CMS Manual System	Department of Health & Human Services (DHHS)				
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)				
Transmittal 12717	Date: July 18, 2024				
	Change Request 13683				

SUBJECT: Thirteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to address several provider enrollment topics. These include, but are not limited to -- (1) Denials and revocations; (2) Deactivations; (3) Reassignment of benefits; (4) Ownership; and (5) Model letters.

EFFECTIVE DATE: August 19, 2024

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: August 19, 2024

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	10/10.2/10.2.1.8.1/Rural Emergency Hospitals (REHs)
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.2.8/Portable X-Ray Suppliers (PXRSs)
R	10/10.2/10.2.6/Medicare Diabetes Prevention Program (MDPP) Suppliers
R	10/10.3/10.3.1.2.4/Section 4 (Practice Location Information) – Form CMS-855B
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	10/10.4/10.4.7.3/Revocation Reasons
R	10/10.4/10.4.7.5/Additional Revocation Policies
R	10/10.4/10.4.8/Deactivations
R	10/10.6/10.6.1.1.5/HHA and Hospice Ownership Changes
R	10/10.6/10.6.2/Establishing Effective Dates
R	10/10.6/10.6.7.1/Organizational Owning and Managing Information
R	10/10.6/10.6.7.2/Individual Owning and Managing Information
R	10/10.6/10.6.21.1/Additional Miscellaneous Enrollment Topics
R	10/10.7/Model Letters
R	10/10.7/10.7.5.1/Part A/B Certified Provider and Supplier Letter Templates – Post-Transition

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. 100-08Transmittal: 12717Date: July 18, 2024Change Request: 13683

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EFFECTIVE DATE August 19, 2024

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: August 19, 2024 I. GENERAL INFORMATION

A. Background: The purpose of this CR is to clarify certain Medicare provider enrollment policies in Chapter 10 of Pub. 100-08. These policies include, but are not limited to -- (1) Denials and revocations; (2) Deactivations; (3) Reassignment of benefits; (4) Ownership; and (5) Model letters.

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

II. BUSINESS REQUIREMENTS TABLE

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

Numbe r	Requiremen t	Responsibility								
		A/B MAC		DME	Shared-System Maintainers			Other		
		A	В	HH H	MA C	FIS S	MC S	VM S	CW F	
13683.1	The contractor shall observe and adhere to the applicable policy changes outlined in this CR.	X	X	X						NPEAST , NPWES T
13683.2	The contractor shall observe the edits to the various model letters included in this CR.	X	X	Х						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsibility	7	
			A/	Έ	DME	CEDI
			MA	AC		
					MAC	
		Α	В	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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

V. CONTACTS

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

VI. 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. 12717; Issued: 07-18- 24)

Transmittals for Chapter 10

10.2.1.8.1 – Rural Emergency Hospitals (REHs)

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

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

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

• A CAH or rural hospital wishing to convert to an REH must submit a Form CMS-855A change of information application, rather than an initial application

- No application fee need be paid
- REHs will be in the "limited" screening category under 42 CFR § 424.518

• REHs fall within 42 CFR § 424.520(a) in terms of establishing an effective date of billing privileges.

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

A. Initial Process

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

1. Submission

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

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

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

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

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

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

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

However, the facility need not submit with its application:

• An application fee

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

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

2. Initial Contractor Review

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

(i) Eligibility -

- The contractor shall review PECOS to ascertain whether the enrolling REH was enrolled as a CAH or rural hospital as of December 27, 2020.
- If the contractor finds that the facility does not meet the above-referenced December 27, 2020, enrollment requirement, the contractor shall follow the procedures in section 10.2.1.8.1(A)(4)(ii) for denying the application without making a referral to the state/Survey & Operations Group Location.
- If the contractor is uncertain as to whether the facility qualified as a "rural hospital" as of December 27, 2020, it may contact its Provider Enrollment & Oversight Group Business Function Lead for assistance.

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

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

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

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

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

3. Processing and PECOS

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

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

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

For submitted initial applications:

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

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

4. Recommendation/Disposition

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

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

B. ePost-SOG Location Procedures

1. Denial

If the SOG Location denies the REH's request for participation, it will notify the contractor thereof. The contractor shall accordingly follow the procedures in this chapter for denying non-transitioned certified provider/supplier applications. (No prior PEOG approval of the denial is needed.) The facility's CAH or rural hospital enrollment, however, remains as is.

2. Approval

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

C. Additional Considerations

1. Letters

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

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

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

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

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

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

D. Enrolled REHs

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

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

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

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

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" - Background

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

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

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

To account for such technological advances in diagnostic testing, we revised § 410.33 in the CY 2022 Physician Fee Schedule final rule such that **IDTFs that have no beneficiary**

interaction, treatment, or testing whatsoever at their practice location are wholly exempt from the following requirements in § 410.33(g).

- <u>§ 410.33(g)(6)</u>) 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.
- <u>§ 410.33(g)(8)</u>) The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF.
- <u>§ 410.33(g)(9)</u>) 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, inperson 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 \S 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 <u>both</u> 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, he or she must meet § 410.33(c)(1)'s requirements for the direct, in-person tests and § 410.33(c)(2)'s requirements for the indirect, non-in-person tests.

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

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

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

B. IDTF Standards

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

1. Operates its business in compliance with all applicable federal and state licensure and regulatory requirements for the health and safety of patients (\S 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 (\S 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. (\S 410.33(g)(12))

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

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

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

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

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

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

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

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

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

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

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

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

C. Leasing and Staffing

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

An IDTF is not required to report equipment that the IDTF is leasing for a period less than 90 days unless the IDTF is leasing equipment for services that they have not already reported on

a Form CMS-855B IDTF Attachment. For all new services being provided, IDTFs would need to complete a change of information to include the equipment and CPT/HCPCS codes that will be billed. Any accreditation for the services provided would need to be obtained by the IDTF.

D. Sharing of Space and Equipment

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

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

E. Multi-State IDTFs

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

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

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

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

F. One Enrollment per Practice Location

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

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

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

G. Interpreting Physicians

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

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

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare
- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so
- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The contractor may need to contact another contractor to obtain this information.) If the applicant does not list any interpreting physicians, the contractor need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

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

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

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

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

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

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

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

J. IDTF Technician Licensure and Certification Requirements

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

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

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

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

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

Not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all

supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

M. IDTF - Information about Supervising Physicians

The contractor shall ensure and document in PECOS that each supervising physician is: (1) licensed to practice in the state(s) where the diagnostic tests he or she supervises will be performed; (2) Medicare-enrolled; and (3) not currently excluded or debarred. The physician(s) need not necessarily be Medicare-enrolled in the state where the IDTF is enrolled; moreover, the physician need not be furnishing medical services outside of his/her role as a supervising physician (i.e., he/she need not have his/her own medical practice separate from the IDTF). If the physician is enrolled in another state or with another contractor, however, the contractor shall ensure that he or she is appropriately licensed in that state.

In addition:

- Each physician of the group who actually performs an IDTF supervisory function must be listed.
- If a supervising physician has been recently added or changed, the updated information must be reported via a Form CMS-855B change request. The new physician must have met all of the supervising physician requirements at the time any tests were performed.
- If the contractor knows that a reported supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.
- If the supervising physician is enrolling in Medicare and does not intend to perform medical services outside of his/her role as a supervising physician: (1) the contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a PTAN; (2) the physician shall list the IDTF's address as a practice location; and (3) the space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

With respect to physician verification, the contractor shall contact each supervisory physician by telephone to verify that the physician: (1) actually exists (e.g., is not using a false or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities.

