law from billing for any service.

- Be furnished by a paramedic ALS intercept supplier that meets the following conditions: (1) is certified to furnish ALS services as required in § 410.41(b)(2); and (2) bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.

6. Specialty Care Transport (SCT) - Inter-facility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (e.g., emergency or critical care nursing, emergency medicine, respiratory care, cardiovascular care, or an EMT-Paramedic with additional training).

C. Ambulance Qualifications

1. Vehicle Design and Equipment

Section 410.41(a) states that a vehicle used as an ambulance must meet the following requirements:

- Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all state and local laws governing an emergency transportation vehicle.

- Be equipped with emergency warning lights and sirens, as required by state or local laws.

- Be equipped with telecommunications equipment as required by state or local law to include, at a minimum, one two-way voice radio or wireless telephone.

- Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by state or local laws.

2. Vehicle Personnel

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

Per 42 CFR § 410.41(b)(2), an ALS vehicle must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must: (i) meet the BLS vehicle staff requirements described in 42 CFR § 410.41(b)(1); and (ii) must also have one of the two staff members be certified as a paramedic or an emergency medical technician by the state or local authority where the services are being furnished to perform one or more ALS services.

D. Completion of the Form CMS-855B

Pub. 100-02, chapter 10, section 10.1.3 states that, in determining whether the vehicles and personnel of the ambulance supplier meet all of the above requirements, the contractor may accept the supplier's statement (absent information to the contrary) that its vehicles and personnel meet all of the requirements if the statement itself meets the requirements of section 10.1.3. However, section 10.1.3 does not obviate the need for the supplier to complete and submit to the contractor the Form CMS-855B (including Attachment 1 and all supporting documents), and does not excuse the contractor from having to verify the data on the Form CMS-855B in accordance with this chapter and all other applicable CMS instructions. In other words, the "statement" referred to in section 10.1.3 does not supplant or replace the Form CMS-855B enrollment process.

E. Geographic Area: Single Contractor Jurisdiction

If an ambulance supplier will furnish all of its services in the same contractor jurisdiction, the supplier should list:

- Each site at which its vehicles are garaged in Section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)

- Each site from which its personnel are dispatched in Section 4A. (The site is considered a practice location for enrollment purposes, including with respect to payment of the application fee.)

- Its base of operations – which, for ambulance companies, is their primary headquarters – in Section 4E. (The supplier can only have one base of operations.)

If the supplier will furnish services in more than one contractor jurisdiction, the applicable instructions in sections 10.2.2.10(F) and (G) and 10.3.1(B)(1)(d)(iii) of this chapter apply.

F. Geographic Area: Multiple States

The supplier must list the geographic areas in which it provides services. If the supplier indicates that it furnishes services:

- In more than one contractor's jurisdiction, it must submit a separate Form CMS-855B to each contractor.

- In more than one state but within the same contractor jurisdiction, the contractor shall review sections 10.2.2(G)(7), 10.3, and 10.3.1(B)(1)(d)(iii) of this chapter to determine whether a separate enrollment for the additional state is required.

G. Practice Locations

For purposes of provider enrollment (and as indicated in section 10.2.2.10(E) above), the following are considered ambulance "practice locations":

- A site at which the supplier's vehicles are garaged

- A site from which the supplier's personnel are dispatched

- The supplier's base of operations (i.e., the supplier's primary headquarters). The supplier can only have one base of operations.

Hence, if an ambulance supplier submits a Form CMS-855B to add to its enrollment record a site at which the supplier's vehicles are garaged or from which personnel are dispatched, the supplier must pay an application fee.

Consider the following scenarios:

a. The ambulance supplier is enrolling and performing services in multiple states but within only one contractor jurisdiction: The supplier would have to list on its Form CMS-855B each city/state/zip code in which it performs services. Its base of operations and all other practice locations would also have to be listed, and all licensure/certification requirements would have to be met for each state in which it performs services. However, separate Form CMS-855B applications for each state would only be required if all five conditions described in section 10.3.1(B)(1)(d)(iii) of this chapter are met.

b. The ambulance supplier is enrolling (and has its base of operations) in Contractor Jurisdiction X. Its vehicles perform services in X and in adjacent Contractor Jurisdiction Y: The supplier would have to enroll with X and Y. For its Contractor X Form CMS-855B, the supplier would have to list all of the data mentioned in Example (a) above. For its Contractor Y Form CMS-855B, the supplier would have to (1) list the cities/zip codes in Y in which it performs services, (2) list its Jurisdiction X base of operations and any practice locations in Jurisdiction Y, and (3) meet all licensure/certification requirements for the state(s) in Y in which the supplier performs services.

H. Licensure Information

With respect to licensure:

- The contractor shall ensure that the supplier is appropriately licensed and/or certified, as applicable.

- An air ambulance supplier that is enrolling in a state to which it flies in order to pick up patients (that is, a state other than where its base of operations is located) is not required to have a practice location or place of business in that state. So long as the air ambulance supplier meets all other criteria for enrollment in Medicare, the contractor for that state may not deny the supplier's enrollment application solely on the grounds that the supplier does not have a practice location in that state. (This policy only applies to air ambulance suppliers.)

I. Paramedic Intercept Information

If the applicant indicates that it has a paramedic intercept arrangement, it must include a copy of the agreement/contract with its application.

J. Air Ambulances

Air ambulance suppliers must submit proof that it or its leasing company possesses a valid charter flight license (FAA Part 135 Certificate) for the aircraft being used as an air ambulance. Any of the following constitutes acceptable proof:

- If the air ambulance supplier or provider owns the aircraft, the owner's name on the FAA Part 135 certificate must be the same as the supplier's or provider's name on the enrollment application.

- If the air ambulance supplier or provider owns the aircraft but contracts with an air services vendor to supply pilots, training, and/or vehicle maintenance, the FAA Part 135 certificate must be issued in the name of the air services vendor. A certification from the supplier or provider must also attest that it has an agreement with the air services vendor and must list the date of that agreement. A copy of the FAA Part 135 certificate must accompany the enrollment application.

- If the air ambulance supplier or provider leases the aircraft from another entity, a copy of the lease agreement must accompany the enrollment application. The name of the company leasing the aircraft from that other entity must be the same as the supplier's or provider's name on the enrollment application.

  The air ambulance supplier shall maintain all applicable federal and state licenses and certifications, including pilot certifications, instrument and medical certifications, and air worthiness certifications.

In addition:

- The contractor shall access the following FAA Web site on a quarterly basis to validate all licenses/certifications of air ambulance operators that are enrolled with the contractor: https://www.faa.gov/about/officeorg/headquartersoffices/avs/faa-certificated-aircraft-operators-legal-part-135-holders. This helps ensure that the supplier's licenses/certifications are active and in good standing.

- The contractor shall deny or revoke the enrollment of an air ambulance supplier if the supplier does not maintain its FAA certification or any other applicable licenses.

- Section 424.516(e)(3) states that within 30 days of any revocation or suspension of a federal or state license or certification (including an FAA certification), an air ambulance supplier must report the revocation or suspension of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported: (i) specific pilot certifications including, but not limited to, instrument and medical certifications; and (2) airworthiness certification.

K. Hospital-Based Ambulances

An ambulance service that is owned and operated by a hospital need not complete a Form CMS-855B if:

- The ambulance services will appear on the hospital's cost-report; and

- The hospital possesses all licenses required by the state or locality to operate the ambulance service.

If the hospital decides to divest itself of the ambulance service, the latter will have to complete a Form CMS-855B if it wishes to bill Medicare.

10.2.3.15 – Speech Language Pathologists in Private Practice

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

The CMS Pub. 100-02, chapter 15, section 230.3 sets forth the definition of "qualified speech language pathologist" in § 484.115(n) as an individual who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

- *Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; OR*
- *In the case of an individual who furnishes services in a state which does not license speech-language pathologists:*

  a. *Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);*
  b. *Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and*
  c. *Successfully completed a national examination in speech-language pathology approved by the Secretary.*

Accordingly, an individual must meet this definition of "qualified speech language pathologist" to enroll as a speech language pathologist in private practice (SLPPP). This is in addition to meeting the private practice requirements in §§ 410.62(c)(1)(ii) through (iv) in which the individual must:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the state in which the individual practices, and practice only within the scope of the individual's license and/or certification.

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual in one of the following practice types: a solo practice, partnership, group practice, or as an employee of one of these.

(iii) Bill Medicare only for services furnished in one of the following:

(A) A speech-language pathologist's private practice office space that meets all of the following: (1) the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services and during the hours that the therapist engages in practice at that location; and (2) the space must be owned, leased, or rented by the practice, and used for the exclusive purpose of operating the practice; or

(B) A patient's home not including any institution that is a hospital, a CAH, or a SNF.

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

Individuals should check the "Qualified Speech Language Pathologist" box on the Form CMS-855I when enrolling as an SLPPP.

For more information on speech language pathologists in private practice, refer to Pub. 100-02, chapter 15, section 230.

10.4.1.4.2 - Returns

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Reasons/Grounds for Return

(See 42 CFR § 424.526 for regulatory provisions regarding application returns.)

Notwithstanding any other directive to the contrary in this chapter or another CMS directive, the contractor (including *an NPE*) may immediately return the enrollment application to the provider only in the instances described below and which are outlined in § 424.526(a)(1) through (13). Except as otherwise indicated in the specific return reason, this policy applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations, etc.) (Note that some of these return reasons may no longer apply or will be rendered moot with the advent of PECOS 2.0):

(1) The provider/supplier sent its paper Form CMS-855, Form CMS-588, or Form CMS-20134 to the incorrect contractor for processing (e.g., the application was sent to Contractor X instead of Contractor Y).

(2) The contractor received the application more than 60 days prior to the effective date listed on the application. (This does not apply to (i) initial Form CMS-855A applications and (ii) ambulatory surgical centers and portable x-ray suppliers submitting an initial Form CMS-855B application.)

(3) The seller or buyer in a CHOW submitted its Form CMS-855A or Form CMS-855B application more than 90 days prior to the anticipated date of the sale.

(4) The contractor received an initial application more than 180 days prior to the effective date listed on an application from an ambulatory surgical center, a portable x-ray supplier, or a provider/supplier submitting a Form CMS-855A application.

(5) The contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider/supplier submitted an initial application prior to the expiration of their existing reenrollment bar or reapplication bar.

(7) The application is not needed for (or is inapplicable to) the transaction in question. Examples include, but are not limited to, the following:

- A rebuttal decision has been issued (therefore, the submitted Form CMS-855, Form CMS-588, or Form CMS-20134 is not needed). (See section 10.4.8.1(A) of this chapter for more information.)

- The application is to be returned per section 10.6.1.1.3.1.1 of this chapter.

(8) The provider/supplier submitted a revalidation application more than 7 months prior to their revalidation due date.

(9) The MDPP supplier submitted an application with a coach start date more than 30 days in the future.

(10) A provider/supplier requests that their application be withdrawn prior to or during processing.

(11) A provider/supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider/supplier submits a paper Form CMS-855 or Form CMS-20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider/supplier submits a Form CMS-855A or Form CMS-855B initial application followed by a Form CMS-855A or Form CMS-855B change of ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS-855A or Form CMS-855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS-855A or Form CMS-855B application.

(The difference between a "rejected" application and a "returned" application is that the former is typically based on the provider's failure to respond to the contractor's request for missing or clarifying information. A "returned" application is effectively considered a non-submission.)

Note that the contractor need not request additional information in any of these scenarios. For instance, if the application is not necessary for the particular transaction, the contractor can return the application immediately; if the provider already submitted an application fee, the contractor shall follow existing instructions regarding the return of the fee.

B. Procedures for Returning the Application

If the contractor returns the application, the following apply:

(i) The contractor shall notify the provider via the applicable return letter (sent by mail, the PCV, or e-mail) that the application is being returned, the reason(s) for the return, and how to reapply.

(ii) The contractor shall not enter the application into PECOS. No L & T record shall be created.

(iii) Any application resubmission requires a brand new certification statement page containing a signature and date. The provider cannot simply add its signature to the original certification statement it submitted. (This does not apply to e-signature situations.)

(iv) For paper applications, the contractor shall: (A) keep the original application and supporting documents and return a copy; (B) make a copy or scan of the application and documents and return the originals to the provider; or (C) simply send a letter to the provider (in lieu of sending the originals or a copy thereof) explaining that the application is being returned (though not physically returned) and why. (If the contractor chooses the third approach and the provider requests a copy of its application, the contractor should fax or mail it to the provider.)

See section 10.3 of this chapter for more information regarding the return of applications.

C. Special Situations Concerning Changes of Information and Changes of Ownership

1. Expiration of Timeframe for Reporting Changes - If the contractor returns a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to its PEOG BFL notifying the latter of the return. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

2. Timeframe Not Yet Expired - If the contractor returns a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in section 10.4.1.4.2(C)(1) after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

3 Second Return, Rejection, or Denial – If, per section 10.4.1.4.2, the provider resubmits the change of information or CHOW application and the contractor either returns it again, rejects it, or denies it, the contractor shall send the e-mail referenced in section 10.4.1.4.2(C)(1) regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

D. Reactivations

If the contractor returns a reactivation application, the provider's Medicare billing privileges shall remain deactivated.

E. Revalidations

If the contractor returns a revalidation application, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider's Medicare billing privileges under 42 CFR § 424.540(a)(3) if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If the provider indeed resubmits the application and the contractor returns it again, rejects it, or denies it, the contractor shall – absent another CMS instruction to the contrary - deactivate the provider's billing privileges, assuming the applicable time period has expired.

10.4.1.4.3 - Rejections

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Background

1. Rejection Reasons

a. Section 424.525(a)(1)(i) through (x) – Submission of Complete Information

In accordance with 42 CFR § 424.525(a)(1)(i) through (x), the contractor (including *an NPE*) may reject the provider's application if the provider fails to furnish complete information on the enrollment application within 30 calendar days from the date the contractor requested the missing information. For purposes of this policy, this includes situations where the provider submitted an application that falls into one of the following categories and, upon the contractor's request to submit a new or corrected complete application, the provider failed to do so within 30 days of the request:

(i) The application is missing data required by CMS or the contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application.

(v) The application is signed by a person unauthorized to do so under this 42 CFR Part 424, subpart P.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS-855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS-855 application. (For example, the provider or supplier submitted a Form CMS-855A application when a Form CMS-855B application was required.)

(Note that certain rejection grounds are inapplicable to PECOS applications (e.g., Form CMS-855 application was completed in pencil, certification statement is missing)).

b. Section 424.525(a)(2) - Documentation

In accordance with 42 CFR § 424.525(a)(2), the contractor (including *an NPE*) may reject the application if the provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the application.

c. Section 424.525(a)(3) – Application Fee

Consistent with 42 CFR § 424.525(a)(3), the contractor (including *an NPE*) may reject the application if the institutional provider (as that term is defined in § 424.502) does not submit the application fee in the designated amount or a hardship waiver request (1) with the application at the time of filing and (2) after development for the fee by the contractor. This means that the contractor shall develop for a non-submitted fee rather than return the application. (It need not develop for a waiver, however.) If the institutional provider fails to submit the fee (or a waiver) within 30 days of the request, the contractor can reject the application.

2. Applicability

a. Development

The applications described in subsections (A)(1)(a) through (c) above shall be developed, rather than returned. For instance, if a provider submits an application completed in pencil, the contractor shall request the provider to submit a new application, either in ink or via Internet-based PECOS.

b. Transaction and Form Types

Per § 424.525(e)---and except as otherwise specified in the applicable reason for rejection---§ 424.525(a)(1) through (3) apply to all CMS provider enrollment application submissions, including, but not limited to, the following:

- Form CMS-855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.
- Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.
- Form CMS-20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.
- Any electronic or successor versions of the forms identified in paragraphs § 424.525(e)(1) through (3).)

B. Timeframe

The 30-day clock identified in § 424.525(a) starts on the date the contractor mails, faxes, or e-mails (e.g., via the PCV) the development letter or other request for information to the provider. If the contractor makes a follow-up request for information, the 30-day clock does not start anew; rather, it keeps running from the date the development letter was sent. However, the contractor has the discretion to extend the 30-day timeframe if it determines that the provider is actively working with the contractor to resolve any outstanding issues.

C. Incomplete Responses

The provider must furnish all missing and clarifying data and/or documentation requested by the contractor within the applicable timeframe. If the provider furnishes some, but not all, of the requested information, the contractor is not required to contact the provider again to request the remaining data. It can simply reject the application at the expiration of the aforementioned 30-day period. Consider the following example:

EXAMPLE: A provider submits a Form CMS-855A in which Section 3 is blank. On March 1, the contractor requests that Section 3 be fully completed. On March 14, the provider submits an application with the Final Adverse Action History question completed. However, the report of each

adverse action, date, applicable body, and resolution data fields remains blank. The contractor need not make a second request for this data to be furnished. It can reject the application on March 31, or 30 days after its initial request was made.

D. Creation - Paper Applications Only

If the contractor cannot complete the intake or data entry process in PECOS because of missing data and the application is subsequently rejected, the contractor shall disposition the application accordingly in PECOS consistent with existing CMS guidance.

E. Other Impacts of a Rejection

1. Changes of Information and CHOWs

a. Expiration of Timeframe for Reporting Changes - If the contractor rejects a change of information or CHOW submission per this chapter and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to its PEOG BFL notifying the BFL of the rejection. PEOG will determine whether the provider/supplier's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

b. Timeframe Not Yet Expired - If the contractor rejects a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in subsection (E)(1)(a) above after the expiration of said time period unless the provider/supplier has resubmitted the change request/CHOW.

c. Second Rejection, Return, or Denial – If, per subsection (E)(1)(b) above, the provider resubmits the change of information or CHOW application and the contractor either rejects it again, returns it, or denies it, the contractor shall send the e-mail referenced in subsection (E)(1)(a) above regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

F. Reactivations

If the contractor rejects a reactivation application, the provider's Medicare billing privileges shall remain deactivated.

G. Revalidations

If the contractor rejects a revalidation application per this chapter 10, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider/supplier's Medicare billing privileges under 42 CFR § 424.540(a)(3) if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider/supplier's billing privileges after the applicable time period expires unless the provider/supplier has resubmitted the revalidation application. If the provider/supplier indeed resubmits the application and the contractor rejects it again, returns it, or denies it, the contractor shall – absent a CMS instruction to the contrary - deactivate the provider's billing privileges, assuming the applicable time period has expired.

H. Additional Rejection Policies

1. Resubmission after Rejection

If the provider's application is rejected, the provider must complete and submit a new Form CMS-855 or CMS-20134 (either via paper or Internet-based PECOS) and all necessary documentation.

2. Applicability

Unless stated otherwise in this chapter or another CMS directive, this section 10.4.1.4.3 applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, CHOW applications, revalidations, and reactivations).

3. Physicians and Non-Physician Practitioners

Incomplete applications submitted by physicians and non-physician practitioners shall be rejected (unless a denial reason exists) if they fail to provide the requested information within the designated timeframe.

4. Notice

If the contractor rejects an application, it shall notify the provider via letter (sent via fax, mail, the PCV, or e-mail) that the application is being rejected, the reason(s) for the rejection, and how to reapply. Absent a CMS instruction or directive to the contrary, the letter shall be sent to the provider no later than 5 business days after the contractor concludes that the provider's application should be rejected.

5. Copy of Application

Paper Applications - If the contractor rejects an application, it shall either (1) keep the original application and all supporting documents or (2) maintain the scanned submission of the application and documents in PECOS and return the originals to the provider. If the contractor chooses the former approach and the provider requests a copy of its application, the contractor may fax or mail it to the provider.

PECOS – Since the application was submitted electronically via PECOS and all supporting documents were uploaded consistent with section 10.3 of this chapter, the contractor need not return any documents to the provider.

10.4.2.1 - Denials – General Principles

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Notification Letters for Denials

If the contractor finds a legal basis for denying an application - and, if applicable under section 10.4.2 et seq., section 10.6.6, or another CMS directive, receives approval from PEOG for said denial - the contractor shall deny the application and notify the provider by letter. Except as stated otherwise in this chapter, the denial letter shall contain:

(i) A legal (i.e., regulatory) basis for each reason for the denial;

(ii) A clear explanation of why the application is being denied, including the facts or evidence that the contractor used in making its determination;

(iii) An explanation of why the provider does not meet the applicable enrollment criteria;

(iv) The appropriate regulatory basis (e.g., 42 CFR § 424.530(a)(1)) for the denial. (The contractor shall not use provisions from this chapter 10 as the basis for denial.)

(v) Procedures for submitting a corrective action plan (CAP, for denials based on 42 CFR § 424.530(a)(1)); and

(vi) Complete and accurate information about the provider's further appeal rights.

In addition, the letter shall follow the format of the applicable model denial letter in section 10.7 et seq. of this chapter.

There is no reenrollment bar for denied applications. Reenrollment bars apply only to *revocations.*

B. **When Prior PEOG Approval of the Denial Necessary**

For cases involving 42 CFR § 424.530(a)(1) (Noncompliance – Not Professionally Licensed Individual Practitioners), § 424.530(a)(2) (Provider or Supplier Conduct), 42 CFR § 424.530(a)(3) (Felony Convictions), § 424.530(a)(4) (False or Misleading Information or Application), § 424.530(a)(6) (Medicare Debt), § 424.530(a)(7) (Payment Suspension), § 424.530(a)(11) (Prescribing Authority), § 424.530(a)(12) (Revoked Under Different Name, Numerical Identifier, or Business Identity), § 424.530(a)(13) (Affiliation that Poses an Undue Risk), § 424.530(a)(14) (Other Program Termination or Suspension),), § 424.530(a)(15) (Patient Harm), § 424.530(a)(17) (False Claims Act Civil Judgments), *and § 424.530(a)(18) (Supplier standard or condition violation),* the contractor shall obtain approval of both the denial *action* and the denial letter from PEOG via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox prior to sending the denial letter. The contractor shall also obtain prior PEOG approval of the denial *action* and denial letter if otherwise required to do so in this chapter or another CMS directive (i.e., certain denial situations other than those described in this subsection 10.4.2.1(B) require prior PEOG approval, such as those outlined in section 10.6.6). (Note that MDPP denials no longer require prior PEOG approval except in cases where such approval is otherwise mandated per this section 10.4.2.1(B) (e.g., MDPP denials under (a)(3), (a)(4), etc.)

PEOG will notify the contractor of its determination (including, as applicable, whether a reapplication bar under § 424.530(f) is to be imposed) and instruct the contractor as to how to proceed. Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider via certified mail no later than 5 business days after PEOG concludes that the provider's application should be denied. The contractor shall not proceed with finalizing the denial until it receives the above-mentioned guidance from PEOG. If this guidance is delayed, the contractor shall carve the impacted application(s) out of its timeliness reporting; the contractor shall document and report the impacted application(s) in its Monthly Status Reports.

C. When Prior PEOG Approval of the Denial Unnecessary – Timeframe for Sending Letter

Absent a CMS instruction or directive to the contrary, the denial letter shall be sent to the provider/supplier via certified mail no later than 5 business days after the contractor determines that the provider's application should be denied.

D. No Denial Recommendation to State

If the applicant is a certified provider or certified supplier and a denial reason is implicated, the contractor need not submit a recommendation for denial to the state/SOG Location. Except as stated otherwise in this chapter, the contractor can simply: (1) deny the application (though, as explained in this chapter, some denials might require prior PEOG approval); (2) close out the PECOS record; (3) send a denial letter to the provider; and (4) copy the state and the SOG Location on said letter.

E. PECOS Entry

All denied applications and all applicable denial reasons shall be entered into PECOS, including fingerprint and non-covered provider or supplier type denials. For non-covered provider or supplier type denials, the contractor shall select the "Other" specialty/provider/supplier type option and input the type listed on the application.

10.4.2.2 - Denial Reasons

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Denial Reason 1– Not in Compliance with Medicare Requirements (42 CFR §424.530(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in this Title 42 or on the enrollment application applicable to its provider or supplier type and has not submitted a plan of corrective action as outlined in 42 CFR part 488." Such non-compliance includes, but is not limited to, the following situations:

i. The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

ii. The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

iii. The provider or supplier is not appropriately licensed.

iv. The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.

v. The provider or supplier does not meet CMS regulatory requirements for the specialty that it seeks to enroll as. (See section 10.2.8 of this chapter for examples of suppliers that are not eligible to participate.)

vi. The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

vii. The applicant does not qualify as a provider of services or a supplier of medical and health services. (For instance, the applicant is not recognized by any federal statute as a Medicare provider

or supplier (see section 10.2.8 of this chapter.)) An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in § 1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

viii. The provider or supplier does not otherwise meet general enrollment requirements.

(With respect to (v) above – and, as applicable, (iii) and (iv) - the contractor's denial letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider or supplier type. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

NOTE: The contractor must identify in its denial letter the exact provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.

(NOTE: For (a)(1) denials involving an individual practitioner who is not appropriately licensed due to a disciplinary action, PEOG -- rather than the contractor -- will make all denial determinations for this noncompliance requirement).

B. Denial Reason 2– Excluded/Debarred from Federal Program (42 CFR § 424.530(a)(2))

(i) "The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel (such as a billing specialist, accountant, or human resources specialist) furnishing services payable by a federal health care program, of the provider or supplier is—

(A) Excluded from Medicare, Medicaid, or any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

(B) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act."

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.

(Unless stated otherwise in section 10.6.6 of this chapter or in another CMS directive, the contractor need not review the OIG exclusion list for any "health care or administrative or management services personnel" who are not otherwise required to be reported on the enrollment application.)

C. Denial Reason 3 – Felony Conviction (42 CFR § 424.530(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, director, of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR § 1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries.

(i) Offenses include, but are not limited in scope and severity to:

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit resulting in a conviction of criminal neglect or misconduct.

(D) Any felonies outlined in section 1128 of the Social Security Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(iii) The individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier."

While a reenrollment bar is established for revoked providers/suppliers, this does not preclude the contractor from denying reenrollment to a provider/supplier that was convicted of a felony within the preceding 10-year period or that otherwise does not meet all of the criteria necessary to enroll in Medicare.

Note that if an MDPP coach meets the above felony requirements, this would not itself warrant a denial of the MDPP supplier under § 424.535(a)(3). This is because the coach, not the MDPP supplier, has the felony conviction. The MDPP supplier could, however, be denied enrollment under § 424.530(a)(1) (non-compliance with enrollment requirements) for having an ineligible coach.

As explained in section 10.6.6 of this chapter, the contractor shall submit all felonies found on Form CMS-855 and CMS-20134 applications to PEOG for review via ProviderEnrollmentRevocations@cms.hhs.gov. (See section 10.6.6 for more information.)

D. Denial Reason 4– False or Misleading Information on Application (42 CFR § 424.530(a)(4))

"The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program."

E. Denial Reason 5– On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR §424.530(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Denial Reason 6– Medicare Debt (42 CFR § 424.530(a)(6))

1. Background

Consistent with 42 CFR § 424.530(a)(6), an enrollment application may be denied if:

(i) The provider, supplier, or owner thereof (as defined in § 424.502) has an existing Medicare debt:

(ii) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof was previously the owner of a provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily terminated, involuntarily terminated, or revoked, and all the following criteria are met:

(A) The owner left the provider or supplier with the Medicare debt within 1 year before or after that provider or supplier's voluntary termination, involuntary termination, or revocation.

(B) The Medicare debt has not been fully repaid.

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse. In making this determination [under § 424.530(a)(6)(ii)], CMS considers the following factors:

(1) The amount of the Medicare debt.

(2) The length and timeframe that the enrolling provider, supplier, or owner thereof was an owner of the prior entity.

(3) The percentage of the enrolling provider, supplier, or owner's ownership of the prior entity.

(4) Whether the Medicare debt is currently being appealed.

(5) Whether the enrolling provider, supplier, or owner thereof was an owner of the prior entity at the time the Medicare debt was incurred."

In addition, a denial of Medicare enrollment under paragraph (a)(6)(ii) can be avoided if the enrolling provider, supplier, or owner thereof does either of the following: (1) satisfies the criteria set forth in § 401.607 and agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt; or (2) repays the debt in full.

2. Contractor's Determination of Overpayment

When processing a Form CMS-855A, CMS-855B, CMS-855I, CMS-855S, or CMS-20134 initial or change of ownership application (if applicable), the contractor shall determine – using a system generated monthly listing – whether the provider, supplier, or any owner listed in Section 5 or 6 of the application has an existing or delinquent Medicare overpayment, as described in section 10.4.2.2(F)(1) above and § 424.530(a)(6). If such an overpayment exists, the contractor shall deny the application, using 42 CFR §424.530(a)(6) as the basis. However, prior PEOG approval is required before proceeding with the denial. The contractor shall under no circumstances deny an application under § 424.530(a)(6) without receiving PEOG approval to do so.

3. Examples

Example #1: Dr. X, a sole proprietor, has a $70,000 overpayment. Three months later, *Dr. X* joins Group Y and becomes a 50 percent owner thereof. Group Y submits an initial enrollment

application two months thereafter. Group Y's enrollment could be denied because Dr. X is an owner.

Example #2: Dr. Smith's practice ("Smith Medicine") is set up as a sole proprietorship. Dr. Smith incurs a $50,000 overpayment. Dr. Smith terminates Medicare enrollment. Six months later, Dr. Smith tries to enroll as a sole proprietorship; the practice is named "JS Medicine." A denial is warranted because § 424.530(a)(6) applies to physicians and the $50,000 overpayment was attached to Dr. Smith as the sole proprietor.

Example #3 - Same scenario as example #2, but assume that Dr. Smith's new practice is an LLC of which Dr. Smith is only a 30 percent owner. A denial is still warranted because Dr. Smith is an owner of the enrolling supplier and the $50,000 overpayment was attached to Dr. Smith.

Example #4 - Smith is a nurse practitioner in a solo practice. The practice ("Smith Medicine") is set up as a closely-held corporation, of which Smith is the 100 percent owner. Smith Medicine is assessed a $20,000 overpayment. Smith terminates the Medicare enrollment. Nine months later, Smith submits a Form CMS-855I application to enroll Smith as a new individual supplier. The business will be established as a sole proprietorship. A denial is not warranted because the $20,000 overpayment was attached to Smith Medicine, not to Smith.

In each of these examples, however, denial could be avoided if (1) the party with the overpayment is on a Medicare-approved plan of repayment or (2) the overpayments in question are currently being offset or being appealed.

4. Additional Considerations Involving § 424.530(a)(6)

The contractor shall also observe the following with respect to § 424.530(a)(6):

a. In determining whether an overpayment exists, the contractor need only review its own records; it need not contact other contractors to determine whether the person or entity has an overpayment in those contractor jurisdictions.

b. The instructions in this section 10.4.2.2(F) apply only to (i) initial enrollments and (ii) new owners in a change of ownership.

c. The term "owner" under § 424.502 means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

d. If the person or entity had an overpayment at the time the application was filed but repaid it in full by the time the contractor performed the review described in this section 10.4.2.2(F), the contractor shall not deny the application based on § 424.530(a)(6).

G. Denial Reason 7– Medicare or Medicaid Payment Suspension (42 CFR § 424.530(a)(7))

(i) The provider or supplier, or any owning or managing employee or organization of the provider or supplier, is currently under a Medicare or Medicaid payment suspension as defined in §§ 405.370 through 405.372 or in § 455.23 of this chapter.

(ii) CMS may apply the provision in this paragraph (a)(7) to the provider or supplier under any of the provider's, supplier's, or owning or managing employee's or organization's current or former names, numerical identifiers, or business identities or to any of its existing enrollments.

(iii) In determining whether a denial is appropriate, CMS considers the following factors:

(A) The specific behavior in question.

(B) Whether the provider or supplier is the subject of other similar investigations.

(C) Any other information that CMS deems relevant to its determination.

H. Denial Reason 8– Home Health Agency (HHA) Capitalization (42 CFR § 424.530(a)(8))

An HHA submitting an initial application for enrollment:

a. Cannot, within 30 days of a CMS or Medicare contractor request, furnish supporting documentation verifying that the HHA meets the initial reserve operating funds requirement in 42 CFR § 489.28(a); or

b. Fails to satisfy the initial reserve operating funds requirement in 42 CFR § 489.28(a).

I. Denial Reason 9– Hardship Exception Denial and Fee Not Paid (42 CFR § 424.530(a)(9))

"The institutional provider's (as that term is defined in 42 CFR § 424.502) hardship exception request is not granted, and the institutional provider does not submit the required application fee within 30 days of notification that the hardship exception request was not approved."

(This denial reason should only be used when the institutional provider fails to submit the application fee after its hardship request was denied. The contractor shall use § 424.530(a)(1) as a basis for denial when the institutional provider: (a) does not submit a hardship exception request and fails to submit the application fee within the prescribed timeframes; or (b) submits the fee, but it cannot be deposited into a government-owned account.)

J. Denial Reason 10– Temporary Moratorium (42 CFR § 424.530(a)(10))

"The provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." (This denial reason applies to initial enrollment applications and practice location additions.)

K. Denial Reason 11 – Prescribing Authority (42 CFR § 424.530(a)(11))

"1. A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause; or

2. The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits the enrollment application to the Medicare contractor."

(Except as otherwise stated in this chapter or in another CMS directive, the contractor need not verify whether an individual's DEA certificate was surrendered in response to a show cause order.)

NOTE: With respect to (a)(11), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

L. Denial Reason 12 (42 CFR § 424.530(a)(12) - Revoked Under Different Name, Numerical Identifier, or Business Identity)

"The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired. In making its determination, CMS considers the following factors:

(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);
(ii) Geographic location;
(iii) Provider or supplier type;
(iv) Business structure; or
(v) Any evidence indicating that the two parties [the revoked provider/supplier and the newly-enrolling provider/supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

NOTE: With respect to (a)(12), PEOG – rather than the contractor – will make all determinations regarding whether a provider or supplier was revoked under a different name, numerical identifier or business identity.

M. Denial Reason 13 (42 CFR § 424.530(a)(13) - Affiliation that Poses an Undue Risk)

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 (specifically, the factors listed in 42 CFR § 424.519(f)) that poses an undue risk of fraud, waste, and abuse to the Medicare program."

An affiliation is defined as any of the following:

(i) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
(ii) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
(iii) An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of § 424.519 only, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.
(iv) An interest in which an individual is acting as an officer or director of a corporation.
(v) Any reassignment relationship under § 424.80.

NOTE: With respect to (a)(13), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has an affiliation per 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse.

N. Denial Reason 14 (42 CFR § 424.530(a)(14) – Other Program Termination or Suspension)

"(1) The provider or supplier is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program; or (2) the provider or supplier's license is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling."