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

P. IDTF - Changes of Supervising Physicians

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

If the contractor receives notification from a supervising physician that he/she is no longer supervising tests at the IDTF, the contractor shall request from the supplier a Form CMS-855B change of information. If the IDTF did not have another supervising physician listed on the current application, the IDTF must submit a change of information adding a new supervising physician. If the IDTF does not provide this information, the contractor shall proceed with non-compliance revocation procedures as noted in section 10.4(M) of this chapter.

Q. Desk and Site Reviews

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

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.
- To the extent applicable, the IDTF meets the criteria outlined in sections 10.6.20(A) and 10.6.20(B) of this chapter.
- The IDTF meets the supplier standards in 42 CFR § 410.33.

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

R. Mobile Units

Mobile units must list their geographic service areas in Section 4 of the Form CMS-855B. Based on the information furnished therein, the NSVC will generally perform the site visit

via one of the following methods: (1) the mobile unit visits the office of the NSVC (or some other agreed-to location) for inspection; (2) the NSVC visits the mobile unit's base of operations to inspect the unit; or (3) the NSVC obtains an advance schedule of the locations at which the IDTF will be performing services and conducts the site visit at one of those locations.

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

- How they will perform these types of supervision on a mobile basis;
- What their responsibilities are; and
- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self-referral for testing (in particular, this concerns potentially illegal compensation to the supervisory physician from the IDTF).

S. Addition of Codes

An enrolled IDTF that wants to perform additional CPT-4 or HCPCS codes must submit a Form CMS-855B change request. If the additional procedures are of a type and supervision level similar to those previously reported (e.g., an IDTF that performs MRIs for shoulders wants to perform MRIs for hips), a new site visit is typically not required, though the contractor reserves the right to request that the NSVC perform one.

If, however, the enrolled IDTF wants to perform additional procedures that are <u>not</u> similar to those previously reported (e.g., an IDTF that conducts sleep studies wants to perform ultrasound tests or skeletal x-rays), the contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

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

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

T. IDTF That Performs Diagnostic Mammography

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

U. IDTF Ownership of CLIA Laboratory

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

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

Pursuant to 42 CFR §§ 424.530(a)(1)/(18) and 424.535(a)(1)/(23), an IDTF's enrollment may be denied or revoked if it violates any applicable standard in § 410.33(g). The contractor shall abide by the following in such situations:

1. (a)(1) – Prior approval unnecessary

For violations of any of the following supplier standards in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(1). Prior PEOG approval is unnecessary. Corrective action plan (CAP) rights under §§ 424.530(a)(1) or 424.535(a)(1) apply.

• § 410.33(g)(1) through (g)(6) as well as (g)(8) through (17).

2. (a)(1) and (a)(23) – Prior approval unnecessary

For violations of the following supplier standard in § 410.33(g), the contractor shall deny or revoke enrollment under, respectively, §§ 424.530(a)(1) or 424.535(a)(23). Prior PEOG approval is unnecessary. CAP rights under §§ 424.530(a)(1) apply but no CAP rights apply for § 424.535(a)(23) revocations.

• § 410.33(g)(7)

10.2.2.8 – Portable X-Ray Suppliers (PXRSs)

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

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

A. Background

To qualify as a PXRS, an entity must meet the conditions for coverage discussed in 42 CFR 486.100-110.

A PXRS can be simultaneously enrolled as a mobile independent diagnostic testing facility (IDTF), though they cannot bill for the same service. A PXRS requires a state survey, while a mobile IDTF does not (although an IDTF requires a site visit).

A PXRS does not have a supplier agreement.

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

1. Receipt of Application

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

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

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

(C) Ensure that the PXRS has submitted all documentation otherwise required per this chapter. For PXRS initial enrollment, this includes the Form CMS-1880 (Request for Certification as Supplier of Portable X-Ray Suppliers)

If the Form CMS-1880 is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.2.8(B) prohibits the contractor from returning or rejecting the PXRS application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.2.8(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) A site visit need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.2.8(B)(2)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order a site visit as described in this chapter.

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

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments.
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the supplier-signed Form CMS-1880
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

*B*ased on the information received from the contractor, PEOG wil*l* (1) assign an effective date, (2) assign a CCN, and (3) enter the applicable data into ASPEN, and (4) approve (with possible edits) the approval letter.

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

C. Site Visits

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

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

application prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Reassignment

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

E. Practice Location Information

In Section 4 of the Form CMS-855B, the PXRS must furnish certain information, including:

- Whether it furnishes services from a "mobile facility" or "portable unit." (A PXRS can be either, though it usually is a portable unit.) A "mobile facility" typically describes a vehicle that travels from place to place to perform services <u>inside</u> the vehicle. Examples of such vehicles include mobile homes and trailers. A portable unit involves a supplier transporting medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.
- Its base of operations. This is from where personnel are dispatched and where equipment is stored. It may or may not be the same address as the practice location.
- All geographic locations at which services will be rendered.
- Vehicle information if the services will be performed <u>inside</u> or <u>from</u> the vehicle. Unless stated otherwise in this chapter or in another CMS directive, copies of all licenses and registrations must be submitted as well.

F. Additional Enrollment Information

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

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

When enrolling the PXRS, and except as otherwise stated in this chapter or as otherwise instructed by PEOG, the contractor shall use the effective date that is indicated on the state approval letter/notice. This is the date from which the supplier can bill for services.

G. PXRS Changes of Ownership (CHOWs) and Changes of Information

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

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

H. Additional Information

For more information on PXRSs, refer to:

- 42 CFR §§ 486.100 486.110
- Pub. 100-07, chapter 2, sections 2420 2424B
- Pub. 100-02, chapter 15, sections 80.4 80.4.4
- Pub. 100-04, chapter 13, sections 90 90.5

10.2.6 - Medicare Diabetes Prevention Program (MDPP) Suppliers

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

A. General Background Information

MDPP is a structured lifestyle intervention that includes dietary coaching, lifestyle intervention, and moderate physical activity, all with the goal of preventing the onset of diabetes in individuals who are pre-diabetic. An entity or individual seeking to furnish MDPP services to Medicare beneficiaries must enroll as an "MDPP supplier" via the Form CMS-20134. Such suppliers must meet the following enrollment requirements:

- Has: (1) MDPP preliminary recognition; (2) full recognition as determined by the Center for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP); or (3) full CDC recognition plus DPRP recognition.
- Maintains a valid TIN and NPI at the organizational level
- Passed screening requirements at a high categorical risk level per § 424.518(c) upon initial enrollment and revalidate at the moderate categorical risk level per § 424.518(b) and
- Complies with the supplier standards

MDPP supplier applicants do not require any licensure, accreditation, or certificates to be eligible to enroll as an MDPP supplier. Rather, the CDC administers the curriculum for the MDPP and monitors the organization's fidelity to and success with furnishing the services. Thus, organizations with preliminary or full recognition from the CDC's DPRP indicate that they are prepared to deliver MDPP services.

As a part of the expanded CMMI model, CMS will only accept in-person MDPP suppliers to enroll in Medicare. *MDPP suppliers can provide any combination of in-person and distance learning sessions and they would still be considered in-person MDPP suppliers. In June* 2024, CDC released the 2024 Diabetes Prevention Recognition Program (DPRP) Standards (<u>https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures</u>) that included five types of CDC DPRP organization recognition codes: "in-person", "in-person with a distance learning component", "distance learning", "online", and "combination with an online component". The contractor can approve MDPP applications for organizations that demonstrate an "in-person" or an "in-person with a distance learning component" *CDC DPRP recognition code*.