In determining whether a denial under § 424.530(a)(14) is appropriate, CMS considers the following factors:

a. The reason(s) for the termination, suspension, or revocation;

b. Whether, as applicable, the provider or supplier is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one state's Medicaid program), has been subject to any other sanctions during its participation in other programs or by any other state licensing boards, or has had any other final adverse actions (as that term is defined in § 424.502) imposed against it; and

c. Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(14), PEOG -- rather than the contractor – will make all determinations regarding whether a provider or supplier has a termination or suspension from another program or has a license that is currently revoked or suspended in a state other than that in which the provider or supplier is enrolling.

O. Denial Reason 15 (42 CFR § 424.530(a)(15) – Patient Harm)

"The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm

(B) The nature of the physician's or other eligible professional's conduct

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to, procedures or practices; (ii) required compliance appearances before state oversight board members; (iii) license restriction(s) regarding the ability to treat certain types of patients; (iv) administrative/monetary penalties; and (v) formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon."

Section 424.530(a)(15) does not apply to actions or orders pertaining exclusively to either of the following: (i) required participation in rehabilitation or mental/behavioral health programs; or (ii) required abstinence from drugs or alcohol and random drug testing.

NOTE: With respect to (a)(15), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

P. Denial Reason 17 – False Claims Act Judgment (42 CFR § 424.530(a)(17))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted)

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502)

(F) Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(17), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

Q. Denial Reason 18 – Standard or Condition Violation (42 CFR § 424.530(a)(18))

(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (c).

(All denials based wholly, or in part, on § 424.530(a)(18) shall be sent to PEOG to obtain approval of both the denial action itself and the denial letter. The contractor's denial letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the

provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

(See section 10.4.2.3 for more information regarding § 424.530(a)(18).)

10.4.2.3 – Additional Denial Policies

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Post-Denial Submission of Enrollment Application

A denied provider may not submit a new enrollment application until:

(i) If the initial denial was not appealed, the provider's appeal rights have lapsed;

(ii) If the initial denial was appealed, the provider has received notification that the determination was upheld; or

(iii) The reapplication bar has expired, if applicable.

The contractor shall return an application submitted before the aforementioned have occurred.

B. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR § 424.530(c), if the denial was due to adverse activity (e.g., exclusion, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel of the provider or supplier furnishing services payable by a federal health care program, the denial may be reversed (with PEOG approval) if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

C. Denials - Changes of Information and Changes of Ownership (CHOWs)

1. Expiration of Timeframe for Reporting Changes

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to the CMS MedicareProviderEnrollment@cms.hhs.gov mailbox notifying PEOG of the denial. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

2. Timeframe Not Yet Expired

If the contractor denies a change of information or CHOW submission and the applicable 90-day or 30-day period for reporting the change has not yet expired, the contractor shall send the e-mail referenced in subsection (C)(1) above after the expiration of said time period unless the provider has resubmitted the change request/CHOW.

3. Second Rejection, Return, or Denial

If, per subsection (C)(2) above, the provider resubmits the change of information or CHOW application and the contractor either denies it again, returns it, or rejects it, the contractor shall send the e-mail referenced in subsection (C)(1) above regardless of whether the applicable timeframe has expired. PEOG will determine whether the provider's Medicare billing privileges should be deactivated or revoked and will notify the contractor of its decision.

D. Reactivations

If the contractor denies a reactivation application, the provider's Medicare billing privileges shall remain deactivated or revoked.

E. Revalidations

If the contractor denies a revalidation application, the contractor shall – unless an existing CMS instruction or directive states otherwise - deactivate the provider's Medicare billing privileges if the applicable time period for submitting the revalidation application has expired. If it has not expired, the contractor shall deactivate the provider's billing privileges after the applicable time period expires unless the provider has resubmitted the revalidation application. If, per the previous sentence, the provider resubmits the application and the contractor denies it again, returns it, or rejects it, the contractor shall - unless an existing CMS instruction or directive states otherwise – revoke the provider's billing privileges, assuming the applicable time period has expired.

F. Appeals of Denials

For information regarding the provider enrollment appeals process, see section 10.6.18 of this chapter.

G. Use of 424.530(a)(1)

1. (A)(1) Versus (A)(5)

If a denial is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.530(a)(5) (rather than § 424.530(a)(1)) as the denial reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(18)

If a denial is warranted due to non-compliance with one of the standards and conditions referenced in § 424.530(a)(18) – and except as otherwise directed in this chapter *or in another CMS directive* - the contractor shall use § 424.530(a)(18) (rather than § 424.530(a)(1)) as the denial reason. No CAP rights are therefore involved.

10.4.7.1 – Revocations – Background and General Requirements

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Introduction

Medicare revokes currently enrolled providers/suppliers' Medicare billing privileges and corresponding provider/supplier agreements pursuant to federal regulations at 42 CFR § 424.535. (A

Medicare revocation is a "termination" as defined at 42 CFR § 455.101.) A revocation of Medicare billing privileges does not affect a provider's ability to submit claims to non-Medicare payers using the provider's NPI.

If the contractor determines that a provider's billing privileges should be revoked or receives information from PEOG that a provider's billing privileges should be revoked, it shall undertake activities to process the revocation, apply the revocation in PECOS, notify the provider, and afford appeal rights. This section 10.4.7.1 includes, but is not limited to, information concerning the contractor's responsibilities to:

(i) Prepare a draft revocation letter

(ii) E-mail the letter to the appropriate PEOG mailbox with additional pertinent information regarding the basis for revocation

(iii) Receive PEOG's determination and follow PEOG's instructions regarding the case

(iv) If PEOG authorizes the revocation: (a) revoke the provider's billing privileges effective on the appropriate date; (b) establish the applicable reenrollment bar; (c) update PECOS with the appropriate reenrollment bar length; (d) assess an overpayment, as applicable; and (e) send the revocation letter (including affording appeal rights) to the provider via certified mail.

B. Administrative Requirements

This section 10.4.7.1(B) addresses (in greater specificity than section 10.4.7.1(A)) certain contractor administrative activities pertaining to revocations. As stated in section 10.4.7.1(A), however, the contractor shall take into account the instructions in sections 10.6.6 and 10.7 et seq.

1. Processing Timeframes

If the contractor receives approval from PEOG (or receives an unrelated request from PEOG) to revoke a provider's billing privileges, the contractor shall complete all steps associated with the revocation no later than five (5) business days from the date it received PEOG's approval/request. The contractor shall notify PEOG that it has completed all revocation steps no later than three (3) business days after completion.

2. Revocation Letters - Contents

i. General Information

When the contractor discovers a basis for revoking a provider's enrollment under 42 CFR § 424.535 - and, if applicable under section 10.6.6 of this chapter or another CMS directive, receives PEOG's approval for the revocation - the contractor shall revoke billing privileges and notify the provider by letter. The revocation letter shall contain:

(a) A legal (i.e., regulatory, such as § 424.535(a)(3) or §424.535(a)(9)) basis for each reason for revocation (the contractor shall not use provisions from this chapter as the basis for revocation);

(b) A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence that the contractor used in making its determination;

(c) An explanation of why the provider does not meet the applicable enrollment criteria;

(d) The effective date of the revocation;

(e) Procedures for submitting a CAP (if revoked under § 424.535(a)(1));

(f) Complete and accurate information about the provider's appeal rights;

(g) Any other information contained in or required by the applicable model letter in section 10.7 et seq.

ii. One Letter Per Enrollment

The contractor shall issue a unique revocation letter per enrollment. For example, regarding revocation letters for solely owned organizations, when revoking a physician/non-physician practitioner's billing privileges and those of *the* solely owned organization, the contractor shall issue **two** revocation letter: one for the individual and the other for the solely owned organization. The contractor shall not issue one letter to convey revoked Medicare billing privileges for both the individual and the solely owned organization.

3. Revocation Letters – PEOG Approval

Using the guidance in this section 10.4.7.1(B) et seq., section 10.6.6, and section 10.7 et seq., the contractor shall determine whether it must submit its draft revocation letter to PEOG for approval prior to sending it to the provider.

i. Prior PEOG Approval Required

If prior PEOG approval of the letter is required, the contractor shall submit the letter to the appropriate PEOG mailbox for PEOG review. PEOG will examine the letter for technical correctness and determine matters such as: (1) whether the revocation affects the revoked provider's other *enrollments*; (2) the length and application of the reenrollment bar; and (3) the revocation effective date. PEOG will notify the contractor of the outcome of its review and instruct the contractor how to proceed.

The contractor shall not begin finalizing the revocation until it receives guidance from PEOG.

The contractor may not alter an approved revocation letter; if it needs to revise said letter, the contractor shall submit the letter to PEOG for a new review via the process described above.

Unless CMS has directed otherwise, the contractor shall document and report the impacted application/enrollment in its Monthly Status Reports.

ii. When PEOG Approval of Revocation Letter is Unnecessary

The contractor need not obtain prior PEOG approval of the revocation and the revocation letter if the revocation *is solely based on* any of the following situations:

- § 424.535(a)(1) (for (a)(1) noncompliance issues other than Noncompliance – Not Professionally Licensed Individual Practitioners OR except as otherwise required in this chapter or another CMS directive)

- § 424.535(a)(6)

- § 424.535(a)(11)

4. Issuing the Revocation Letter to the Provider

The contractor shall send revocation letters by USPS certified mail. (The contractor may e-mail a follow-up copy of the letter after issuing it via USPS certified mail.) The contractor shall date and mail the letter on the same business day.

10.4.7.3 – Revocation Reasons

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

Sections 10.4.7.3(A) through (V) list the revocation reasons in 42 CFR § 424.535. Section 10.4.7.3(W) discusses extensions of revocations per 42 CFR § 424.535(i).

A. Revocation Reason 1 – Noncompliance (42 CFR § 424.535(a)(1))

"The provider or supplier is determined not to be in compliance with the enrollment requirements in this Title 42 or in the enrollment application applicable to its provider or supplier type and has not submitted a plan of corrective action as outlined in 42 CFR Part 488. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter."

(Title 42 includes the principal provider enrollment regulations in 42 CFR Part 424, subpart P; the IDTF enrollment standards in 42 CFR § 410.33; the OTP enrollment standards in 42 CFR § 424.67; etc.)

Noncompliance includes but is not limited to: (1) the provider/supplier no longer has a physical business address or mobile unit where services can be rendered; (2) the provider/supplier does not have a place where patient records are stored to determine the amounts due such provider or other person; and/or (3) the provider/supplier no longer meets or maintains general enrollment requirements. Noncompliance also includes situations when the provider/supplier has failed to pay any user fees as assessed under 42 CFR Part 488.

Other situations (some of which were mentioned in the previous paragraph) in which § 424.535(a)(1) may be used as a revocation reason include, but are not limited to, the following:

- The provider or supplier does not have a physical business address or mobile unit where services can be rendered.

- The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.

- The provider or supplier is not appropriately licensed. (NOTE: For (a)(1) revocations involving an individual practitioner who is not appropriately licensed due to a disciplinary action, PEOG --

rather than the contractor -- will make all determinations to revoke for this noncompliance requirement).

- The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.

- The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.

- The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.

- The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider/supplier's notification from CMS or its contractor to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information. (This revocation reason will not apply if CMS has instructed the contractor to use deactivation reason § 424.540(a)(3) in lieu thereof.)

- The provider or supplier does not otherwise meet general enrollment requirements.

(Concerning the last bullet above – and, as applicable, bullets 3, 4 and 5 – the contractor's revocation letter shall cite the appropriate statutory and/or regulatory citation(s) containing the specific licensure/certification/authorization requirement(s) for that provider/supplier type.)

Special Instructions Regarding Certified Providers/Suppliers – The SOG Location may involuntarily terminate a certified provider/supplier if the latter no longer meets CMS requirements, conditions of participation, or conditions of coverage. When this occurs, CMS terminates the provider'/supplier's provider agreement and notifies the contractor thereof. Upon receipt of the CMS notice (and except as otherwise stated in this chapter), the contractor shall follow the revocation procedures in this chapter (including, as applicable, those in section 10.6.6)), using § 424.535(a)(1) as the revocation basis; the contractor shall not process the involuntary termination as a deactivation based upon a voluntary withdrawal from Medicare.

Note that the contractor need not (but certainly may) contact the SOG Location to obtain further details of the termination.

B. Revocation Reason 2 – Provider or Supplier Conduct (42 CFR § 424.535(a)(2))

"(i) The provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management personnel furnishing services payable by a federal health care program, of the provider or supplier is:

(A) Excluded from the Medicare, Medicaid, and any other federal health care program, as defined in 42 CFR § 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(B) Is debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the FASA implementing

regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76.

(ii) The individuals and organizations identified in paragraph (a)(2)(i) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier."

If the contractor finds an excluded party (and unless section 10.6.6 states otherwise, in which case the latter section takes precedence), the contractor shall notify its PEOG BFL immediately. PEOG will notify the Contracting Officer's Representative (COR) for the appropriate Unified Program Integrity Contractor (UPIC). The COR will, in turn, contact the OIG for further investigation.

C. Revocation Reason 3 – Felony Conviction (42 CFR § 424.535(a)(3))

"The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR §1001.2) of a federal or state felony offense that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries. [Under § 424.535(a)(3)(ii),] [o]ffenses include, but are not limited in scope and severity to:

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
- Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

[Under § 424.535(a)(3)(iii),] revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses."]

[Under § 424.535(a)(3)(iv),] the individuals and organizations identified in paragraph (a)(3) of this section include, but are not limited to, W–2 employees and contracted individuals and organizations of the provider or supplier.]

The expiration of a reenrollment bar issued pursuant to 42 CFR § 424.535(c) does not preclude CMS or its contractors from denying reenrollment to a provider that (i) was convicted of a felony within the preceding 10-year period or (ii) otherwise does not meet all criteria necessary to enroll in Medicare.

D. Revocation Reason 4 – False or Misleading Information on Application (42 CFR § 424.535(a)(4))

"The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current laws and regulations.)"

E. Revocation Reason 5 - On-Site Review/Other Reliable Evidence that Requirements Not Met (42 CFR § 424.535(a)(5))

"Upon on-site review or other reliable evidence, CMS determines that the provider or supplier:

(i) Is not operational to furnish Medicare-covered items or services; or
(ii) Otherwise fails to satisfy any Medicare enrollment requirement."

F. Revocation Reason 6 - Hardship Exception Denial and Fee Not Paid (42 CFR §424.535(a)(6))

(i) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(ii) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(iii) Either of the following occurs:

- CMS is not able to deposit the full application amount into a government-owned account; or

- The funds are not able to be credited to the United States Treasury;

(iv) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(v) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

G. Revocation Reason 7 – Misuse of Billing Number (42 CFR § 424.535(a)(7))

"The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers that enter into a valid reassignment of benefits as specified in 42 CFR § 424.80 or a change of ownership as outlined in 42 CFR § 489.18."

H. Revocation Reason 8 – Abuse of Billing Privileges (42 CFR § 424.535(a)(8))

"Abuse of billing privileges includes either of the following:

(i) The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations:

(A) Where the beneficiary is deceased.

(B) The directing physician or beneficiary is not in the state or country when services were furnished.

(C) When the equipment necessary for testing is not present where the testing is said to have occurred.

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following factors:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502) and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination."

(**NOTE**: Concerning (a)(8), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider has a pattern or practice of submitting non-compliant claims; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

I. Revocation Reason 9 – Failure to Report (42 CFR § 424.535(a)(9))

"The provider or supplier failed to comply with the reporting requirements specified in 42 CFR § 424.516(d) or (e), § 410.33(g)(2), or § 424.57(c)(2) [which pertain to the reporting of changes in adverse actions and practice locations]."

With respect to § 424.535(a)(9) (and except as otherwise stated in section 10.6.6):

- If the provider reports a change in practice location more than 30 days after the effective date of the change, the contractor shall not pursue a revocation on this basis. However, if the contractor independently determines – through an on-site inspection under 42 CFR § 424.535(a)(5)(ii) or via another verification process - that the provider's address has changed but the provider has not notified the contractor thereof within the aforementioned 30-day timeframe, the contractor may pursue a revocation (e.g., seeking PEOG's approval to revoke).

- If an IDTF reports a change in ownership, change of location, change in general supervision or change in adverse legal action more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

- If a DMEPOS supplier reports a change of information more than 30 days after the effective date of the change, the contractor may pursue a revocation on this basis (e.g., seeking PEOG's approval to revoke).

J. Revocation Reason 10 – Failure to Document or Provide CMS Access to Documentation (42 CFR § 424.535(a)(10))

"The provider or supplier did not comply with the documentation requirements specified in 42 CFR § 424.516(f). A provider that furnishes any covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to maintain documentation for 7 years."

K. Revocation Reason 11 - Home Health Agency (HHA) Capitalization (42 CFR § 424.535(a)(11))

"An HHA fails to furnish - within 30 days of a CMS or contractor request - supporting documentation verifying that the HHA meets the initial reserve operating funds requirement found in 42 CFR § 489.28(a)."

L. Revocation Reason 12 – Other Program Termination (42 CFR § 424.535(a)(12))

"The provider or supplier is terminated, revoked, or otherwise barred from participation in a particular State Medicaid Agency or any other federal health care program."

In making its determination, CMS considers the following factors listed in 42 CFR § 424.535(a)(12):

"(A) The reason(s) for the termination or revocation;

(B) Whether the provider or supplier is currently terminated, revoked, or otherwise barred from more than one program (for example, more than one state's Medicaid program) or has been subject to any other sanctions during its participation in other programs; and;

(C) Any other information that CMS deems relevant to its determination."

Under § 424.535(a)(12)(ii), "Medicare may not revoke [a provider/supplier's Medicare billing privileges] unless and until the provider or supplier has exhausted all applicable appeal rights or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal."

M. Revocation Reason 13 - Prescribing Authority (42 CFR § 424.535(a)(13))

"(i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked or is surrendered in response to an order to show cause; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician's or other eligible professional's ability to prescribe drugs."

N. Revocation Reason 14 – Improper Prescribing Practices (42 CFR § 424.535(a)(14))

"CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part B or D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed;

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which the individual practices, and the reason(s) for the action(s);

(E) Whether the physician or eligible professional has any history of final adverse actions (as that term is defined in § 424.502);

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted - that is, for indications neither approved by the FDA nor medically accepted under section 1860D-2(e)(4) of the Act - and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient."

(**NOTE**: Concerning (a)(14), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider/supplier has a pattern or practice of prescribing Part B or D drugs; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

O. Revocation Reason 15 – False Claims Act Judgment (42 CFR § 424.535(a)(15))

"(i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the False Claims Act (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted)

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502)

(F) Any other information that CMS deems relevant to its determination."

NOTE: With respect to (a)(15), PEOG -- rather than the contractor – will make all determinations regarding whether this provision applies.

P. Revocation Reason 17 – Debt Referred to the United States Department of Treasury (42 CFR § 424.535(a)(17))

"The provider or supplier has failed to repay a debt that CMS appropriately refers to the United States Department of Treasury." In determining whether a revocation is appropriate, CMS considers the following factors:

"(i)(A) The reason(s) for the failure to fully repay the debt (to the extent this can be determined);

(B) Whether the provider or supplier has attempted to repay the debt (to the extent this can be determined);

(C) Whether the provider or supplier has responded to CMS' requests for payment (to the extent this can be determined);

(D) Whether the provider or supplier has any history of final adverse actions or Medicare or Medicaid payment suspensions;

(E) The amount of the debt; and

(F) Any other evidence that CMS deems relevant to its determination."

(NOTE: With respect to (a)(17):

- Section 424.535(a)(17)(ii) excludes from paragraph (a)(17)(i)'s purview those cases where: (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired.

- PEOG – rather than the contractor – will make all (a)(17) determinations.

Q. Revocation Reason 18 – Revoked Under a Different Name, Numerical Identifier or Business Identity (42 CFR § 424.535(a)(18))

"The provider or supplier is currently revoked [from Medicare] under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired." In making its determination, CMS considers the following factors:

"(i) Owning and managing employees and organizations (regardless of whether they have been disclosed on the Form CMS-855 [or CMS-20134] application);

(ii) Geographic location;

(iii) Provider or supplier type;

(iv) Business structure; or

(v) Any evidence indicating that the two parties [the revoked provider or supplier and newly enrolling provider or supplier] are similar or that the provider or supplier was created to circumvent the revocation or reenrollment bar."

(NOTE: Concerning (a)(18), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier was revoked under a different name, numerical identifier, or business identity.)

R. Revocation Reason 19 – Affiliation that Poses an Undue Risk (42 CFR § 424.535(a)(19))

1. Specific Reason

"The provider or supplier has or has had an affiliation under 42 CFR § 424.519 that poses an undue risk of fraud, waste and abuse to the Medicare program." In making this determination, CMS considers the following factors listed in 42 CFR § 424.519(f)(1) through (6):

"(1) The duration of the affiliation

(2) Whether the affiliation still exists and, if not, how long ago it ended

(3) The degree and extent of the affiliation

(4) If applicable, the reason for the termination of the affiliation

(5) Regarding the affiliated provider/supplier's disclosable event [under § 424.519(b)]:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt: (A) the amount of the debt; (B) whether the affiliated provider or supplier is repaying the debt; and (C) to whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that CMS deems relevant to its determination."

2. Definition of Affiliation

For purposes of § 424.519 only, 42 CFR § 424.502 defines "affiliation" as:

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of [§ 424.519 only], sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

- An interest in which an individual is acting as an officer or director of a corporation.

- Any reassignment relationship under § 424.80."

(NOTE: Concerning (a)(19), PEOG -- rather than the contractor -- will make all determinations regarding whether a provider/supplier has an affiliation per § 424.519 that poses an undue risk of fraud, waste, and abuse.)

S. Revocation Reason 20 – Billing from a Non-Compliant Location (42 CFR § 424.535(a)(20))

"CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. In determining whether and how many of the provider/supplier's enrollments (involving the non-compliant location or other locations) should be revoked, CMS considers the following factors [enumerated in § 424.535(a)(20)(i) through (vii)]:

- The reason(s) for and the specific facts behind the location's non-compliance;

- The number of additional locations involved;

- The provider or suppliers possibly history of final adverse actions or Medicare or Medicaid payment suspensions;

- The degree of risk the location's continuance poses to the Medicare Trust Funds;

- The length of time that the location was considered non-compliant;

- The amount that was billed for services performed at or items furnished from the non-compliant location; and,

- Any other evidence that CMS deems relevant to its determination."

(NOTE: Concerning (a)(20), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier has performed services or furnished items from a location that did not comply with Medicare enrollment requirements.)

T. Revocation Reason 21 – Abusive Ordering, Certifying, Referring, or Prescribing of Part A or B Services, Items or Drugs (42 CFR § 424.535(a)(21))

"The physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements." In making its determination, CMS considers the following factors [enumerated in § 424.535(i) through (ix)]:

- Whether the physician or eligible professional's diagnosis supports the order, certification, referral or prescription in question;

- Whether there are instances where the necessary evaluation of the patient for whom the order, certification, referral or prescription could have not occurred (for example: the patient was deceased or out of state at the time of the alleged office visit);

- The number and types of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state(s) in which the individual practices and the reason(s) for the action(s);

- Whether the physician or eligible professional has any history of final adverse actions (as defined by 42 CFR § 424.502);

- The length of time over which the pattern or practice has continued;

- How long the physician or eligible professional has been enrolled in Medicare;

- The number of type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that resulted in a final judgement against the physician or eligible professional or the physician or eligible professional paid a settlement to the plaintiff(s) (to the extent this can be determined);

- Whether any State Medicaid Agency (SMA) or other public health insurance program has restricted, suspended, revoked or terminated the physician's or eligible professional's ability to practice medicine and reason for any such restriction, suspension, revocation or termination; and

- Any other information that CMS deems relevant to its determination.

(NOTE: Concerning (a)(21), PEOG – rather than the contractor – will make all determinations regarding whether a physician or eligible professional has a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items, or drugs that is abusive, threatening to the safety of Medicare beneficiaries, or fails to meet Medicare requirements).

U. Revocation Reason 22 – Patient Harm (42 CFR § 424.535(a)(22))

The physician or other eligible professional has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors [enumerated in § 424.535(a)(22)(i)(A) through (E)):

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(i) License restriction(s) pertaining to certain procedures or practices.

(ii) Required compliance appearances before State medical board members.

(iii) License restriction(s) regarding the ability to treat certain types of patients.

(iv) Administrative or monetary penalties.

(v) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician/other eligible professional's conduct and the degree of harm thereto or impact upon."

(Per 42 CFR § 424.535(a)(22)(ii), paragraph (a)(22) does not apply to actions or orders pertaining exclusively to either of the following:

- Required participation in rehabilitation or mental/behavioral health programs; or
- Required abstinence from drugs or alcohol and random drug testing.)

V. Revocation Reason 23 – Standard or Condition Violation (42 CFR § 424.535(a)(23))

(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (c).

(All revocations based wholly, or in part, on § 424.535(a)(23) shall be sent to PEOG to obtain approval of both the revocation action itself and the revocation letter.) The contractor's revocation letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

(See section 10.4.7.5(A) for more information regarding § 424.535(a)(23).)

W. Extension of Revocation

If a provider's Medicare enrollment is revoked under § 424.535(a), CMS may revoke any and all of the provider's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types. In determining whether to revoke a provider's other enrollments, CMS considers the following factors:

(i) The reason for the revocation and the facts of the case;

(ii) Whether any final adverse actions have been imposed against the provider or supplier regarding its other enrollments;

(iii) The number and type(s) of other enrollments; and

(iv) Any other information that CMS deems relevant to its determination.

10.4.7.4 – Reenrollment Bar

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

If any inconsistency exists between an instruction in this section 10.4.7.4 and a directive in section 10.6.6, the latter instruction takes precedence. In addition, the contractor shall adhere to any instruction in section 10.6.6 that addresses a reenrollment bar matter not discussed in section 10.4.7.4.

A. Background

As stated in 42 CFR § 424.535(c), if a provider/supplier has billing privileges revoked, the provider/supplier is barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10

years, depending on the severity of the basis for revocation. In addition, CMS may impose a reenrollment bar of up to 20 years if the provider/supplier is being revoked from Medicare for the second time.

Per § 424.535(c), the reenrollment bar does not apply if the revocation: (i) is based on § 424.535(a)(1); and (ii) stems from a provider/supplier's failure to respond timely to a revalidation request or other request for information. If both of these conditions are met, no reenrollment bar will be applied.

The contractor shall update PECOS to reflect that the individual cannot participate in Medicare for the applicable length of the reenrollment bar. Except as otherwise stated in this chapter, PEOG (rather than the contractor) determines reenrollment bars that exceed 3 years.

In addition, CMS may add up to 3 more years to the provider/supplier's reenrollment bar if it determines that the provider/supplier is attempting to circumvent its existing reenrollment bar.

B. Establishment of Length

The following serves merely as general, non-binding guidance regarding the establishment of the length of reenrollment bars. It is crucial to note that every situation must and will be judged on its own merits, facts, and circumstances. It should not be assumed that a particular timeframe will always be applied to a specific revocation reason in all cases. CMS retains the discretion to apply a reenrollment bar period that is different from that indicated below (though which in no case will be greater than 10 to 20 years).

- § 424.535(a)(1) (Noncompliance) – 1 year
- §424.535(a)(6) (Grounds Related to Screening) – 1 year
- §424.535(a)(11) (Initial Reserve Operating Funds) – 1 year

The following revocation reasons will receive reenrollment bar lengths per CMS discretion:

- §424.535(a)(1) (Noncompliance- Not Professionally Licensed Individual Practitioners)
- §424.535(a)(2) (Provider or supplier conduct)
- §424.535(a)(3) (Felonies)
- §424.535(a)(4) (False or misleading information)
- §424.535(a)(5) (On-site review)
- §424.535(a)(7) (Misuse of billing number)
- §424.535(a)(8) (Abuse of billing privileges)
- §424.535(a)(9) (Failure to Report)
- §424.535(a)(10) (Failure to document or provide CMS access to documentation)
- §424.535(a)(12) (Other program termination)
- §424.535(a)(13) (Prescribing authority)
- §424.535(a)(14) (Improper Prescribing Practices)
- §424.535(a)(15) (False Claims Act Civil Judgment)
- §424.535(a)(17) (Debt Referred to the United States Department of Treasury)
- §424.535(a)(18) (Revoked Under a Different Name, Numerical Identifier or Business Identity)
- §424.535(a)(19) (Affiliation that Poses an Undue Risk)
- §424.535(a)(20) (Billing from a Non-Compliant Location)

- §424.535(a)(21) (Abusive ordering, certifying, referring, or prescribing of Part A or B services, items, or drugs)
- §424.535(a)(22) (Patient Harm)
- *§424.535(a)(23) (Supplier Standard or Condition Violation)*

C. Applicability of Bar

1. Revocation Reasons Other Than § 424.535(a)(1), (a)(5), (a)(6), (a)(9), (a)(10), (a)(11), and (a)(23)

In general, and except as stated otherwise in this chapter or in another CMS directive, any reenrollment bar at a minimum applies to all enrollments under the provider's PECOS or legacy enrollment record at the TIN level.

2. Revocation Reasons § 424.535(a)(1), (a)(5), (a)(6), (a)(9), (a)(10), (a)(11), and (a)(23)

In general (and except as stated otherwise in this chapter), for these seven revocation reasons any reenrollment bar applies only to the specific enrollment that was the subject of the reenrollment bar. If there is any effort to reestablish a revoked enrollment(s) under a different name, numerical identifier, or business identity, the contractor shall contact the ProviderEnrollmentRevocations@cms.hhs.gov mailbox for guidance. Instances where the provider might be attempting to do so include - but are not limited to – the following:

SCENARIO 1 - Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ's lone location was at 1 Jones Street. XYZ's billing privileges were revoked after it was determined that the site was non-operational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has one location at 1 Jones Street in the same city in which XYZ Medical Supplies is located. Smith is listed as a 75 percent owner.

SCENARIO 2 - Jones and Smith were 50 percent owners of World Home Health, a partnership. One year after World Home Health was revoked under § 424.535(a)(9), the contractor receives an initial application from XYZ Home Health, a corporation of which Jones is the sole owner/member.

D. Discussing Provider Enrollment Appeals Process in Revocation Letter

(If a conflict exists between the instructions in this section 10.4.7.4(D) and those in either (i) those in section 10.6.18 or (ii) the language in the applicable model letter in section 10.7 et seq., the guidance in section 10.6.18 or the model letter takes precedence.)

In the revocation letter, the contractor shall include information concerning the provider's appeal rights. The following table summarizes where the provider must send a corrective action plan (CAP) and/or reconsideration request.

	CAP requests should be sent to:		**Reconsideration request should be sent to:**	
Revocation Regulation	**Institutional***	**Non-institutional**	**Institutional***	**Non-Institutional**
424.535(a)(1) related to an enrollment requirement (i.e., 425.516)	Alone or in combination: CMS	MAC	CMS	MAC

	CAP requests should be sent to:		Reconsideration request should be sent to:	
Revocation Regulation	**Institutional***	**Non-institutional**	**Institutional***	**Non-Institutional**
424.535(a)(1) Licensure	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(1) DME or IDTF	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(2) Exclusion	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(2) Debarment	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(3)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(4)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(5)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(6)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(7)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(9)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(10)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(11)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(12)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(13)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(14)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(15)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(17)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(18)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(19)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(20)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(21)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(22)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(23)	No CAP rights	No CAP rights	CMS	CMS

* Institutional providers:

- Ambulance Service Supplier
- Ambulatory Surgery Centers
- CLIA Labs
- Community Mental Health Center
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals
- End Stage Renal Disease (ESRDs)
- Federally Qualified Health Centers (FQHCs)
- Histocompatibility Laboratories
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices

- Hospitals and Hospital Units
- Independent Diagnostic Testing Facilities (IDTFs)
- Intensive Cardiac Rehabilitation
- Indian Health Service Facility
- Mammography Screening Centers
- Mass Immunization/Flu Roster Billers
- Medicare Diabetes Prevention Programs (MDPPs)
- Opioid Treatment Centers (OTPs)
- Organ Procurement Organizations (OPOs)
- Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
- Pharmacies
- Portable X-Ray Suppliers (PXRSs)
- Radiation Therapy Centers
- Rehabilitation Services
- Religious Non-Medical Health Care Institutions (RNCHIs)
- Rural Health Clinics (RHCs)
- Skilled Nursing Facilities (SNFs)

The CMS defines "institutional provider" in 42 CFR § 424.502 to mean any provider/supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (except physician and non-physician practitioner organizations), or Form CMS-855S, or the associated Internet-based PECOS enrollment application. (Note that MDPP suppliers no longer fall within this regulatory definition of institutional provider. Per 42 CFR § 424.205(b)(5), the provider enrollment application fee is inapplicable to all MDPP suppliers that submit a Form CMS-20134 enrollment application. Solely for purposes of appeal submissions, however, MDPP suppliers are included in the bulleted list above.)

10.4.7.5 – Additional Revocation Policies

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Use of § 424.535(a)(1)

1. (A)(1) Versus (A)(5)

If a revocation is warranted because the provider/supplier's location is vacant, occupied by another party, closed during office hours, etc., or a state survey failure is involved, the contractor shall use § 424.535(a)(5) (rather than § 424.535(a)(1)) as the revocation reason. (This applies to both certified and non-certified providers/suppliers.) No CAP rights are therefore involved.

2. (A)(1) Versus (A)(23)

a. General Requirement

If a revocation is warranted due to non-compliance with one of the standards and conditions referenced in § 424.535(a)(23) – and except as otherwise stated in this chapter (e.g., section 10.2.2.4(V)) *or in another CMS directive* -- the contractor shall use § 424.535(a)(23) (rather than § 424.535(a)(1)) as the revocation reason. No CAP rights are therefore involved.

b. Special OTP and HIT Supplier Instructions

The instructions in subsections (b)(i) and (ii) apply notwithstanding any provision to the contrary in this chapter.

i. OTP

If a revocation is warranted due to non-compliance with a provision in § 424.67(e), the contractor shall use § 424.535(a)(1) as the revocation reason. No prior referral to PEOG is required, and CAP rights apply. The only exception involves potential revocations based on a violation of § 424.67(b)(6). In such cases, the contractor shall refer the matter to PEOG via normal channels for review and follow any direction PEOG furnishes.

ii. HIT Supplier

If a revocation is warranted due to non-compliance with a provision in § 424.68(e), the contractor shall use § 424.535(a)(1) as the revocation reason. No prior referral to PEOG is required, and CAP rights apply. The only exception involves potential revocations based on a violation of § 424.68(c)(3), in which case the contractor shall use § 424.535(a)(23) as the revocation reason.

B. Submission of Claims for Services Furnished Before Revocation

Per 42 CFR § 424.535(h), a revoked provider or supplier (other than a home health agency (HHA)) must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter. A revoked HHA must submit all claims for items and services within 60 days after the later of: (1) the effective date of the revocation, or (2) the date that the HHA's last payable episode ends.