B. MDPP Supplier Standards

All MDPP suppliers must comply with MDPP supplier standards to obtain and retain Medicare billing privileges. Consistent with 42 CFR § 424.205(*c*), each MDPP supplier must

certify on its Form CMS-20134 enrollment application that it meets and will continue to meet the following standards (listed in 424.205(c)) and all other requirements:

- Must have and maintain: (1) MDPP preliminary recognition; (2) full CDC recognition; or
 (3) full CDC recognition plus DPRP recognition.
- (2) Must not currently have its billing privileges terminated or be excluded by a state Medicaid agency
- (3) Must not permit MDPP services to be furnished by or include on its roster any individual coach who meets the ineligibility criteria in 424.205(d)(1)
- (4) Must maintain at least one administrative location on an appropriate site. All administrative locations, must be reported on their CMS-20134 form and may be subject to site visits. (See § 424.205(c)(4) for more information regarding site requirements.)
- (5) Must update the enrollment application within 30 days for any change of ownership, change to the coach roster, change of practice location (including additions and deletions of locations), and final adverse legal action history, and update all other changes within 90 days
- (6) Must maintain a primary business telephone that is operating at administrative locations or directly where services are furnished. The associated telephone number must be listed with the name of the business in public view.
- (7) Must not convey or reassign a supplier billing number
- (8) Must not deny an MDPP beneficiary access to MDPP services during the MDPP benefit period, including conditioning access to MDPP services on the basis of an MDPP beneficiary's weight, health status, or achievement of performance goals (with certain exceptions described in § 424.205(c)(8)(i))
- (9) Must not---nor may other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf---directly or indirectly commit any act or omission, or adopt any policy that coerces or otherwise influences an MDPP beneficiary's decision to begin accessing MDPP services or change to a different MDPP supplier specifically
- (10) Must offer an MDPP beneficiary no fewer than the services described in § 424.205(c)(10)
- (11) Must disclose detailed information about the MDPP benefit to each beneficiary to whom it furnishes MDPP services before the initial core session is furnished, including the set of services, eligibility requirements, the once-per-lifetime nature of MDPP services, and the standards in § 424.205(c)
- (12) Must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP related complaints. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. This information must be kept at each administrative location and made available to CMS or its contractors upon request
- (13) Must maintain a crosswalk file which indicates how participant identifications for the purposes of CDC performance data correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary. The MDPP supplier must submit the crosswalk file to CMS or its contractor
- (14) Must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core benefit
- (15) Must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, as well as the documentation requirements outlined § 424.205(f)

The CMS will notify the contractor when an MDPP supplier within its jurisdiction has moved from preliminary or full recognition down to pending and therefore no longer maintains eligibility as an MDPP supplier.

For those suppliers that no longer have a valid recognition level to maintain their MDPP supplier enrollment, the contractor shall take the necessary steps to revoke the supplier's billing privileges.

Violations of the supplier standards are determined as non-compliance and the associated enrolment denial and revocation authorities would apply.

10.3.1.2.4 – Section 4 (Practice Location Information) – Form CMS-855B (*Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24*)

A. Reporting and Verification Policies

1. <u>ZIP Code</u> – The supplier must submit the 9-digit ZIP Code for each practice location listed.

2. <u>Practice Location Name</u> - For suppliers paid via the Multi-Carrier System (MCS), the practice location name entered into PECOS shall be the legal business name. (Beginning with PECOS 2.0, however, the DBA name can be entered as the practice location name.)

3. <u>Practice Location Verification</u> – Except as stated otherwise in this chapter or in another CMS directive, the contractor shall verify that the practice locations listed on the application actually exist and are valid addresses with the United States Postal Service (USPS). PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS Store, mailboxes, etc.), or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry.

4. <u>Phone Number Verification</u> - *The contractor need not verify the supplier's telephone number listed on the application, though the supplier must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.*

5. <u>Special Certified Supplier Instructions (ASCs and Portable X-Ray Suppliers (PXRS))</u> - If the supplier's address and/or telephone number cannot be verified, the contractor shall request clarifying information from the supplier. If the supplier states that the facility and its phone number are not yet operational, the contractor may continue processing the application. However, it shall indicate in its recommendation letter that the address and telephone number of the facility could not be verified. For purposes of PECOS, the contractor can temporarily use the date the certification statement was signed as the effective date.

6. Specific Section 4 Subsection Policies

a. <u>Practice Location Type</u> - In Section 4A, if the "type of practice location" checkbox is blank, the contractor can confirm the information via the PCV, e-mail, or fax.

b. <u>Section 4B</u> - If neither box is checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the "special payments" address is indeed the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in Section 4B must be completed via the Form CMS-855B.

c. <u>Updated Questionnaire</u> - If the supplier (1) is adding a practice location and (2) is normally required to complete a questionnaire in the Form CMS-855B specific to its supplier type (i.e.: physical or occupational therapist groups), the entity must submit an updated questionnaire to incorporate services rendered at the new location.

d. Section 4E – If the "Check here" box in Section 4E is not checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the base of operations address is the same as the practice location, no further development is needed. If the supplier indicates that the base of operations is at a different location, the address in Section 4E must be furnished via the Form CMS-855B.

e. <u>Section 4F</u> - If the vehicle certificates are furnished but the applicable Form CMS-855B sections are blank, the contractor can verify via telephone, the PCV, e-mail, or fax that said vehicles are the only ones the supplier has.

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in Pub. 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or EFT payments shall be flagged if returned from the post office or banking institution, respectively, as this may indicate that the supplier's "special payment" address (the Practice Location Information section of the Form CMS-855B) or EFT information has changed. The supplier should submit a Form CMS-855B to change this address; if the supplier does not have an established enrollment record in PECOS, it must complete an entire Form CMS-855B. (For DMEPOS suppliers, the DME MAC is responsible for obtaining, updating, and processing Form CMS-588 changes.)

If a supplier is closing his/her/its business and has a termination date (e.g., he/she is retiring), the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the supplier to complete the "special payment" address section of the Form CMS-855B and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

For new enrollees, all payments must be made via EFT. The contractor shall thus ensure that the supplier has completed and signed the Form CMS-588 and shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

If an enrolled supplier that currently receives paper checks submits a Form CMS-855 change request – no matter what the change involves – the supplier must also submit:

- A Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.
- The contractor shall also verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

(Once a supplier changes its method of payment from paper checks to EFT, it must continue using EFT. A supplier cannot switch from EFT to paper checks.)

The "special payment" address may only be one of the following:

- One of the supplier's practice locations
- A P.O. Box
- The supplier's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement at least with respect to any special payments that might be made may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.
- Correspondence address
- A lockbox. The contractor shall request additional information if it has any reason to suspect that the arrangement at least with respect to any special payments that might be made may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.

D. Out-of-State Practice Locations

(The policies in this section 10.3.1.2.4(D) apply unless CMS instructs otherwise in this chapter or in another directive.)

If a supplier is adding a practice location in another state that is within the contractor's jurisdiction, a separate, initial Form CMS-855B enrollment application is not required if the following 5 conditions are met:

(i) The location is not part of a separate organization (e.g., a separate corporation, partnership);

(ii) The location does not have a separate TIN and LBN;

(iii) The state in which the new location is being added does not require the location to be surveyed;

(iv) Neither the new location nor its owner is required to sign a separate certified supplier agreement; and

(v) The location is not an IDTF, ASC, or other supplier type that must individually and separately enroll each of its locations.