Nothing in § 424.535(h) impacts the requirements of 42 CFR § 424.44 regarding the timely filing of claims.

C. Reporting Revocations/Terminations to the State Medicaid Agencies and Children's Health Program (CHIP)

(If the instructions in this section 10.4.7.5(C) conflict with those in another CMS directive, the latter takes precedence.)

Section 6401(b)(2) of the Patient Protection and Affordable Health Care Act (i.e., the Affordable Care Act) was enacted on March 23, 2010. It requires that CMS establish a process for making available to each State Medicaid Plan or Child Health Plan the name, NPI, and other identifying information regarding any revoked or denied Medicare provider/supplier. Accordingly, CMS provides a monthly revoked and denied provider list to all contractors via the Share Point Ensemble site.

The contractor shall:

- Access this list on the 5th day of each month via the Share Point Ensemble site

- Review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS

- Document any appeal actions a provider/supplier may have submitted after the provider/supplier's revocation or denial

- Update the last three columns on the tab named “Filtered Revocations” of the spreadsheet for every provider/supplier revocation or denial

The contractor shall not make any other modifications to the format of this form or its contents.

The following are the only authorized entries to be made on the report:

Appeal Submitted:
Yes - (Definition: An appeal has been received. (This includes either a CAP or Reconsideration request or notification of an ALJ or DAB action.))
No - (Definition: No appeal of any type has been submitted)

Appeal Type:
CAP
Reconsideration
ALJ
DAB

Appeal Status:
Under Review
Revocation Upheld
Revocation Overturned
Denial Upheld
Denial Overturned
CAP accepted
CAP denied
Reconsideration Accepted
Reconsideration Denied

If a contractor is reporting that no appeal has been submitted, the appeal type and status columns will be noted as N/A.

If an appeal action has been submitted to PEOG for certified providers/suppliers, the contractor shall access the PEOG appeals log via the Share Point Ensemble site to determine the appeal status to include on the spreadsheet.

The contractor shall submit their completed reports by the 20th of each month to the CGI Share Point Ensemble site.

D. Opting-Out after Revocation

Revoked suppliers cannot order, certify, or prescribe Part A or B services, items, or drugs to Medicare beneficiaries if they opt-out of Medicare after revocation. For example, if Dr. Thompson is Medicare-revoked, Dr. Thompson cannot opt-out and order back and knee orthoses for Dr. Thompson’s patients.

E. Overpayments Based Upon Revocations

The contractor shall commence procedures to collect overpayment after the timeframe for the appeal of the revocation has expired or within 10 days of the final appeal determination at the first level of appeal. Overpayments are processed in accordance with 42 CFR Part 405, subpart C.

If a revocation has a prospective effective date, the contractor shall assess an overpayment back to the date that is the more recent of the following:

- The date when Medicare claims are determined to be ineligible for payment; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

The date when Medicare claims are determined to be ineligible for payment may, but will not always, match the inactive date of the enrollment as reflected in PECOS and in MCS or FISS. Again, in determining an overpayment, the contractor shall use the starting date upon which claims are ineligible for reimbursement, not the date the enrollment is inactive according to PECOS and MCS or FISS.

In accordance with 42 CFR § 424.565, if a physician, non-physician practitioner, physician organization, or non-physician practitioner organization fails to comply with the reporting requirements specified in 42 CFR § 424.516(d)(1)(ii), the contractor may assess an overpayment back to a date that is the more recent of the following:

- The date of the final adverse action or change in practice location; or

- The date that is within 4 years from the date of the initial claim determination or redetermination for good cause as defined in 42 CFR § 405.986 (42 CFR § 405.980).

F. Other Sources of Potential Bases for Revocations

When CMS instructs the contractor to take revocation action, PEOG communicates such direction; neither the UPIC, the state agency, CMS Field Office, nor CMS Regional Office (RO) (including SOG Location) personnel can direct a contractor to revoke a provider/supplier. However, some of these entities may refer a potential revocation to PEOG. This section 10.4.7.5(E) discusses the operational aspects of these referrals.

1. UPICs

a. Background

If, through its investigations, the UPIC believes that a particular provider/supplier's Medicare billing privileges should be revoked, it shall develop a case file - including the reason(s) for revocation and the data described in subsection (E)(1)(b) below - and submit the file and all supporting documentation to PEOG.

PEOG will review the case file and:

- Return the case file to UPIC for additional development, or
- Consider approving the UPIC's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the applicable contractor to revoke the provider/supplier; and (2) notify the applicable contracting officer's representative (COR).

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

b. Contents of Request

The revocation request shall contain the following information:

- Provider/supplier name; administrative location(s); community setting(s), if applicable type (e.g., DMEPOS supplier); Provider Transaction Access Number (PTAN); National Provider Identifier (NPI); applicable Medicare Administrative Contractor
- Name(s), e-mail address(es), and phone number(s) of investigators
- Tracking number
- Provider/supplier's billing status (Active? Inactive? For how long?)
- Whether the provider/supplier is a Fraud Prevention System provider/supplier
- Source/Special Project
- Whether the provider/supplier is under a current payment suspension
- Legal basis for revocation
- Relevant facts
- Application of facts to revocation reason
- Any other notable facts
- Effective date (per 42 CFR § 424.535(g))
- Supporting documentation
- Photos (which should be copied and pasted within the document)

2. CMS Field Office or RO Revocations

If a CMS Field Office (FO) or (RO) believes that Revocation Reason 8 (see 42 CFR § 424.535(a)(8) is appropriate in a certain case), the FO/RO will develop a case file - including the reason(s) for revocation - and submit the file and all supporting documentation to PEOG. The case file must include the name, all known identification numbers (including the NPI and associated PTAN(s)), and

locations of the provider/supplier, as well as detailed information to substantiate the revocation action.

If PEOG concurs with the FO/RO's revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) accordingly notify the FO/RO.

(See section 10.4.3 of this chapter for information on the contractor's responsibilities concerning involuntary terminations received from the SOG Location.)

3. OIG Identified Revocations

PEOG is responsible for actions based on HHS OIG Identified revocations.

G. MDPP Supplier Revocation for Use of an Ineligible Coach

1. Background

Section 424.205(h)(1)(v) established a new revocation reason for MDPP suppliers. It permits revocation if the MDPP supplier knowingly permitted an ineligible coach to furnish MDPP services to beneficiaries, despite being previously removed from the MDPP supplier's roster through a CAP.

If a contractor or UPIC suspects this scenario, it shall develop a case file - including the revocation reason(s) - and submit the file and all supporting documentation to PEOG. The contractor shall provide PEOG with the information described in section 10.4.7.5(E)(1)(b).

PEOG will review the case file and:

- Return the case file to the contractor for additional development, or
- Consider approving the contractor's recommendation for revocation.

If PEOG approves the revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) notify the applicable COR.

If the contractor receives a direct request from a UPIC to revoke a provider/supplier, it shall refer the matter to its PEOG BFL if it is unsure whether the UPIC received prior PEOG approval of the revocation.

2. Effective Dates

An MDPP supplier revoked under § 424.205(h)(1)(v) does not have CAP rights. The revocation becomes effective 30 days after the contractor sends notice of the revocation.

3. Reenrollment Bar

As stated in § 424.205(h), if an MDPP supplier has its billing privileges revoked, it is barred from participating in Medicare from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation.

10.4.8 – Deactivations

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

A. Bases for Contractor Action

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor shall – without prior approval from its PEOG BFL - deactivate a provider/supplier's entire enrollment record and Medicare billing privileges when:

(i) The provider/supplier fails to respond to a revalidation request.

(ii) The provider/supplier fails to respond timely to a revalidation development request.

(iii) The provider/supplier is enrolled in an approved status with neither an active reassignment nor practice location for 90 days or longer. (The deactivation basis shall be 42 CFR § 424.540(a)(4), which permits deactivation if the provider/supplier is not in compliance with all enrollment requirements. See sections 10.4.8(B) and (D) below for more information on this new deactivation ground.)

(iv) The provider/supplier deactivates an EFT agreement and remains enrolled but does not submit a new EFT agreement within 90 days. (The deactivation basis shall be 42 CFR § 424.540(a)(2).)

(v) The provider/supplier is deceased, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the provider's/supplier's death; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(6) below.)

(vi) The provider or supplier is voluntarily withdrawing from Medicare, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the voluntary withdrawal; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(7) below.)

(vii) The provider's or supplier's license has expired and the provider or supplier has not billed while the license was expired. (The deactivation basis shall be 42 CFR § 424.540(a)(4).)

The contractor shall not take deactivation action except as specified and permitted in this chapter or other CMS directives. CMS particularly reiterates that – consistent with existing policy -- the contractor shall not on its own volition deactivate any provider/supplier for non-billing under § 424.540(a)(1). All § 424.540(a)(1) deactivations can only be implemented at CMS' explicit direction.

B. Regulatory Reasons for Deactivation in § 424.540(a)

1. Grounds

Section 424.540(a) lists eight deactivation grounds:

Section 424.540(a)(1) - The provider/supplier does not submit any Medicare claims for 6 consecutive calendar months. The 6-month period will begin the 1st day of the 1st month without a claim submission through the last day of the 6th month without a submitted claim.

Section 424.540(a)(2) - The provider/supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under Title 42. (For example, a provider/supplier type falling within the purview of § 424.516(e)(1) and (2) failed to report a change in ownership or control within (i) 30 calendar days of when the change occurred, or (b) 90 calendar days of when the change occurred for all other information on the enrollment application.)

If the provider/supplier submits a change of information and (a) it appears the change was not reported within 90 days of the change, (b) the contractor did not previously take administrative action against the provider/supplier, and (c) no revocation action is applicable, the contractor should process the change of information without deactivating the provider/supplier's enrollment.

Section 424.540(a)(3) - The provider/supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

Section 424.540(a)(4) - The provider/supplier is not in compliance with all enrollment requirements. (See section 10.4.8(D) below for more information.)

Section 424.540(a)(5) - The provider's/supplier's practice location is non-operational or otherwise invalid. (See section 10.4.8(D) below for more information.)

Section 424.540(a)(6) - The provider/supplier is deceased.

Section 424.540(a)(7) - The provider/supplier is voluntarily withdrawing from Medicare.

Section 424.540(a)(8) - The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

C. Effective Dates

(See § 424.540(d) for regulations concerning deactivation effective dates.)

The effective dates of a deactivation are as follows:

a. Non-Billing (§ 424.540(a)(1)) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the deactivation is imposed.

b. Section 424.540(a)(2), (3), and (4) (see subsection (B) above) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/ supplier became non-compliant. *For example, suppose a provider has a new 10 percent owner as of May 1 and, per § 424.516, must report the change within 30 days – that is, by May 31. The provider fails to do so. The deactivation effective date is the date on which the provider became non-compliant, or June 1.*

c. Section 424.540(a)(5) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider's/supplier's practice location became non-operational or otherwise invalid.

d. Section 424.540(a)(6) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of death of the provider/supplier.

e. Section 424.540(a)(7) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/supplier voluntarily withdrew from Medicare.

f. Section 424.540(a)(8) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of the sale. (Note that PEOG will ultimately determine this effective date during its review of the case per subsection (F) below.)

(See subsection 10.4.8(E) below for additional information on § 424.540(a)(7). See subsection 10.4.8(F) below for additional information on § 424.540(a)(8)).

D. Sections 424.540(a)(4) and (a)(5)

(This section 10.4.8(D) is inapplicable to the situations described in section 10.4.8(A)(iii) and (iv). These two scenarios do not require any referral to PEOG; the contractor can take deactivation action on its own volition.)

The grounds for deactivation under § 424.540(a)(4) and (a)(5) mirror the revocation reasons described in, respectively, § 424.535(a)(1) and (a)(5). When sending a potential § 424.535(a)(1) and (a)(5) revocation case to PEOG for review per section 10.4.7.1(A) of this chapter, PEOG will determine whether a revocation or a deactivation (under § 424.540(a)(4) or (a)(5)) is appropriate. The contractor shall not deactivate a provider or supplier under § 424.540(a)(4) or (a)(5) unless PEOG specifically directs the contractor to do so.

E. Section 424.540(a)(7)

See section 10.6.1.3 of this chapter for information regarding certified provider/supplier voluntary terminations and section 10.4.3(B) for information on non-certified supplier voluntary terminations.

F. Section 424.540(a)(8)

See section 10.6.1.1.5 of this chapter for information regarding seller CHOWs.

G. Miscellaneous

1. Except for deactivations under § 424.540(a)(8) (see § 424.550(b)(1)) and § 424.540(a)(7)**, t**he deactivation of Medicare billing privileges does not affect a provider/supplier's participation agreement.

2. Prior to deactivating an HHA's billing privileges for any reason (including under the "36-month rule"), the contractor shall refer the matter to its PEOG BFL for review and approval. The only exception for PEOG BFL review and approval is a deactivation due to failure to comply with a revalidation request.

3. Notwithstanding any other instruction to the contrary in this chapter, the provider/supplier may submit a rebuttal for deactivations imposed pursuant to § 424.540(a)(7) or (8). For these two rebuttal reasons, the contractor shall abide by the rebuttal policies in section 10.4.8.1. Note, however, that

any such rebuttal only applies to the deactivation of billing privileges and not to the provider agreement termination.

10.5- Timeliness and Accuracy Standards

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

Sections 10.5(A) through 10.5(B)(4) of this chapter address the timeliness and accuracy standards applicable to the processing of Form CMS-855, Form CMS-20134 applications (initial and change of information and revalidation) and opt-out affidavits. Even though the provisions of 42 CFR § 405.818 contain processing timeframes that differ than those in sections 10.5(A) through 10.5(B)(4), the contractor shall adhere to the standards specified in sections 10.5(A) through 10.5(B)(4).

The term "PECOS applications" means web-based applications. For special instructions regarding the processing of applications submitted via PECOS 2.0, see section 10.3 of this chapter. The PECOS instructions in section 10.3 take precedence over those in this section 10.5.

Note that the date of receipt of a PECOS application is the date the contractor received it, not the date on which the application required the contractor's manual intervention per section 10.3.

The processing of an application or opt-out affidavit generally includes, but is not limited to, the following activities:

- For paper applications - Receipt of the application or opt-out affidavit in the contractor's mailroom and forwarding it to the appropriate office for review. (This is the intake process.)
- For PECOS applications - Electronic receipt of the application.
- For paper applications – Completing the intake process.
- Ensuring that the information on the application or opt-out affidavit is verified.
- Requesting and receiving clarifying information.
- Site visit (if necessary).
- Requesting fingerprints (if necessary).
- For certified providers/suppliers (and as applicable to the transaction and/or provider/supplier type), formal notification to the state and/or CMS Survey & Operations Group (SOG) Location of the contractor's approval, denial, or recommendation for approval of the application.

(Note: The timeliness metrics discussed in this section are a combination of Part A applications and Part B applications and opt-out affidavits.)

For purposes of sections 10.5(A) and 10.5(B) below:

- The term "site visit" means that the provider or supplier requires an on-site review to determine whether the provider or supplier is operational based on the provider/supplier type.

- The term “development” means that the contractor needs to contact the provider or supplier for additional information. (A development request (via letter, fax, email, the PCV, or telephone contact for development) to the provider or supplier is considered to be the first development request.)

- The term “fingerprinting” means that 5 percent or greater owners (including partners who own at least 5 percent) of a provider or supplier is required to submit fingerprints for an additional level of screening.

A. Standards for Initial and Change of Information Applications and Opt-Out Affidavits

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term “initial applications” also includes:

- Form CMS-855 or Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the new owner.

- “Complete” Form CMS-855 or Form CMS-20134 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, or (c) as a Form CMS-855 or Form CMS-20134 reactivation.

- Opt-out affidavits submitted for an eligible practitioner’s first opt-out period.

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term “changes of information” also includes:

- Form CMS-855 and Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the old owner.

- Form CMS-588 changes submitted without a need for an accompanying complete Form CMS-855 or Form CMS-20134 application.

- Reassignment applications that are not part of an initial, revalidation, or reactivation application (e.g., adding a new reassignment, changing an existing reassignment).

- Form CMS-855 and Form CMS-20134 voluntary terminations.

- Opt-out early termination requests (of initial opt-out affidavits), changes of information and cancellation requests.

Initial and change of information application and opt-out timeliness standards shall be reported together. Likewise, initial, change of information, and opt-out affidavit accuracy shall be reported together.

1. Paper Initial and Change of Information Applications and Opt-Out Affidavits - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 65 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 100 calendar days of receipt.

b. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 30 calendar days of receipt.

The contractor shall process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 65 calendar days of receipt.

2. Paper Initial and Change of Information Applications and Opt-Out Affidavits – Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in sections 10.5(A)(1) through 10.5(A)(2) of this chapter) and all other applicable CMS directives.

3. PECOS Initial and Change of Information Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with existing instructions; site visit (if required) and/or requesting fingerprints (if necessary).

a. PECOS Initial and Change of Information Applications That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Initial and Change of Information Applications That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Initial and Change of Information Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications in full accordance with all the instructions in this chapter (excluding the timeliness standards identified in section 10.5(A)(3) above) and all other applicable CMS directives.

B. Standards for Revalidation Applications

For purposes of sections 10.5(B)(1) through 10.5(B)(3)(b) of this chapter, the term "revalidation applications" includes complete Form CMS-855 or Form CMS-20134 revalidation applications submitted by enrolled providers.

1. Paper Revalidation Applications that Require Site Visits, Development and/or Fingerprinting - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting – Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that require site visits, development and/or fingerprinting within 65 calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 100 calendar days of receipt.

b. Paper Revalidation Applications that do not Require Site Visits, Development, and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that do not require site visits, development and/or fingerprinting within 30 calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 65 calendar days of receipt.

2. Paper Revalidation Applications - Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 revalidations in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in section 10.5(B)(1) above) and all other applicable CMS directives.

3. PECOS Revalidation Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with

existing instructions; site visit (if required) and/or requesting fingerprints (if necessary). Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. PECOS Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of all Form CMS-855 and Form CMS- 20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Revalidation Applications That Do Not Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Revalidation Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in sections 10.5(B)(1) and 10.5(B)(3)(b) above) and all other applicable CMS directives.

C. General Timeliness Principles

Unless stated otherwise in this chapter or in another CMS directive, the principles discussed below apply to all applications discussed in sections 10.5(A)(1) through 10.5(B)(3) of this chapter (e.g., change of ownership (CHOW) applications submitted by old and new owners, CMS-588 forms).

1. Clock Stoppages

The processing timeliness clock temporarily stops when the situations identified in section 10.5(C)(1) occur:

- Referring an application to the Office of Inspector General (OIG) or the Unified Program Integrity Contractor (UPIC).
- Waiting for a final sales agreement (e.g., CHOW, acquisition/merger).
- Contacting: (i) the *CMS* Location, and/or state agency regarding a provider-based or CHOW determination; (ii) the *CMS* Location or state agency with a question regarding the application of a CMS policy; (iii) contacting the SOG Location or state agency.
- Referring a provider or supplier to update their information in the National Plan & Provider Enumeration System.

- Contacting CMS' Provider Enrollment & Oversight Group (PEOG) for the following reasons: questions regarding the application, *a* CMS policy; an adverse legal action review; affiliations/overpayments found on the monthly report or PECOS; Advanced Provider Screening criminal alerts; delayed site visits; referrals to PEOG (if required under this chapter) for final review of certain certified provider/supplier applications.

- Referring a provider to the Social Security Administration to resolve a discrepancy involving a social security number or to the Internal Revenue Service to resolve a tax identification number or individual tax identification number issue.

- Contacting another contractor for any type of PECOS update (i.e.: locked associates).

- Contacting the PECOS Maintainer for resolutions to system issues (i.e.: RightNow tickets).

- *Contacting the state licensing board to verify a license or to obtain board order documentation.*

- Practice location and special payment address changes as well as specialty changes with future dates.

- If fingerprints are required, the timeliness clock stops when the fingerprint request is issued and resumes when the contractor receives the results. (If additional information is developed at the same time as the fingerprint request is issued, no action shall be taken on the developed information until after the fingerprint results are received.)

- *Situations can arise where the provider/supplier submits an Internet-based PECOS application and makes edits to it before all signatures are received. This can lock the PECOS Logging and Tracking (L&T), thus preventing the contractor from beginning to process the application until the application is resubmitted. The contractor in this specific situation may apply a clock stoppage between the time the L & T is locked and the time it is unlocked (i.e., the application is submitted). (Note that this instruction may be rendered moot with the implementation of PECOS 2.0.)*

- Any other clock stoppage expressly permitted in this chapter or by CMS

Should a dependent application be needed to continue processing, the processing clock stops when the development is issued and resumes once the development is received.

Consistent with section 10.6.19(I), the contractor shall document in PECOS any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. The contractor will thus be able to furnish explanatory documentation to CMS should the applicable time limits be exceeded. To illustrate, assume that a contractor received an initial Form CMS-855I application on March 1. On March 30, the contractor sent a question to CMS and received a response on April 7. The processing time clock stops from March 31 to April 7. The contractor should document PECOS to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

2. Calendar Days

Unless otherwise stated in this chapter, all days in the processing time clock are "calendar" days, not "business days." If the final day of a metric falls on a weekend or holiday, this remains the day by which the application must be processed. If the contractor cannot finish processing the application until the next business day, it should document in PECOS that the final day of the metric fell on a Saturday/Sunday/holiday and furnish any additional explanation as needed.

3. Date-Stamping – Paper Applications Only

All incoming correspondence must be date-stamped on the day it was received in the contractor's mailroom. This includes, but is not limited to:

- Any Form CMS-855 or Form CMS-20134 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- Letters from providers. (The first page of the letter must be date-stamped.)

- Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)

- Data that the provider furnishes (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because some contractors interleaf the new/changed pages within the original application. Thus, it is necessary to determine the sequence in which the application and the additional pages were received.)

(Note: PECOS applications are considered "date stamped" on the date the application was received.)

The timeliness clock begins on the date on which the application/envelope is date-stamped in the contractor's mailroom, not the date on which the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the above bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

In addition, and unless stated otherwise in this chapter or in another CMS directive, all incoming enrollment applications (including change requests) must be submitted via mail (unless circumstances require submission via fax or email).

4. When the Processing Cycle Ends

For (1) Form CMS-855A applications, and (2) Form CMS-855B applications submitted by ambulatory surgical centers (ASCs) or portable x-ray suppliers, the processing cycle ends on the date that the contractor enters a final status in PECOS (e.g., denied, returned, rejected, approval recommended) rather than the date on which the contractor sends formal notification of approval recommended, etc., to the state or SOG Location. (Note that accompanying applications (e.g., Form CMS-855I reassignment application submitted with a Form CMS-855B for an ASC) would also end their processing cycle).

In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the state), the cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

For (1) Form CMS-855I applications, (2) Form CMS-855B applications from suppliers other than ASCs and portable x-ray suppliers, (3) Form CMS-20134 and (4) Form CMS-855S applications the processing cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

5. PECOS Applications

See section 10.3 of this chapter for additional information on the processing of PECOS applications.

10.6.1.2 – Changes of Information – Transitioned Certified Providers and Suppliers

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

(Until further notice from CMS, the instructions in this section 10.6.1.2 apply only to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, FQHCs, Part A OPT/OSP providers, ASCs, PXRSs, hospitals, hospices, and ESRD facilities. The contractor shall continue to use the existing change of information instructions--now in section 10.6.22.1 of this chapter--for all non-transitioned certified provider/supplier types.

When executing the instructions in this section 10.6.1.2, the contractor can disregard directives that obviously do not apply to the transitioned provider/supplier type in question (e.g., references to hospitals).

All references to the SOG Location (formerly the "RO") in this section 10.6.1.2 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

The instructions in this section 10.6.1.2 address the handling of changes of information involving certified providers and certified suppliers. With the transition of certain functions from the SOG Locations to the contractors and the Provider Enrollment & Oversight Group (PEOG), the processing instructions for these changes of information are slightly different from previous guidance. In particular: (1) the SOG Locations will be much less involved in the process; (2) tie-in and tie-out notices will no longer be issued; (3) the contractor will be responsible for finalizing changes previously requiring SOG Location approval; and (4) recommendations of approval will be made to (and reviewed by) the state agency (hereafter occasionally referenced simply as "state") only and not the SOG Location.

Except as stated otherwise:

(1) Any provider-specific instructions in section 10.2.1 et seq. of this chapter pertaining to changes of information (e.g., relocation of a federally qualified health clinic site; addition or deletion of an OPT/OSP extension site) take precedence over those in this section 10.6.1.2.

(2) Any instructions pertaining to ownership changes in section 10.6.1.1 et seq. of this chapter take precedence over those in this section 10.6.1.2.

(3) Any instructions pertaining to voluntary terminations of entire enrollments and/or provider agreements in section 10.6.1.3 of this chapter take precedence over those in this section 10.6.1.2.

(4) Any instructions in this section 10.6.1.2 concerning the voluntary termination of a branch, sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.1.2 when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Changes of Information Requiring Recommendation to the State

1. Types

The following Form CMS-855 transactions require an approval recommendation to (and review by) the state prior to approval:

- Addition or relocation/change of outpatient physical therapy/outpatient speech pathology extension site
- Addition of HHA branch
- Addition or deletion of a prospective payment system (PPS)-excluded psychiatric unit, rehabilitation unit, or transplant program.
- Addition or deletion of swing-bed approval (see Section 2A2 of the Form CMS-855A)
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Addition, deletion, or relocation of a hospice practice location
- Addition, change, and/or relocation of a hospital practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)
- Addition of PXRS practice location

2. Initial Contractor Review and Recommendation

The contractor shall process the change request consistent with the instructions in this chapter (e.g., verification of data, developing for missing or conflicting data). If the contractor determines that the change/addition should be approved, it shall send the appropriate recommendation letter (see section 10.7 et seq.) to the state with all applicable documentation that the contractor currently sends in such situations. The SOG Location need not be copied on the letter.

Nothing in this section 10.6.1.2(A)(2):

- Prohibits the contractor from returning or rejecting the application if grounds for doing so exist.
- Supersedes any applicable requirement for performing a site visit (including the timing of such visits).

3. State Review and Contractor Receipt of Recommendation

The state will review the recommendation of approval, the application, and any other pertinent information. If the state decides to perform a survey, it will do so and notify the contractor thereof.

a. State Recommends Approval

If the state concludes that the change/addition should be approved, it will make a recommendation to this effect to the contractor, typically via a Form CMS-1539 and/or similar confirming documentation. No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov containing general identifying data about the provider (including LBN, NPI, CCN, specialty, facility name and address), a copy of the Form CMS-1539 (or other similar documentation evidencing the state's approval recommendation, if available), the draft provider approval letter, and a description of the change to be made. *The e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note that the data in the subject line need not be repeated in the e-mail body.)*

If, to the contractor's knowledge, a new CCN is required, the name and address of the new entity requiring the CCN should be furnished along with the effective date. If a termination is involved (e.g., HHA branch), the contractor shall include the old CCN and the termination date in the e-mail.

Once PEOG responds to the contractor, the latter may finalize its processing of the application (e.g., sending copies of the provider notification of approval to the state and, if applicable, accrediting organization; switching the PECOS record from "approval recommended" to "approved").

b. State Does Not Recommend Approval

If the state does not recommend approval, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov for guidance. The e-*mail s*hall contain: *(i)* the identifying data *as* described in (3)(a) above *(including a copy of the draft denial letter)*; *(ii) the e-mail subject line data as described in (3)(a) above and in section 10.6.21*; *(iii)* a copy of the notification from the state *(e.g., Form CMS-1539)* declining to recommend approval; and *(iv)* any other information the contractor deems pertinent. PEOG will review the matter and furnish the contractor additional instructions. *Once PEOG's review is completed---and absent any PEOG directive to the contrary---the contractor shall follow the denial procedures outlined in this chapter.*

This includes sending the denial letter to the provider/supplier and, if/as required per this chapter, a copy to the state and/or accrediting organization.

4. Additional Policies

a. Post-Recommendation Inquiries - Once the contractor has made its recommendation for approval to the state, any inquiry the contractor receives from the provider regarding the status of its change request shall be referred to the state.

b. Pending State Recommendation - So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive the state's recommendation after 120 days, it may contact the state to see if its recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to ascertain the recommendation's status.

c. State Practice - The PECOS record should not be switched to "Approved" until the contractor receives the state's approval recommendation. However, if the contractor knows that the state in question generally does not review this type of transaction, the contractor need not send the transaction to the state and shall instead follow the instructions in section 10.6.1.2(B) below.

B. Post-Approval State Notification Required

1. Post-Approval Correspondence

Form CMS-855 changes that do not mandate a recommendation to the state but do require post-approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) include:

(i) Except as described in section 10.6.1.2(A), deletions/voluntary terminations of practice locations or hospital subunits. (Note that this scenario is different from cases where the provider is voluntary terminating its enrollment as a whole (per section 10.6.1.3 of this chapter) rather than simply terminating a single location or subunit within its enrollment.)

(ii) LBN, TIN, or "doing business as name" changes that do not involve a CHOW.

(iii) Except as described in section 10.6.1.2(A), address changes that generally do not require a survey of the new location.

(iv) Addition, change, and/or relocation of a hospital practice location for which a survey is not required. *(For purposes of this requirement only, the term "hospital practice location" does not include hospital physician/practitioner group practice locations. Additions/changes/relocations of such locations do not require post-approval notification to the state, the AO, or PEOG.)*

(v) Deletion of an OPT/OSP extension site or practice location.

(vi) Ownership changes that involve neither a 42 CFR § 489.18 CHOW nor a § 424.550(b) exempt or non-exempt change in HHA majority ownership (e.g., a 15 percent owner of a hospice sells the 15 percent ownership stake).

No post-approval correspondence with PEOG is necessary in situations (ii), (iii), (iv), and (vi) above.

For situations (i) and (v), correspondence with PEOG is only required if the deletion involves the termination of a CCN and subsequent update of ASPEN (e.g., deletion of hospital sub-unit).

The contractor shall:

(1) Inform PEOG, the state, and the AO (if appropriate) of the changed information (via any mechanism it chooses, including copying PEOG/state/AO on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction. Such notice to the PEOG/state/AO shall specify the type of information that is changing. (Prior PEOG approval of the change is not required, though PEOG will update applicable national database as needed.)

(2) Switch the PECOS record to "Approved."

C. All Other Changes of Information

1. General Principle

For all Form CMS-855 change requests not identified in section 10.6.1.2(A)(1) and (B) above (and except as stated in subsection (C)(2) below), the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made; and (2) switch the PECOS record to "Approved." The contractor need not notify the state, SOG Location, or PEOG of the change.

2. FQHCs

If an FQHC is adding, deleting, or changing a Section 13 contact person , the contractor shall send an approval letter via e-mail and copy the MedicareProviderEnrollment@cms.hhs.gov mailbox (with "FQHC COI" in the subject line) thereon. (Aside from this exception, all other instructions in subsection (C)(1) apply to this scenario.) See section 10.2.1.4(D) of this chapter for more information on FQHC changes of information.

D. Revalidations, Reactivations, and Complete Form CMS-855 Applications

1. When Referral Required - In situations where the provider submits a (1) Form CMS-855 reactivation, (2) Form CMS-855 revalidation, or (3) full Form CMS-855 as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in section 10.6.1.2(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855, the contractor shall make a recommendation to the state and await the state's approval recommendation before switching the record to "Approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state needs to consider is the new hospital unit.

2. No Referral Required - If the application contains new/changed data falling within one of the categories in section 10.6.1.2(B), the contractor can switch the PECOS record to "Approved." It shall also inform the state of the changed information (via any mechanism it chooses, including copying the state on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction.

E. Unsolicited Notifications from State

If the contractor receives notice of a provider's change of information from the state but the provider never submitted the required Form CMS-855 change request to the contractor, the contractor shall: (1) alert the state of the situation; and (2) contact the provider and have it complete and submit the change request. However, if the data in question is not collected on the Form CMS-855, the contractor need not make this request.

F. Special ESRD Instructions

Notwithstanding any other contrary instruction in this chapter, if an ESRD change of information application results in the issuance of a new or additional CCN, the contractor shall copy the ESRD Network on the approval letter it sends to the provider. The contact information for the ESRD Network can be found at https://esrdnetworks.org/membership/esrd-networks-contact-information/.

G. Clock Stoppages and Processing Alternatives

While awaiting PEOG's reply on any matter in this section 10.6.1.2 in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.2 negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.2.

10.6.12 – Opting-Out of Medicare

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

Physicians and practitioners are typically required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. They are also not permitted to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare-covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to CMS Pub. 100-02, Chapter 15, sections 40 - 40.39 for more information regarding the maintenance of opt-out affidavits and the effects of improper billing of claims during an opt-out period.

The instructions in this section 10.6.12 address the contractor's processing of opt-out affidavits. (See Pub. 100-02, chapter 15, section 40.8 for private contract definitions and requirements.)

A. Who May Opt-Out of Medicare

Only the following physicians and practitioners (sometimes collectively referenced as "eligible practitioners" in this section) can "opt-out" of Medicare:

Physicians who are:

- Doctors of medicine or osteopathy,
- Doctors of dental surgery or dental medicine,
- Doctors of podiatry, or
- Doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the state in which such function or action is performed.

Non-physician practitioners who are:

- Physician assistants,
- Nurse practitioners,
- Clinical nurse specialists,
- Certified registered nurse anesthetists,
- Certified nurse midwives,
- Clinical psychologists,
- Clinical social workers,
- Registered dietitians or nutrition professionals who are legally authorized to practice by the state and otherwise meet Medicare requirements,
- Mental health counselors, or
- Marriage and family therapists

(Organizations are not permitted to opt-out of Medicare.)

This means that neither the eligible practitioner nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the eligible practitioner out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the eligible practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. (The contract, though, must be signed before the services are provided so the beneficiary is fully aware of the eligible practitioner's opt-out status.) Moreover, the eligible practitioner must submit an affidavit to Medicare expressing a decision to opt-out of the program. The contractor's provider enrollment unit must process these affidavits.

Eligible practitioners who opt-out of Medicare are not the same as non-participating physicians/suppliers. The latter are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment-related basis as required by law (e.g., for drugs, ambulance services, etc.). Non-participating physicians/suppliers must therefore comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Opt-out eligible practitioners, on the other hand, are excused from the mandatory claim submission, assignment, and limiting charge rules, though **only** when they maintain compliance with all of the requirements for opting out.

In an emergency care or urgent care situation, an eligible practitioner who has opted out may treat a Medicare beneficiary with whom the eligible practitioner does not have a private contract. In those circumstances, the eligible practitioner must complete a Form CMS-855 application.