Consider the following scenarios:

<u>EXAMPLE 1</u> - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y. The new location will be under JGP, Inc. JGP will not be establishing a separate corporation, LBN, or TIN for the fourth location. Since there is no state agency or SOG Location involvement with group practices, all five conditions are met. JGP can add the fourth location via a change of information request, rather than an initial application. The change request must include all information relevant to the new location (e.g., licensure, new managing employees). (For paper applications only---and to the extent required---the contractor shall create a separate PECOS enrollment record for the State Y location.)

<u>EXAMPLE 2</u> - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location

in State Y but under a newly created, separate entity - Jones Group Practice, LP. The fourth location must be enrolled via a separate, initial Form CMS-855B.

<u>EXAMPLE 3</u> - The contractor's jurisdiction consists of States X, Y and Z. Jones Group Practice (JGP), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Q. Since State Q is not within the contractor's jurisdiction, a separate initial enrollment for the fourth location is necessary.

E. Unavoidable Phone Number or Address Changes - Unless CMS specifies otherwise, any change in the supplier's phone number or address that the supplier did not cause (e.g., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-855B.

10.4.2.1 - Denials – General Principles

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

A. Notification Letters for Denials

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

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

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

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

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

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

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

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

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

(NOTE: See section 10.2.2.4(V) of this chapter for instructions regarding the application of 42 CFR § 424.530(a)(1) and (18) to IDTF denials. In the event of any inconsistency, the section 10.2.2.4(V) guidance takes precedence over that in section 10.4.2 et seq.)

B. When Prior PEOG Approval of the Denial Necessary

For cases involving 42 CFR § 424.530(a)(1) (Noncompliance – Not Professionally Licensed Individual Practitioners), § 424.530(a)(2) (Provider or Supplier Conduct), 42 CFR § 424.530(a)(3) (Felony Convictions), § 424.530(a)(4) (False or Misleading Information or Application), § 424.530(a)(6) (Medicare Debt), § 424.530(a)(7) (Payment Suspension), § 424.530(a)(11) (Prescribing Authority), § 424.530(a)(12) (Revoked Under Different Name,

Numerical Identifier, or Business Identity), § 424.530(a)(13) (Affiliation that Poses an Undue Risk), § 424.530(a)(14) (Other Program Termination or Suspension),), § 424.530(a)(15) (Patient Harm), and § 424.530(a)(17) (False Claims Act Civil Judgments), the contractor shall obtain approval of both the denial and the denial letter from PEOG via the ProviderEnrollmentRevocations@cms.hhs.gov mailbox prior to sending the denial letter. The contractor shall also obtain prior PEOG approval of the denial and denial letter if otherwise required to do so in this chapter or another CMS directive (i.e., certain denial situations other than those described in this subsection 10.4.2.1(B) require prior PEOG approval is otherwise mandated per this section 10.4.2.1(B) (e.g., MDPP denials under (a)(3), (a)(4), etc.)

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

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

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

D. No Denial Recommendation to State

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

E. PECOS Entry

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

10.4.2.2 - Denial Reasons

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

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

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

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

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

iii. The provider or supplier is not appropriately licensed.

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

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

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

vii. The applicant does not qualify as a provider of services or a supplier of medical and health services. (For instance, the applicant is not recognized by any federal statute as a Medicare provider or supplier (see section 10.2.8 of this chapter.)) An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in § 1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

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

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

NOTE: The contractor must identify in its denial letter the <u>exact</u> 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

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 <u>all</u> 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.

1. 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.

2. Examples

<u>Example #1</u>: Dr. X, a sole proprietor, has a \$70,000 overpayment. Three months later, he joins Group Y and becomes a 50 percent owner thereof. Group Y submits an initial enrollment application two months thereafter. Group Y's enrollment could be denied because Dr. X is an owner.

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

<u>Example #3</u> - Same scenario as example #2, but assume that his new practice is an LLC of which he is only a 30 percent owner. A denial is still warranted because he is an owner of the enrolling supplier and the \$50,000 overpayment was attached to him.

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

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

3. 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 <u>managing employee</u> or organization of the provider or supplier, is currently under a Medicare or <u>Medicaid payment</u> suspension as defined in <u>§§ 405.370</u> through 405.372 or in <u>§ 455.23</u> of this chapter.

(ii) <u>CMS</u> 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 <u>managing employee</u>'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, <u>CMS</u> 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 <u>CMS</u> 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 <u>after</u> its hardship request was denied. The contractor shall use § 424.530(a)(1) as a basis for denial when the institutional provider: (a) does not submit a hardship exception request and fails to submit the application fee within the prescribed timeframes; or (b) submits the fee, but it cannot be deposited into a government-owned account.)

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

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

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

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

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

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

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

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

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

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

(ii) Geographic location;

(iii) Provider or supplier type;

(iv) Business structure; or

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

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

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

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

An affiliation is defined as any of the following:

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

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

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

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

(v) Any reassignment relationship under § 424.80.

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

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

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

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

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

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

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

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

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

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

(A) The nature of the patient harm

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

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

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

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

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

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

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

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

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

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

- (B) The types of provider or supplier actions involved
- (C) The monetary amount of the judgment
- (D) When the judgment occurred

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

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

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

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

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

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

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

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

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

(Similar to current practice with respect to § 424.530(a)(1), the contractor can make denial determinations under § 424.530(a)(18) without prior PEOG approval. The contractor's denial letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

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

10.4.2.3 – Additional Denial Policies

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

A. Post-Denial Submission of Enrollment Application

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

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

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

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

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

B. 30-Day Effective Date of Denial

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

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

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

1. Expiration of Timeframe for Reporting Changes

If the contractor denies a change of information or CHOW submission and the applicable 90day or 30-day period for reporting the change has expired, the contractor shall send an e-mail to the CMS <u>MedicareProviderEnrollment@cms.hhs.gov</u> 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 90day 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 <u>unless</u> the provider has resubmitted the revalidation application. If, per the previous sentence, the provider resubmits the application and the contractor denies it again, returns it, or rejects it, the contractor shall - unless an existing CMS instruction or directive states otherwise – revoke the provider's billing privileges, assuming the applicable time period has expired.

F. Appeals of Denials

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

G. Use of 424.530(a)(1)

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

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

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

If a denial is warranted due to non-compliance with one of the standards and conditions referenced in § 424.530(a)(18) – *and except as otherwise directed in this chapter (e.g., section 10.2.2.4(V))* – the contractor shall use § 424.530(a)(18) (rather than § 424.530(a)(1)) as the denial reason. No CAP rights are therefore involved.

10.4.7.3 – Revocation Reasons

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

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

(NOTE: See section 10.2.2.4(V) of this chapter for instructions regarding the application of 42 CFR § 424.535(a)(1) and (23) to IDTF revocations. In the event of any inconsistency, the section 10.2.2.4(V) guidance takes precedence over that in section 10.4.7 et seq.)

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

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

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

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

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

- The provider or supplier does not have a physical business address or mobile unit where services can be rendered.
- The provider or supplier does not have a place where patient records are stored to determine the amounts due such provider or other person.
- The provider or supplier is not appropriately licensed. (NOTE: For (a)(1) revocations involving an individual practitioner who is not appropriately licensed due to a disciplinary action, PEOG -- rather than the contractor -- will make all determinations to revoke for this noncompliance requirement).
- The provider or supplier is not authorized by the federal/state/local government to perform the services that it intends to render.
- The provider or supplier does not meet CMS regulatory requirements for the specialty that it is enrolled as.
- The provider or supplier does not have a valid social security number (SSN) or employer identification number (EIN) for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or authorized or delegated official.
- The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider/supplier's notification from CMS or its contractor to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(This revocation reason will not apply if CMS has instructed the contractor to use deactivation reason 424.540(a)(3) in lieu thereof.)

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

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

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

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

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

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

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

(B) Is debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76.

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

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

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

"The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted (as that term is defined in 42 CFR §1001.2) of a federal or state felony offense that CMS determines

to be detrimental to the best interests of the Medicare program and its beneficiaries. [Under 424.535(a)(3)(ii),] [o]ffenses include, but are not limited in scope and severity to:

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

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

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

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

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

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

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

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

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

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

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

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

(iii) Either of the following occurs:

- CMS is not able to deposit the full application amount into a government-owned account; or
- The funds are not able to be credited to the United States Treasury;

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

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

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

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

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

"Abuse of billing privileges includes either of the following:

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

(A) Where the beneficiary is deceased.

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

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

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

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

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

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

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

(NOTE: Concerning (a)(8), PEOG -- rather than the contractor -- will (1) make all determinations regarding whether a provider has a pattern or practice of submitting non-

compliant claims; (2) consider the relevant factors; and (3) accumulate all information needed to make such determinations.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible

professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

(H) Any other relevant information provided to CMS.

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

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

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

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

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

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

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

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

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

(B) The types of provider or supplier actions involved

(C) The monetary amount of the judgment

(D) When the judgment occurred

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

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

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

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

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

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

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

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

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

(E) The amount of the debt; and

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

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

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

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

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

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

- (ii) Geographic location;
- (iii) Provider or supplier type;
- (iv) Business structure; or

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

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

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

1. Specific Reason

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

"(1) The duration of the affiliation

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

(3) The degree and extent of the affiliation

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

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

(i) The type of disclosable event.

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

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

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

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

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

2. Definition of Affiliation

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

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

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

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

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

- The reason(s) for and the specific facts behind the location's non-compliance;
- The number of additional locations involved;
- The provider or suppliers possibly history of final adverse actions or Medicare or Medicaid payment suspensions;
- The degree of risk the location's continuance poses to the Medicare Trust Funds;
- The length of time that the location was considered non-compliant;
- The amount that was billed for services performed at or items furnished from the noncompliant location; and,
- Any other evidence that CMS deems relevant to its determination."

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

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

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

- Whether the physician or eligible professional's diagnosis supports the order, certification, referral or prescription in question;
- Whether there are instances where the necessary evaluation of the patient for whom the order, certification, referral or prescription could have not occurred (for example: the patient was deceased or out of state at the time of the alleged office visit);
- The number and types of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state(s) in which he or she practices and the reason(s) for the action(s);

- Whether the physician or eligible professional has any history of final adverse actions (as defined by 42 CFR § 424.502);
- The length of time over which the pattern or practice has continued;
- How long the physician or eligible professional has been enrolled in Medicare;
- The number of type(s) of malpractice suits that have been filed against the physician or eligible professional related to ordering, certifying, referring or prescribing that resulted in a final judgement against the physician or eligible professional or the physician or eligible professional paid a settlement to the plaintiff(s) (to the extent this can be determined);
- Whether any State Medicaid Agency (SMA) or other public health insurance program has restricted, suspended, revoked or terminated the physician's or eligible professional's ability to practice medicine and reason for any such restriction, suspension, revocation or termination; and
- Any other information that CMS deems relevant to its determination.

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

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

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

(A) The nature of the patient harm.

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

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

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

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

(iii) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(iv) Administrative or monetary penalties.

(v) Formal reprimand(s).

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

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

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

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

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

(i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g). (See section 10.2.2.4(V) for more information. The instructions in that section supersede those in this section 10.4.7.3(V).)

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

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

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

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

(The contractor can make revocation determinations under § 424.535(a)(23) without prior PEOG approval. The contractor's revocation letter shall cite the exact statutory and/or regulatory citation(s) containing the specific standard/condition with which the provider/supplier is non-compliant. For a listing of some of these statutes and regulations, refer to section 10.2 et seq. of this chapter.)

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

W. Extension of Revocation

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

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

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

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

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

10.4.7.5 – Additional Revocation Policies

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

A. Use of § 424.535(a)(1)

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

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

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

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

B. Submission of Claims for Services Furnished Before Revocation

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

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

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

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

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

The contractor shall:

- Access this list on the 5th day of each month via the Share Point Ensemble site
- Review the monthly revoked and denied provider list for the names of Medicare providers revoked and denied in PECOS
- Document any appeal actions a provider/supplier may have submitted after the provider/supplier's revocation or denial
- Update the last three columns on the tab named "Filtered Revocations" of the spreadsheet for every provider/supplier revocation or denial

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

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

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

Appeal Type: CAP Reconsideration ALJ DAB

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

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

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

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

D. Opting-Out after Revocation

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

E. Overpayments Based Upon Revocations

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

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

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

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

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

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

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

F. Other Sources of Potential Bases for Revocations

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

1. UPICs

a. Background

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

PEOG will review the case file and:

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

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

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

b. Contents of Request

The revocation request shall contain the following information:

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

2. CMS Field Office or RO Revocations

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

If PEOG concurs with the FO/RO's revocation recommendation, PEOG will: (1) instruct the contractor to revoke the provider/supplier; and (2) accordingly notify the FO/RO.

(See section 10.4.3 of this chapter for information on the contractor's responsibilities concerning involuntary terminations received from the SOG Location.)

3. OIG Identified Revocations

PEOG is responsible for actions based on HHS OIG Identified revocations.

G. MDPP Supplier Revocation for Use of an Ineligible Coach

1. Background

Section 424.205(h)(1)(v) established a new revocation reason for MDPP suppliers. It permits revocation if the MDPP supplier knowingly permitted an ineligible coach to furnish MDPP services to beneficiaries, despite being previously removed from the MDPP supplier's roster through a CAP.

If a contractor or UPIC suspects this scenario, it shall develop a case file - including the revocation reason(s) - and submit the file and all supporting documentation to PEOG. The contractor shall provide PEOG with the information described in section 10.4.7.5(E)(1)(b).

PEOG will review the case file and:

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

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

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

2. Effective Dates

An MDPP supplier revoked under 424.205(h)(1)(v) does not have CAP rights. The revocation becomes effective 30 days after the contractor sends notice of the revocation.

3. Reenrollment Bar

As stated in § 424.205(h), if an MDPP supplier has its billing privileges revoked, it is barred from participating in Medicare from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation.

10.4.8 – Deactivations

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

A. Bases for Contractor Action

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor shall – without prior approval from its PEOG BFL - deactivate a provider/supplier's entire enrollment record and Medicare billing privileges when:

(i) The provider/supplier fails to respond to a revalidation request.

(ii) The provider/supplier fails to respond timely to a revalidation development request.

(iii) The provider/supplier is enrolled in an approved status with neither an active reassignment nor practice location for 90 days or longer. (The deactivation basis shall be 42 CFR § 424.540(a)(4), which permits deactivation if the provider/supplier is not in compliance with all enrollment requirements. See sections 10.4.8(B) and (D) below for more information on this new deactivation ground.)

(iv) The provider/supplier deactivates an EFT agreement and remains enrolled but does not submit a new EFT agreement within 90 days. (The deactivation basis shall be 42 CFR § 424.540(a)(4).)

(v) The provider/supplier is deceased, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the provider's/supplier's death; <u>and</u> (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. <u>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 <u>CMS' explicit direction.</u></u>

B. Regulatory Reasons for Deactivation in § 424.540(a)

1. Grounds

Section 424.540(a) lists eight deactivation grounds:

<u>Section 424.540(a)(1)</u> - 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 6^{th} month without a submitted claim.