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, chapter 15, section 40.9, the affidavit shall state that, upon signing the affidavit, the eligible practitioner agrees to the following requirements:

- Except for emergency or urgent care services, during the opt-out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;

- The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary;

- During the opt-out period, the eligible practitioner understands that the eligible practitioner may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- An eligible practitioner who opts out of Medicare acknowledges that, during the opt-out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;

- On acknowledgment by the eligible practitioner to the effect that, during the opt- out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;

- Acknowledge that the eligible practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the eligible practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the eligible practitioner has not previously privately contracted) without regard to any payment arrangements the eligible practitioner may make;

- With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

- Acknowledge that the eligible practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services;

- Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and

- Be filed with all MACs that have jurisdiction over claims the eligible practitioner would otherwise file with Medicare; the initial two-year opt-out period will begin the date on which the

affidavit meeting the requirements of 42 C.F.R. § 405.420 is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs the latter's first private contract with a Medicare beneficiary.

(See Pub. 100-02, chapter 15, section 40.9 for more information on the requirements of opt-out affidavits. See also section 10.6.12(B)(5) below for acceptable opt-out formats.)

The contractor shall review initial opt-out affidavits to ensure that they contain the following information about the eligible practitioner to create an affidavit record in PECOS:

- Full name (first, middle and last),
- Birthdate,
- Address, telephone number, and e-mail address
- License information,
- NPI (if one has been obtained),
- SSN (if no NPI has been issued, though note that this cannot be an individual tax identification number (ITIN)), and
- Contact person name, telephone number, and e-mail address (if different from the opting-out physician or practitioner)

If, to create a PECOS affidavit record, the contractor needs to obtain data that is missing from an affidavit, it may (1) obtain this information from other sources (such as the state license board) or (2) contact the eligible practitioner only **one time** directly. The contractor shall **not** use Internet-based PECOS or the Form CMS-855 to secure the data from the eligible practitioner, for the eligible practitioner **is not** enrolling in Medicare. If the eligible practitioner is requested to submit missing information to permit the processing of the affidavit and fails to do so within 30 days, the contractor shall reject the opt-out affidavit.

2. Opting-Out and Ordering/Certifying/Referring

If an eligible practitioner who wishes to opt-out elects to order/certify/refer Medicare items or services, the contractor shall develop for the date of birth (if not provided on the affidavit):

If this information is requested but not received, the eligible practitioner's affidavit can still be processed; however, the eligible practitioner cannot be listed as an ordering/certifying/referring provider.

3. Adverse Actions

The contractor shall review the List of Excluded Individuals and Entities (LEIE) and the System for Award Management (SAM) for all eligible practitioners who submit opt-out affidavits. Excluded eligible practitioners may opt-out of Medicare but cannot order certify/refer.

As noted in 42 CFR § 405.425(i) and (j), individuals who are revoked from Medicare cannot order, certify, or refer Part A or B services or items to Medicare beneficiaries if they opt-out of Medicare after revocation.

4. No Dual Status

a. Form CMS-855O - Eligible practitioners cannot be enrolled via the Form CMS-855O and actively opted-out simultaneously. Prior to processing an initial Form CMS-855O or opt-out affidavit submission, the contractor shall *ascertain whether* an approved Form CMS-855O enrollment or valid opt-out affidavit does not exist in PECOS. If:

- *The individual submits an initial Form CMS-855O and has a valid opt-out affidavit on file --* The contractor shall return the application.
- *The individual submits an opt-out affidavit and has an active Form CMS-855O enrollment – The contractor may process the opt-out affidavit and, as applicable, follow existing procedures for deactivating the existing enrollment.*

b. Form CMS-855I – A Form CMS-855I enrollment can simultaneously exist with a valid opt-out affidavit **only** if the Form CMS-855I is to bill for emergency services. If a Form CMS-855I is received **and** an opt-out affidavit is active, the contractor shall contact the eligible practitioner (via any means) to clarify if the latter submitted the application to solely bill for emergency services provided to a beneficiary. If so, the application shall be processed via normal procedures. If not, the application may be returned. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

An eligible practitioner who has opted out of Medicare need not also enroll via the Form CMS-855O if the eligible practitioner wishes to order/refer/certify (e.g., providing the necessary information on the affidavit per this section 10.6.12).

5. Acceptable Opt-Out Affidavit Formats

The contractor may provide a sample opt-out affidavit form for eligible practitioners to complete. The opt-out affidavit form must provide spaces for the eligible practitioners to furnish their personal information.

Eligible practitioners may also create their own affidavit. If the eligible practitioner elects to do so, the affidavit should include information found in section 10.6.12(B)(1) to ensure timely processing of the opt-out affidavit.

The contractor and eligible practitioners may use the information below as an opt-out affidavit form.

I, {Enter Physician/Non-Physician Practitioner Name}, being duly sworn, depose and say:

- Opt-out is for a period of two years. At the end of the two-year period, my opt-out status will automatically renew. If I wish to cancel the automatic extension, I understand that I must notify my Medicare Administrative Contractor (MAC) in writing at least 30 days prior to the start of the next two-year opt-out period.

- Except for emergency or urgent care services (as specified in the Medicare Benefit Policy Manual Publication 100-02, Chapter 15 §40.28), during the opt-out period I will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services.

- I will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will I permit any entity acting on my behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 40.28.

- During the opt-out period, I understand that I may receive no direct or indirect Medicare payment for services that I furnish to Medicare beneficiaries with whom I have privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under Medicare Advantage.

- I acknowledge that during the opt-out period, my services are not covered under Medicare and that no Medicare payment may be made to any entity for my services, directly or on a capitated basis.

- I acknowledge and agree to be bound by the terms of both the affidavit and the private contracts that I have entered into during the opt-out period.

- I acknowledge and understand that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by myself during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom I have not previously privately contracted) without regard to any payment arrangements I may make.

- I acknowledge that if I have signed a Part B participation agreement, that such agreement terminates on the effective date of this affidavit.

- I acknowledge and understand that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if I furnish such services.

- I have identified myself sufficiently so that the MAC can ensure that no payment is made to me during the opt-out period. If I have already enrolled in Medicare, I have included my Medicare PTAN, if one has been assigned. If I have not enrolled in Medicare, I have included the information necessary to opt-out.

- I will file this affidavit with all MACs who have jurisdiction over claims that I would otherwise file with Medicare and the initial two- year opt-out period will begin the date the affidavit meeting the requirements of 42 C.F.R. §405.420 is signed, provided the affidavit is filed within 10 days after the physician/practitioner signs the latter's first private contract with a Medicare beneficiary.

Eligible practitioners should also be encouraged to include the following information (to complete an affidavit record in PECOS): Medicare Identification Number (if issued); date of birth; specialty; e-mail address; any request to order/certify/refer.

C. Effective Date of an Opt-Out Period

As noted in Pub. 100-02, chapter 15, section 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

Eligible practitioners need not enroll prior to opting-out of Medicare. If a non-enrolled eligible practitioner submits an opt-out affidavit, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

2. Non-Participating Practitioners

If an eligible practitioner who is a non-participating provider decides to terminate an active Medicare billing enrollment and instead opt-out of Medicare, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

3. Participating Practitioners

If an eligible practitioner who is a participating provider (one who accepts assignment for all Medicare claims) decides to terminate an active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. Per 42 CFR § 405.410(d), an eligible practitioner may opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in 42 CFR § 405.420 is submitted to the applicable contractor(s) at least 30 days before the beginning of the selected calendar quarter. (The contractor shall, however, add 5 calendar days to the 30-day period to allow for mailing.) An opt-out affidavit must therefore be submitted at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is submitted within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, for the affidavit was not submitted at least 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

4. Opt-Out After Enrollment

(This section 10.6.12(C)(4) applies notwithstanding any instruction to the contrary in this chapter.)

If an enrolled physician or eligible practitioner is now opting-out, the existing PECOS enrollment record shall be end-dated the same day as the affidavit effective date.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, the eligible practitioner must apply for enrollment via the Form CMS-855I. Once the eligible practitioner receives a PTAN, the eligible practitioner must submit the claim(s) for any emergency or urgent care service furnished. The contractor shall contact its PEOG BFL for additional guidance when this type of situation arises. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

E. Termination of an Opt-Out Affidavit

As noted in Pub. 100-02, chapter 15, section 40.35, an eligible practitioner who has not previously opted-out may terminate an opt-out period early. However, the eligible practitioner must submit written notification thereof (with the eligible practitioner's signature) no later than 90 days after the effective date of the initial 2-year opt-out period. To properly terminate an affidavit, moreover, the eligible practitioner must:

1. Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of the opt-out);
2. Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;
3. Notify all beneficiaries (or their legal representation) with whom the eligible practitioner entered into private contracts of the eligible practitioner's decision to terminate an opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period and;
4. Refund to each beneficiary with whom the physician or practitioner has privately contracted all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.

For eligible practitioners who were previously enrolled to bill Medicare for services, the contractor shall reactivate the eligible practitioner's enrollment record in PECOS and reinstate the PTAN as if no opt-out affidavit existed. The eligible practitioner may bill for services provided during the opt-out period.

For eligible practitioners who were not previously enrolled to bill Medicare for services, the contractor shall remove the affidavit record from PECOS; this will help ensure that the eligible practitioner can submit the appropriate application(s) (via PECOS or paper Form CMS-855 for individual and/or reassignment enrollment) in order to establish an enrollment record in PECOS and thus bill for services rendered during the opt-out period.

F. Opt-Out Period Auto-Renewal and Cancellation of the Opt-Out Affidavit

1. General Policies

Eligible practitioners who initially opted-out or renewed an affidavit on or after June 16, 2015 need not submit a renewal of their affidavit. The opt-out will be automatically renewed for another 2-year period. Yet if the eligible practitioner decides to cancel the opt-out, the eligible practitioner must submit a written notice to each contractor to which would file claims (absent the opt-out) not later than 30 days before the end of the current 2 year opt-out period.

If the eligible practitioner decides to enroll in Medicare after an opt-out is canceled, the eligible practitioner must submit a Form CMS-855I application. The effective date of enrollment, however, cannot be before the cancellation date of the opt-out period. (For example, suppose an eligible practitioner submits a cancellation of opt-out to end the period on March 31, which is two years from the eligible practitioner's opt-out affidavit effective date. The eligible practitioner's requested effective date of enrollment cannot be before April 1.)

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights.

2. Auto-Renewal Report and Opt-Out Renewal Alert

The contractor shall issue an Opt-Out Renewal Alert Letter (found in section 10.7.14(E) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. For this purpose, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The contractor shall access the report monthly through the Share Point Ensemble site. The contractor shall also review the opt-out report for opted-out eligible practitioners that will auto-renew in the next three-and-a-half months. In addition, the contractor shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date; the eligible practitioner will thus have at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide (1) the date on which the current opt-out period will be auto renewed and (2) the date by which the eligible practitioner will need to submit a cancellation request. The letter will also furnish the eligible practitioner appeal rights if the latter fails to submit a cancellation request and the opt-out renews.

The contractor shall (1) complete the Opt-Out Renewal Alert Letter Report to include the date the Alert Letter was issued, (2) post its reports no later than the 15th of the following month to the Share Point Ensemble site, and (3) email its PEOG BFL when the report has been posted.

If an opted-out eligible practitioner submits a Form CMS-855I without submitting a cancellation request of the opt-out, the contractor shall develop for the cancellation notice. Once the cancellation notice is received, the contractor shall then process the application(s).

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights using the Late Cancellation Request return letter. In addition, if the eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date, the contractor shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

G. Failure to Properly Cancel or Terminate Opt-Out

Eligible practitioners who fail to properly cancel or terminate their opt-out may appeal the decision to continue (1) the auto-renewal of the opt-out or (2) the eligible practitioner's initial opt-out period.

Opt-out approval letters include appeal rights for eligible practitioners who initially opt-out and fail to properly terminate the opt-out within 90 days of the approval.

10.6.15 – Risk-Based Screening

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

Consistent with 42 CFR § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, revalidates its enrollment information, or, in certain circumstances, changes all or part of its ownership.

A. Specific Screening Categories

1. Limited Risk

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- Home infusion therapy suppliers
- Hospitals (including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Organ procurement organizations
- Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A. *(Note that these entities are certified providers and are different from physical therapy groups that enroll via the Form CMS-855B.)*
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics

For providers and suppliers in the "limited" category, the contractor shall process initial, revalidation, and new location applications in accordance with existing instructions.

2. Moderate Risk

a. General Information

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices *via the Form CMS-855B*
- Portable x-ray suppliers (PXRSs)

- Newly Enrolling Opioid Treatment Program (OTP) that were SAMSHA certified prior to October 24, 2018
- Revalidating home health agencies (HHAs)
- Revalidating hospices
- Revalidating DMEPOS suppliers
- Revalidating MDPP suppliers
- Revalidating OTP providers
- Revalidating SNFs
- Pursuant to § 424.518(b)(1)(ix), revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in § 424.518(c)(2)(ii) upon the provider's or supplier's—
  - New/initial enrollment; or
  - Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in § 424.518(c)(1)(viii), when the provider or supplier initially enrolled in Medicare. (See subsection (A)(5) below for more information.)

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 10.6.15(A)(4) of this chapter or another CMS directive applies): (1) process initial, revalidation, and new location applications in accordance with existing instructions; and (2) order an NSVC site visit through PECOS consistent with subsection 2(b) below. (Unless stated otherwise in this chapter, the scope of the site visit shall be consistent with existing instructions.)

b. Provider/Supplier-Specific Information

(i) Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups

If the supplier submits an initial application, revalidation application, or application to add a new practice location, the contractor shall order a site visit. (For new location additions, the site visit shall be of the new location.) The contractor shall not make a final decision regarding the application (or, for initial applications, shall not convey Medicare billing privileges) prior to the completion of the NSVC's site visit and the contractor's review of the results.

(ii) CMHCs, CORFs, Hospices and PXRSs

For site visits regarding these four provider/supplier types, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.1, 10.2.1.2, 10.2.1.7, and 10.2.2.8 of this chapter.

(iii) IDTFs

Initial applications - The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 10.2.2(O)(15) of this chapter.

Revalidations - The NVSC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 10.2.2(I)(15) of this chapter.

IDTF Code Changes - The NSVC will conduct site visits for IDTF code changes as specified in section 10.2.2(I)(17) of this chapter.

(iv) Revalidating HHAs and SNFs

For site visits regarding revalidating HHAs and SNFs, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.6 and 10.2.1.14 of this chapter.

(v) Revalidating DMEPOS Suppliers

A site visit of the DMEPOS supplier shall be conducted prior to the *NPE* making a final decision regarding the revalidation application.

(vi) Revalidating MDPP Suppliers

If an MDPP supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

(vii) Revalidating OTP Providers

If an OTP provider submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. High Risk

a. General Information

Pursuant to 42 CFR § 424.518, the "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs (including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))
- Newly enrolling hospices
- Newly enrolling MDPP suppliers
- Newly enrolling OTP providers that were SAMSHA certified after October 24, 2018
- Newly enrolling SNFs
- DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, SNFs, and hospices submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42.
- Except as stated in § 424.518(b)(1)(ix), revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section pursuant to applicable legal authority due to a

national, state, or local emergency declared under existing law. (See subsection (A)(5) below for more information.)

For newly enrolling providers and suppliers in the "high" level of categorical screening:

(i) The contractor shall process the application in accordance with existing instructions.

(ii) The NSVC will perform a site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the site visit and the contractor's review of the results.

(iii) Their 5 percent or greater direct and indirect owners must undergo fingerprint-based criminal background checks. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of fingerprinting and the contractor's review of the results.

(iv) The contractor shall, upon switching the provider's or supplier's enrollment record to "Approved," enter the provider's risk category as "moderate" into PECOS.

b. Additional Considerations

(i) Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes.

(ii) The addition of a new HHA branch falls within the "moderate" level of categorical screening. A site visit of the branch shall thus be performed consistent with the instructions in this chapter (including those in section 10.2.1.6).

(iii) The addition of a new MDPP supplier administrative location that does not result in a new PTAN does not require an additional site visit. Any additional MDPP supplier administrative location that results in a new PTAN, either due to being in a new jurisdiction or because of a new CDC organizational code, the contractors shall order a site visit of the location through PECOS. This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. Changes of/in Ownership

As explained above and in more detail in section 10.6.21(E)(3), the "high" screening category includes DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, SNFs, and hospices submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42. Accordingly, any change of/in ownership that meets all of the following criteria would fall under (i) or (ii) above:

- Does not involve the triggering of an initial enrollment (e.g., an HHA or hospice change in majority ownership for which no exception applies requires a new enrollment); and
- The change reports either:

- For partnerships: A new partner (general or limited) who owns any percentage (even 1 percent) of the provider/supplier; or
- Excluding partnerships: A new direct or indirect owner of at least 5 percent of the provider/supplier.

Upon receipt of an application described above, the contractor shall process it consistent with the instructions in this chapter and this section 10.6.15. This includes requesting fingerprints from the new owner(s) if the owner has a 5 percent or greater direct or indirect ownership interest. However, the contractor need not also solicit them from the provider/supplier's existing owners; only the new owner(s) need be fingerprinted.

(Note that if a new partner is being reported but the partner owns less than 5 percent of the provider/supplier, the provider/supplier's application must still be processed at the high screening level. However, the new partner need not be fingerprinted. This is because fingerprinting only applies to 5 percent or greater direct or indirect owners. It is therefore possible that, in such a change of ownership transaction, no fingerprinting will have to be conducted at all.)