<u>Section 424.540(a)(2)</u> - 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.

<u>Section 424.540(a)(3)</u> - 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.

<u>Section 424.540(a)(4)</u> - The provider/supplier is not in compliance with all enrollment requirements. (See section 10.4.8(D) below for more information.)

<u>Section 424.540(a)(5)</u> - The provider's/supplier's practice location is non-operational or otherwise invalid. (See section 10.4.8(D) below for more information.)

<u>Section 424.540(a)(6)</u> - The provider/supplier is deceased.

<u>Section 424.540(a)(7)</u> - The provider/supplier is voluntarily withdrawing from Medicare.

<u>Section 424.540(a)(8)</u> - 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. <u>Non-Billing (§ 424.540(a)(1))</u> – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the deactivation is imposed.

b. <u>Section 424.540(a)(2), (3), and (4) (see subsection (B) above)</u> – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/ supplier became non-compliant (e.g., the day after the expiration of the 90-day period in which the provider was required to report a change of information).

c. <u>Section 424.540(a)(5)</u> – 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. <u>Section 424.540(a)(6)</u> - 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. <u>Section 424.540(a)(8)</u> - 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), the 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 "36month 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. <u>Notwithstanding any other instruction to the contrary in this chapter</u>, 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.

10.6.1.1.5 – HHA and Hospice Ownership Changes

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

A. Background – 36-Month Rule

1. General Principles

In accordance with 42 CFR § 424.550(b)(1), if there is a change in majority ownership of an HHA or hospice by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA or hospice must instead:

- Enroll in the Medicare program as a new (initial) HHA or hospice under the provisions of § 424.510, and
- Obtain a state survey or an accreditation from an approved accreditation organization.

For purposes of § 424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR § 424.502) occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA's or hospice's initial enrollment into the Medicare program or the 36 months following the HHA's or hospice's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA or hospice through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's or hospice's most recent change in majority ownership.

2. Exceptions

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

- The HHA or hospice has submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)
- The HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- The HHA or hospice is changing its existing business structure such as from a corporation, a partnership (general or limited), or a limited liability company (LLC) to a corporation, a partnership (general or limited) or an LLC and the owners remain the same.
- An individual owner of the HHA or hospice dies.

In addition, § 424.550(b)(1) does not apply to "indirect" ownership changes. For purposes of the 36-month rule's application, an indirect owner is a party that owns a direct or indirect owner of the provider. Consider the following illustrations:

EXAMPLE 1: Smith Hospice is established as a corporation. It is listed as the provider in Section 2 of the Form CMS-855A. The corporation has four shareholders (W, X, Y, and Z), each of which own 25% of Smith. Since Smith is the enrolling provider and W, X, Y, Z own Smith's stock, W, X, Y, and Z are considered direct owners of Smith. Thus, if W, X, and Y sell their 25% shares to Jones, Jones now directly owns 75% of Smith. A change in majority enrollment under § 424.550(b)(1) has occurred.

EXAMPLE 2: Smith Hospice is established as an LLC. It is listed as the provider in Section 2 of the Form CMS-855A. The corporation has two owners, Company X and Company Y. X owns 80% of Smith, and Y owns 20%. X and Y are accordingly direct owners of Smith. Company Z owns 100% of X, making Z an indirect owner of Smith. Now suppose that Company V purchases Z in its entirety. Since the transaction involves a sale of one of Smith indirect owners, § 424.550(b)(1) is not invoked.

<u>To the extent this previously occurred, hospices and HHAs should not assume that – using the</u> <u>above examples: (1) the corporation is the direct owner of Smith; (2) W, X, Y, and Z were</u> <u>therefore merely indirect owners of Smith; and (3) the sale of W/X/Y's shares to Jones is an</u> <u>indirect ownership change that does not trigger the 36-month rule</u>. To the contrary, the corporation – as Smith Hospice – <u>IS</u> the provider, hence making W/X/Y/Z direct owners of Smith.

3. Timing of 36-Month Period for Hospices

The provisions of 42 CFR § 424.550(b)(1) and (2) with respect to hospices (as enacted in "CMS-1780-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2024") became effective January 1, 2024. This means these provisions impact only those hospice ownership transactions whose effective date is on or after January 1, 2024. However, the provisions can apply irrespective of when the hospice first enrolled in Medicare. Consider the following illustrations:

- Example 1 Smith Hospice initially enrolled in Medicare effective February 1, 2022. Smith undergoes a change in majority ownership effective February 1, 2024. The provisions of § 424.550(b)(1) apply to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.
- Example 2 Jones Hospice initially enrolled in Medicare effective February 1, 2016. Jones undergoes its first change in majority ownership effective February 1, 2024. Section 424.550(b)(1) does not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, that Jones undergoes another change in majority ownership effective February 1, 2025. Section 424.550(b)(1) applies to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2024).
- Example 3 Davis HHA initially enrolled in Medicare effective February 1, 2012. It underwent its first change in majority ownership effective February 1, 2016. This change was not affected by § 424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis underwent another change in majority ownership effective February 1, 2023. This change, too, was unaffected by § 424.550(b)(1), for it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on February 1, 2016). Davis underwent another majority ownership change on February 1, 2025. This change is impacted by § 424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority 1, 2023).

B. Determining the 36-Month Rule's Applicability

If the contractor receives a Form CMS-855A application reporting an HHA or hospice ownership change (and unless a CMS instruction or directive states otherwise), it shall undertake the following steps:

<u>Step 1 – Change in Majority Ownership</u>

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and
- The change involves a party assuming a greater than 50 percent ownership interest in the HHA or hospice.

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of three ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA or hospice, this would constitute a change in majority ownership. This is consistent with the verbiage in the above-mentioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc. Another example of a change in majority ownership would be if a 50 percent owner obtains any additional amount of ownership (regardless of the percentage) and hence becomes a majority owner; thus, for instance, if a 50 percent owner were to acquire an additional .001 percent ownership stake, he or she becomes a majority owner and the transaction involves a change in majority ownership.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally (which will typically be as a change of information under 42 CFR § 424.516(e)). If it does qualify, the contractor shall proceed to Step 2:

Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's or hospice's (1) initial enrollment in Medicare or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA or hospice – regarding the effective date of the HHA's or hospice's most recent change in majority ownership.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.

If the transfer's effective date falls within one of these 36-month timeframes, the contractor shall proceed to Step 3.

Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall determine whether any of the exceptions in 424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

i. The HHA or hospice has submitted 2 consecutive years of full cost reports.

(A) For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. (See 42 CFR § 413.24(h) for a definition of low Medicare utilization.)

(B) The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer; and (2) accepted by the contractor.

ii. The HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

iii. The HHA or hospice is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

(A) If the HHA or hospice is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its PEOG Business Function Lead (BFL) for guidance.

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

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

Step 4 - Determination

If the contractor concludes that one of the aforementioned exceptions applies (and unless a CMS instruction or directive states otherwise), it may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) (via the instructions in section 10.6.1.2 of this chapter) or as a potential change of ownership under 42 CFR § 489.18 (via the instructions in section 10.6.1.1 of this chapter).

If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor apply the 36-month rule to the HHA or hospice and require an initial enrollment based thereon without the prior approval of PEOG. If PEOG agrees with the contractor's determination:

(1) PEOG will terminate the seller in ASPEN.

(2) The contractor shall identify the voluntary termination action in PECOS as a deactivation ---- and hence shall deactivate the HHA's or hospice's billing privileges pursuant to § 424.540(a)(8) --- with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per § 424.540(d)(1)(ii)(E), the effective date of the deactivation shall be the date of the sale.

(3) The contractor shall send to the HHA or hospice the "36-Month Rule Voluntary Termination Letter" in section 10.7.5.1. This letter will include, among other things, rebuttal rights regarding the deactivation as well as language stating that, as a result of § 424.550(b)(1), the HHA or hospice must:

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

(In preparing this letter, the contractor may, if applicable to the situation, change any reference therein to "HHA" or "home health agency" to "hospice.")

(4) The HHA or hospice need not submit a Form CMS-855A voluntary termination application.

Providers and/or their representatives (e.g., attorneys, consultants) shall contact their local MAC with any questions concerning (1) the 36-month rule in general and (2) whether the rule and/or its exceptions apply in a particular provider's case.

C. Additional Notes

The contractor is advised of the following:

1. If the contractor learns of an HHA or hospice ownership change by means other than the submission of a Form CMS-855A application, it shall notify its PEOG BFL immediately.

2. If the contractor determines, under Step 3 above, that one of the § 424.550(b)(2) exceptions is applicable, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It underwent a change in majority ownership

effective February 1, 2012. The contractor determined that the transaction was exempt from § 424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA underwent another change in majority ownership that did not qualify for an exception. The HHA thus had to enroll as a new HHA under § 424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from § 424.550(b)(1).

10.6.2 – Establishing Effective Dates

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

In reviewing this section 10.6.2, it is important that the contractor keep in mind the distinctions between: (1) the date of enrollment/approval; (2) the effective date of billing privileges under 42 CFR § 424.520(d); and (3) the date from which the supplier may retrospectively bill for services under § 424.521(a).

(Note that the date of receipt of a PECOS application is the date on which the contractor received it, not the date on which the application required the contractor's manual intervention per section 10.3.)

A. Date of <u>Enrollment/Approval</u>

This section 10.6.2(A) does not apply to the application of § 424.535(g)(3). See section 10.4.7.2(A)(3) for more information.

For suppliers other than ambulatory surgical centers and portable x-ray suppliers, <u>the date of enrollment is the date the contractor approved the application</u>. The enrollment date cannot be made retroactive. To illustrate, suppose a practitioner met all the requirements needed to enroll in Medicare (other than the submission of a Form CMS-855I) on January 1. He submits his Form CMS-855I to the contractor on May 1, and the contractor approves the application on June 1. The date of enrollment is June 1, not January 1.

B. Establishing Effective Dates <u>of Billing Privileges</u> for Certain Suppliers Under 42 CFR § 424.520(d)

1. Applicability

This section 10.6.2(B) applies to the following individuals and organizations:

- a. Physicians; physician assistants; nurse practitioners; audiologists; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; certified nurse- midwives; clinical social workers; clinical psychologists; independently billing psychologists, registered dietitians or nutrition professionals; physical therapists; occupational therapists; speech-language pathologists; mental health counselors; marriage and family therapists; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified above.
- b. Ambulance suppliers
- c. Part B hospital departments
- d. CLIA labs
- e. Opioid treatment programs.

- f. Mammography centers
- g. Mass immunizers/pharmacies
- h. Radiation therapy centers
- i. Home infusion therapy suppliers

(See 42 CFR §§ 424.520(d)(2) and 424.521(a)(2) for the regulatory listing of these providers/suppliers.)

2. Background

In accordance with 42 CFR § 424.520(d)(1), the effective date of billing privileges for the individuals and organizations identified in § 424.520(d)(2) (and section 10.6.2(B)(1) above) is the later of:

(i) The date the supplier filed an enrollment application that was subsequently approved, or

(ii) The date the supplier first began furnishing services at a new practice location.

NOTE: The date of filing for Form CMS-855 applications is the date on which the contractor received the application, regardless of whether the application was submitted via paper or Internet-based PECOS.

3. Retrospective Billing Under 42 CFR § 424.521(a)

Consistent with 42 CFR § 424.521(a)(1), the individuals and organizations identified in § 424.521(a)(2) (and section 10.6.2(B)(1) above) may retrospectively bill for services when:

(i) The supplier has met all program requirements, including state licensure requirements; and

(ii) The services were provided at the enrolled practice location for up to-

(A) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

(B) 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

The contractor shall interpret the above-mentioned phase "circumstances precluded enrollment" to mean that the supplier meets all program requirements (including state licensure) during the 30-day period before an application was submitted <u>and</u> no final adverse action (as that term is defined in § 424.502) precluded enrollment. If a final adverse action precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved--so long as it is not more than 30 days prior to the date on which the application was submitted.

If the contractor believes that the aforementioned Presidentially-declared disaster exception may apply in a particular case, it shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead for a determination on this issue.

4. Summarizing the Distinction Between Effective Date of Billing Privileges and Retrospective Billing Date

As already discussed, the <u>effective date of billing privileges</u> is "the later of the date of filing or the date (the supplier) first began furnishing services at a new practice location." The <u>retrospective billing date</u>, however, is "up to...30 days prior to (the supplier's) effective date (of enrollment)." To illustrate, suppose that a non-Medicare enrolled physician begins furnishing services at an office on March 1. She submits a Form CMS-855I initial enrollment application on May 1. The application is approved on June 1 (which, as discussed in section 10.6.2(A) above, is the date of enrollment). The physician's <u>effective date of billing</u> <u>privileges</u> is May 1, which is the later of: (1) the date of filing, and (2) the date she began furnishing services. <u>The retrospective billing date</u> is April 1 (or 30 days prior to the effective date of billing privileges), assuming the requirements of 42 CFR § 424.521(a) are met. The effective date entered in PECOS and the Multi-Carrier System will be April 1; claims submitted for services provided before April 1 will not be paid.

C. Effective Date of Reassignment

Consistent with 42 CFR § 424.522(a), the effective date of the reassignment is 30 days before the reassignment application is submitted if all applicable requirements during that period were otherwise met. However, and except as otherwise stated in this section 10.6.2(C), an additional retroactive reassignment period of:

- 30 days shall be applied per § 424.521(a)(1)(i); or
- 90 days shall be applied if a Presidentially declared disaster applies per § 424.521(a)(1)(ii)

(For purposes of this section 10.6.2(C), the dates described in the previous paragraph and bullets will be collectively referenced as the "§ 424.522(a) date.")

Under this, therefore, the retroactive billing period would be 60 days (or 30 days under § 424.522(a) + 30 days per § 424.521(a)(1)(i)) or 120 days (30 days under § 424.522(a) + 90 days if § 424.521(a)(1)(ii) applies). This applies to initial reassignments as part of an initial enrollment or involving an enrolled supplier that is adding a new reassignment.

As noted elsewhere in this chapter, individual physicians and practitioners who wish to reassign their benefits must now complete Section 4(F) of the Form CMS-855I rather than the discontinued Form CMS-855R. With this, the following scenario occasionally arises:

- (1) The physician or practitioner submits a Form CMS-855I to reassign his or her benefits;
- (2) Section 4(F) is either blank or incomplete;
- (3) The contractor develops for a completed Section 4(F); and
- (4) The physician or practitioner submits Section 4(F).

The reassignment effective date in this situation -- assuming the application and Section 4(F) are ultimately approved and all applicable requirements were met during this timeframe -- should be based on the date on which the Form CMS-8551 was initially submitted and not the date on which the physician or practitioner finally submitted Section 4(F). For instance, suppose a reassigning physician submits her Form CMS-8551 on March 1 with Section 4(F) incomplete. She later submits Section 4(F) on March 14. The reassignment effective date is predicated on the March 1 date and not March 14. This means that the extra 30-day or 90-day period goes back from March 1.