The contractor shall also order a site visit of the provider/supplier consistent with existing instructions. In terms of the timing of the HHA, SNF, or hospice site visit, however, the contractor shall adhere to the following:

- No State/SOG Location Approval Required – If the ownership change does not require state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1 of this chapter for more information on this topic), the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.
- State/SOG Location Approval Required - If the ownership change requires state or SOG Location approval under existing CMS instructions, the site visit shall be ordered and performed no later than 5 business days after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.

(See section 10.6.21(E)(3) of this chapter for more information.)

4. Elevating Existing Providers and Suppliers into the High-Risk Screening Category

a. Criteria for Raising Providers/Suppliers to High-Risk

Under § 424.518(c)(3), CMS may adjust (or "bump up") a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

(ii) The provider or supplier:

- Has been excluded from Medicare by the Office of Inspector General;
- Had its billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by: (A) enrolling as a new provider or supplier; or (B) obtaining billing privileges for a new practice location;
- Has been terminated or is otherwise precluded from billing Medicaid;

- Has been excluded from any federal health care program; or
- Has been subject to any final adverse action (as defined in § 424.502) within the previous 10 years.

(iii) *The* CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

b. Extension of Application of a Provider/Supplier's "Bump-Up"

Effective January 6, 2023 (and pursuant to § 424.518(c)(4)), any screening level adjustment under § 424.518(c)(3) also applies to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification number (TIN) as the provider or supplier for which the screening level under § 424.518(c)(3) was originally raised. To illustrate, suppose an entity is enrolled as an ambulance supplier, a CORF, and a home infusion therapy (HIT) supplier. All three providers/suppliers are under the entity's TIN and LBN. The HIT supplier is under a payment suspension and is thus bumped-up to "high." Pursuant to § 424.518(c)(4), the ambulance supplier and CORF will also be moved to "high" because they have the same LBN and TIN as the HIT supplier.

c. List of Bumped-Up Providers/Suppliers

The CMS makes available to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that have been "bumped-up" pursuant to § 424.518(c)(3) and (c)(4). Upon receipt of an initial or revalidation application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions. If the provider or supplier is on the list, the contractor shall process the application using the procedures in the "high" screening category unless the provider is on the list solely because of a revocation for failing to timely respond to a revalidation request. If such is the case, the contractor shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance as to how the situation should be handled.

d. Post-Moratorium Applications

If the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

5. Prior Waiver from Fingerprinting

During the recent COVID-19 public health emergency (PHE), CMS temporarily waived the requirement for fingerprint-based criminal background checks (FBCBCs) for 5 percent or greater owners of newly enrolling providers and suppliers falling within the high-risk screening category in § 424.518(c). CMS seeks to perform FBCBCs for high-risk providers and suppliers that initially enrolled during the PHE upon their revalidation once the PHE ends. This was not previously possible under our prior regulations because the revalidation applications would only be screened at

the moderate-risk level. Pursuant to our regulatory revisions in the CMS CY 2024 Home Health Prospective Payment System final rule, however, CMS --- effective January 1, 2024 ---- may fingerprint the 5 percent or greater direct/indirect owners of these providers/suppliers. Specifically:

(i) Revalidating OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements pursuant to a legally declared national, state, or local emergency declared under existing law --- These providers/suppliers fall within the high-risk screening category and are subject to the fingerprinting requirement as part of their revalidation requirement.

(ii) Once the providers/suppliers in (i) have been fingerprinted, they fall within the moderate-risk category.

Upon receipt of an application from a revalidating OTP that has not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS supplier, revalidating HHA, revalidating MDPP supplier, revalidating SNF, or revalidating hospice, the contractor shall determine whether the provider/supplier was waived from the fingerprinting requirement pursuant to applicable legal authority due to a national, state, or local emergency declared under existing law. If the provider/supplier was waived and has not yet been undergone fingerprinting, the contractor shall process the revalidation using the high-risk screening procedures. If the provider/supplier was not so waived or has otherwise undergone fingerprinting after a waiver, the revalidation application shall be processed consistent with the moderate-risk screening procedures.

Note that any such waiver must have been directed by CMS.

B. Changes of Information (Including Additions and Changes of Practice Locations)

(This subsection (B) does not apply to ownership changes that qualify as a mere change of information (e.g., reporting a new 10 percent owner).) These transactions are addressed in subsection (C) below.)

1. Limited

Changes of information (including additions of practice locations) submitted by providers/suppliers in the "limited" level of categorical screening shall be processed consistent with existing instructions.

2. Moderate

Changes of information submitted by providers/suppliers in the "moderate" level of categorical screening shall be processed consistent with existing instructions, although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15. The site visit shall be performed consistent with the applicable instructions in this chapter (e.g., section 10.2.1.2 for CORFs). The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

3. High

Except as stated below, changes of information submitted by providers/suppliers in the "high" level of categorical screening shall be processed consistent with existing instructions, although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15. The site visit shall be performed consistent with the applicable instructions in this chapter. The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

For purposes of this requirement:

- A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.

- If the provider/supplier's physical location is not changing (e.g., the provider's street name is changing but its actual office space is not), no site visit is required.

- A DMEPOS supplier that is adding a new practice location falls within the "high" screening category. This is because each location must be separately enrolled. The enrollment of a new location thus constitutes an initial enrollment.

- A DMEPOS supplier undergoing a change in TIN with no change in ownership falls within the "moderate screening category.

C. Change of Ownership

1. **Limited**

Changes of ownership (regardless of whether a new TIN is triggered) shall be processed consistent with existing instructions.

2. Moderate

If a provider or supplier is undergoing a change of ownership resulting in a new TIN, the contractor shall:

a. Process the application consistent with existing instructions, and

b. Order a site visit through PECOS in accordance with the following:

- For ownership changes that must be approved by the state or SOG Location under current CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1) of this chapter), the site visit shall be ordered and performed after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

- For ownership changes that do not require state or SOG Location approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.

3. High

See subsection (A)(3)(c) for information on processing changes of/in ownership applications from DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, SNFs, and hospices.

D. Reactivations

a. Limited

Form CMS-855 reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

b. Moderate

Form CMS-855 reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening – including existing DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, and SNFs – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

c. High

Form CMS-855 reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

10.6.21.1 – Additional Miscellaneous Enrollment Topics

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

(The instructions in this section 10.6.21.1 take precedence over all other contrary instructions in this chapter, including, but not limited to, the existing guidance in sections 10.3.1 et al. The policies in this section will eventually be incorporated into the sections of this chapter that are applicable to the subject matter.)

A. Type of Practice Location

For Form CMS-855A, CMS-855B, and CMS-855I applications, the contractor may collect the practice location type in Section 4 of the application via telephone or---if the practice location type is otherwise apparent---may forgo development altogether.

B. Voluntary Terminations for Non-Certified Suppliers

If a non-certified supplier wishes to voluntarily withdraw from Medicare (including deactivating all active PTANs), the supplier must submit the applicable Form CMS-855/20134 to do so. It cannot make this request via letter, phone, etc.

C. Initial Enrollments with Multiple Locations

(This section 10.6.21.1(C) takes precedence over all other instructions in this chapter excluding section 10.3.)

If a high or moderate-risk provider or supplier (hereafter "provider") is initially enrolling in Medicare and has multiple practice locations, the SVC will conduct a site visit of each location rather than simply one selected location. In such instances, the contractor shall note the following:

1. Certified Providers/Suppliers – If, per this chapter, the site visits are to be performed after the contractor receives a recommendation of approval from the state, the contractor shall wait until all site visits are completed before taking the next required step (e.g., referring the application to PEOG to final review).

2. Site Visit Failure – If one of the locations fails its site visit, the contractor shall follow existing guidance for handling such situations (e.g., approving the application but without the failed location).

D. Verification of Telephone Numbers

Except when the provider or supplier has a regulatory supplier standard regarding maintenance of a telephone number (e.g., § 410.33(g)(5) for IDTFs), the contractor need not verify the provider's or supplier's phone number listed on the application, though the provider or supplier must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

If a regularly supplier standard concerning telephone numbers is implicated, the contractor shall not call the supplier's phone number as a means of verification. However, all other applicable means of validating the phone number remain intact.

E. Sales Agreement

For any reported direct ownership change in Section 5 or 6 of the Form CMS-855A – and except as otherwise directed by CMS -- the provider must submit a copy of the legal document(s) that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1(B) of chapter 10 for more information on such documents.) This requirement, however, does not apply to: (1) indirect ownership changes; and (2) ownership changes that are not otherwise required to be reported (e.g., less than 5 percent owner of a corporation).

F. Survey and Certification Application Referrals to PEOG

Per existing guidance and as required, the contractor shall complete and submit the Survey and Certification Checklist with survey and certification applications referred to PEOG for accuracy and completion (e.g., in the instance described in section 10.2.1.7(B)(3)). This is in addition to, and not in lieu of, all other documents the contractor is required to submit with the application (e.g., Form CMS-855A, provider-signed Form CMS-1561) per this chapter or other CMS directive.

G. Validation of CLIA Certifications

(This subsection (G) applies to any situation where the provider/supplier is required – per this chapter or other CMS guidance -- to submit a CLIA certificate.)

If the provider/supplier reports a CLIA number on its enrollment application but fails to submit a copy of any required accompanying CLIA certificate, the contractor shall not request said copy from the provider/supplier. Instead, the contractor shall confirm the provider/supplier's certification status by reviewing the following website:

https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp.

If, and only if, the contractor cannot validate the certification status via the above website, it may request a copy of the CLIA certificate.

If the provider/supplier submits a copy of the certificate and the contractor concludes it is valid, the contractor need not review the above website even if the provider/supplier failed to report the CLIA number on the application. If the provider/supplier determines that the certificate is not valid, it shall review the website without requesting another copy of the certificate. If the website does not validate the provider/supplier's certification status, the contractor may request from the provider/supplier a valid copy of the certificate and/or contact the provider/supplier for clarification per existing development policies.

10.6.23 – Special Instructions for Electronic Funds Transfer (EFT) Accounts and Special Payment Addresses

(Rev. 13415; Issued: 09-18-25; Effective: 10-20-25; Implementation: 10-20-25)

(The instructions in this section 10.6.23 take precedence over all other contrary instructions in this chapter, including, but not limited to, the existing guidance in sections 10.3, 10.3.1.1.4, 10.3.1.2.4, and 10.3.1.3.4. The policies in this section will eventually be incorporated into the sections of this chapter that are applicable to the subject matter.)

A. Enrolled Providers/Suppliers

1. General Policy

A provider/supplier may only have one EFT account and one special payment address (SPA) per enrollment. As a general rule, multiple EFT accounts or SPAs within an existing enrollment will remain in effect only until the provider/supplier submits any update to its EFT information or SPA data, respectively, for any of these accounts or addresses. At that time, the EFT account or SPA for which the provider/supplier submitted the update will become the lone EFT account or SPA (as applicable) for that enrollment.

For purposes of this requirement:

(i) The term "enrollment" means a single enrollment in a single state involving a single provider/supplier type. The particular PTAN arrangement under the enrollment (e.g., a group practice has three practice locations under its Form CMS-855B enrollment, each with a separate PTAN) is irrelevant for purposes of this requirement; again, the requirement is based on the enrollment, not the PTAN.

(ii) Any submitted change to any of the provider/supplier's EFT or SPA data for any EFT account or SPA within an enrollment --- even a change that the provider/supplier did not cause (e.g., a government-generated zip code change) and even if it is for only one of the enrollment's EFT accounts or SPAs --- triggers the aforementioned requirement. The materiality of the change does

not matter. However, the changed data must have actually been submitted via the appropriate CMS form to invoke the requirement; using the example in the previous sentence, this zip code change would not trigger the requirement unless and until the provider/supplier reports it via a CMS form.

(iii) If the provider/supplier reports the changed EFT or SPA data as part of a revalidation, reactivation, or other enrollment transaction other than a change of information (COI), the requirement is invoked to the same extent as with a COI.

(iv) The requirement applies only to the precise enrollment (e.g., "Enrollment A") for which the change was submitted. It is inapplicable to the provider/supplier's other enrollments ("Enrollments B and C"), even if B and C have:

- Multiple EFT accounts or SPAs that match those for which the provider/supplier reported a change to its "Enrollment A" EFT or SPA data; and/or
- The same LBN or TIN as "Enrollment A."

(v) A change in EFT data does not invoke the need to "consolidate" the provider/supplier's SPAs if the provider/supplier has multiple SPAs; likewise, a change in SPA data does not require the "consolidation" of the provider/supplier's multiple EFT accounts. (For purposes of this section 10.6.23, the term "consolidate" simply means reducing the provider/supplier's multiple EFT accounts or SPAs to one.)

(vi) Even if the multiple EFT accounts are with the same banking institution, the aforementioned "consolidation" requirement applies.

(vii) Any EFT and/or SPA consolidation under this section 10.6.23 applies to all PTANs under the single enrollment.

(viii) The consolidation requirement *only* applies *if* the EFT or SPA change that the provider/supplier submitted is approved. *It is inapplicable if the change is denied, rejected, or returned.*

(ix) The term "multiple" EFT accounts or SPAs only applies to active EFT accounts/SPAs.

(x) Except as otherwise noted, any consolidation described in this section 10.6.23 becomes effective on the date of the applicable approval, denial, rejection, or return letter (see subsection (A)(2)(i) below).

Consider the following:

EXAMPLE – Provider X is enrolled as a group practice and a HIT supplier (i.e., two separate enrollments) in State Y. Currently:

- The group practice enrollment has two EFT accounts (one with Smith Bank and one with Jones Bank) and two SPAs (1 James Street and 200 Johnson Street)
- The HIT supplier enrollment has the same two EFT accounts and SPAs as the group practice

Provider X submits a change to its Smith Bank account information for the group practice enrollment. *The change is approved.* In this scenario: (1) the Smith Bank account becomes the lone EFT account for the group practice; (2) the group practice's Jones Bank account becomes inactive in PECOS effective on the date of the notice to the provider/supplier that the originally

submitted EFT or SPA change was approved, denied, etc. (see subsection (A)(2)(i) below); (3) the Smith Bank and Jones Bank accounts for the HIT supplier enrollment are unaffected; and (4) the SPAs for Provider X's two enrollments are unaffected.

2. Operational Procedures

If the contractor receives an EFT or SPA change and determines that the provider/supplier has multiple EFT accounts or SPAs (as applicable and consistent with the guidelines described in subsection (A) above) for that enrollment, the contractor shall follow the procedures described below. (The example in subsection (A) will be used as a format.)

Step 1 – The contractor shall process the EFT data change for the group practice's Smith Bank account as normal.

Step 2 – Upon final completion of its processing of the change *and assuming the change is approved,* the contractor shall:

i. Send the appropriate approval, denial, etc., letter to the provider/supplier consistent with the instructions in this chapter. The contractor shall, however, add the following language to the letter:

"Under CMS policy, a Medicare provider or supplier may only have one ["EFT account" or "special payment address", as applicable] per enrollment. Consistent therewith, [Contractor name] has designated the ["EFT account" or "special payment address", as applicable] for which you reported changed ["EFT" or "special payment address"] information as the sole ["EFT account" or "special payment address"] for this enrollment. This designation is effective as of the date of this letter. All payments previously sent to your other ["EFT account(s)" or "special payment address(es)"] under this enrollment will now be made to the sole designated ["EFT account" or "special payment address"] described above. If you wish to change this sole designated ["EFT account or "special payment address"], you must submit the applicable [Form CMS-588, Form CMS-855, or Form CMS-20134, as applicable] to do so.

Note that the sole designation described above applies only to the enrollment for which you submitted the requested change to your ["EFT" or "special payment address'] data. It is inapplicable to any other enrollments you have."

The contractor may: (1) notwithstanding any other instruction to the contrary in section 10.7 et seq. of this chapter, alter the forgoing language to conform to the provider/supplier's particular factual situation (prior CMS approval is unnecessary); and (2) insert said language in any part of the letter it chooses.

ii. End-date the "other" EFT account(s) or SPA(s) (as applicable) effective the date of the letter described in subsection (A)(2)(i) above. The contractor shall make all payments under the enrollment to the sole account/SPA beginning the day after the date of the letter.

iii. Apply the PTAN(s) associated with the deleted EFT account/SPA to the sole EFT account/SPA.

iv. Complete all other normal steps required under this chapter for finalizing the transaction in question.

B. Providers/Suppliers Initially Enrolling or Undergoing a CHOW Consistent with Principles of 42 CFR § 489.18

The aforementioned policy that a provider/supplier may only have one EFT account and one SPA per enrollment also applies to: (1) providers/suppliers submitting an initial enrollment application; and (2) new owners in a certified provider/supplier CHOW (i.e., a CHOW consistent with the principles of § 489.18). The contractor shall apply this policy to such applications. If, therefore, the provider/supplier/new owner submits the application with more than one EFT account or SPA, the contractor shall develop for a single EFT account or SPA (as applicable) consistent with the instructions in this chapter. If the provider/supplier/new owner fails to comply within 30 days, the contractor shall reject the application pursuant to 42 CFR § 424.525(a)(1).

C. Denied, Rejected, or Returned Changes

If, in the circumstances described above, the submitted EFT or SPA change is denied, rejected, or returned, the contractor shall:

- *Follow existing procedures in this chapter for denying, rejecting, or returning the change (e.g., sending letter). The existing EFT or SPA data as shown in PECOS will remain the same, and no consolidation occurs.*
- *If the denial, rejection, or return results in the expiration of the applicable time period for reporting the change (i.e., 90 days), the contractor shall e-mail its PEOG BFL notifying the BFL of the denial, rejection, or return. PEOG will determine whether the provider's/supplier's billing privileges should be deactivated under § 424.540(a)(2) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.*