The policies in this section 10.6.2(C) apply to: (1) initial reassignments as part of an initial enrollment; and (2) enrolled suppliers that are adding a new reassignment.

D. Effective Date for Certified Providers and Certified Suppliers

Note that 42 CFR § 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Section 489.13 has been revised to state that: (1) the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met; and (2) such requirements include the contractor's review and verification of an application to enroll in Medicare.

E. Effective Date for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Per § 424.57(b), DMEPOS suppliers must meet, among other requirements, the following conditions to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS excluding locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

The contractor shall indicate the supplier's status as approved in PECOS upon the contractor making the determination the supplier meets all of the supplier standards found at § 424.57(c). The date the supplier was approved in PECOS shall be the supplier's effective date.

F. Form CMS-8550 Effective Dates

Notwithstanding any other instruction in the chapter to the contrary, the effective date of a Form CMS-855O enrollment per 42 CFR § 424.522 is the date on which the Medicare contractor received the Form CMS-855O application if all other requirements are met --- meaning the Form CMS-855O was processed to approval.

G. Effective Date for Medicare Diabetes Prevention Program (MDPP) Suppliers

In accordance with 42 CFR § 424.205(f), the effective date of billing privileges for MDPP suppliers is the later of:

- The date the supplier filed an enrollment application that was subsequently approved,
- The date the supplier filed a corrective action plan that was subsequently approved by a Medicare contractor, or
- The date the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number. (For PECOS applications, see section 10.3 of this chapter for information about what constitutes an enrollment record in PECOS.)

Under no circumstances should an effective date for billing privileges be prior to April 1, 2018. For any Form CMS-20134 submitted prior to April 1, 2018, and subsequently

approved, the contractor shall note April 1, 2018, as the MDPP supplier's effective date, even if this date is in the future.

NOTE: The date of filing for paper Form CMS-20134 applications is the date on which the contractor received the application. For Internet-based PECOS applications, the date of filing is the date that the contractor received an electronic version of the enrollment application and a signed certification statement submitted via paper or electronically.

H. Future Effective Dates

If the contractor cannot enter an effective date into PECOS because the provider/supplier, its practice location, etc., is not yet established, the contractor may use the authorized official's date of signature as the temporary effective date. Once the provider/supplier and the effective date are established (e.g., notification from the state is received), the contractor shall change the effective date in PECOS.

10.6.7.1 – Organizational Owning and Managing Information

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

Except as stated otherwise, this section 10.6.7.1 only applies to the Organizational Ownership and/or Managing Control Section of the Forms CMS-855A, CMS-855B, CMS-855S and CMS-20134; it is inapplicable to the Form CMS-855I.

A. Ownership Information Required in Forms CMS-855A, CMS-855B, CMS-855S and CMS-20134

All organizations that have any of the following (referenced in (A)(1) through (A)(4) must be listed in the Organizational Ownership and/or Managing Control section of the Form CMS-855 and CMS-20134 *(hereafter collectively the Form CMS-855)*.

1. 5 percent or greater direct or indirect ownership interest in the provider

(i) Direct Ownership

Examples of direct ownership are as follows:

- As listed in Section 2 of the Form CMS-855, the enrolling SNF is Smith, Inc. All the stock in Smith is owned by Company A.
- Jones Hospice, LLC (which owns four other enrolled hospices) wants to enroll a fifth hospice in Medicare. Company X owns 100% of Jones Hospice, LLC.

In the first example, Company A is considered *the* direct owner of the *SNF/Smith*, *Inc*. Likewise, Company X is *the* direct owner of *Jones Hospice*, *LLC*.

The two crucial factors in ascertaining direct ownership are:

- Which entity/LBN is listed in Section 2 of the Form CMS-855?
- Who are the first-level owners of the entity listed in Section 2?

Using our above examples, Smith, Inc. and Jones, LLC are listed in Section 2. For purposes of reporting ownership, they are considered the enrolling providers. As Companies A and X are the first-level owners of Smith and Jones, respectively, they are considered direct owners.

(ii) Indirect Ownership

Many organizations that directly own a provider are themselves wholly or partly owned by other organizations (or even individuals). This often results from the use of holding companies and parent/subsidiary relationships. Such organizations and individuals are considered "indirect" owners of the provider. *The term "indirect ownership interest" generally means any* ownership interest in an entity that has an ownership interest in the provider/supplier; this also includes an ownership interest in any entity that has an indirect ownership" subsection above, if Company B owned 100% of Company A, Company B is considered *an* indirect owner of *Smith, Inc.;* in sum, a direct owner has an actual ownership interest in the provider (e.g., owns stock in the business, etc.), whereas an indirect owner has an ownership interest in an organization that owns the provider.

(iii) Examples of Direct vs. Indirect Ownership

The following scenario further illustrates the difference between direct and indirect ownership:

EXAMPLE 1: The supplier listed in *Section 2(A)* of the Form CMS-855B is *XYZ Ambulance Company, Inc. XYZ* is wholly (100 percent) owned by Company A. Company A is considered a direct owner of *XYZ*, *which is considered the enrolling supplier*. Now assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of *XYZ*/the supplier.

In terms of the calculation and reporting of indirect ownership interests, consider this *modified* example from the Form CMS-855A (though note that individuals would need to be reported in the Individual Ownership and/or Managing Control section of the Form CMS-855A and Form CMS-20134, discussed further below):

LEVEL 3 (Third- Level)	Individual X	Individual Y
	5%	30%
LEVEL 2 (Second- Level)	Company C	Company B
	60%	40%
LEVEL 1 (First- Level)	Company A	
	100%	
Enrolling Provider	Listed in Section 2 – 2 (ZHS)	Z Hospital System, LLC

EXAMPLE 2

- Company A owns 100% of the Enrolling Provider/ZHS, LLC
- Company B owns 40% of Company A
- Company C owns 60% of Company A
- Individual X owns 5% of Company C
- Individual Y owns 30% of Company B

In Example 2, Company A (Level 1) is the direct owner of the provider identified in Section 2 of the application *(ZHS)*. Companies B and C, as well as Individuals X and Y, are indirect owners of the provider/*ZHS*. The calculation of ownership shares would be as follows:

LEVEL 1

Company A owns 100% of the Enrolling Provider. Company A must be reported.

LEVEL 2

To calculate the percentage of ownership held by Company C of the Enrolling Provider, multiply the percentage of ownership the LEVEL 1 owner has in the Enrolling Provider by the percentage of ownership the LEVEL 2 owner has in that LEVEL 1 owner.

- Company A, the LEVEL 1 (or direct) owner, owns 100% of the *Enrolling Provider*. Company C, a LEVEL 2 owner, owns 60% of Company A. Accordingly, multiply 100% (or 1.0) by 60% (.60). The result is .60. Company C indirectly owns 60% of the Enrolling Provider and must be reported.
- Repeat the same procedure for Company B, the other LEVEL 2 owner. Since Company B owns 40% of Company A, multiply this figure by 100% (again, the ownership stake Company A has in the Enrolling Provider). Company B thus owns 40% of the Enrolling Provider and must be reported.

This process is continued until all LEVEL 2 owners have been accounted for.

LEVEL 3

To calculate the percentage of ownership that Individual X has in the Enrolling Provider, multiply the percentage of ownership the LEVEL 2 owner has in the Enrolling Provider by the percentage of ownership the LEVEL 3 owner has in that LEVEL 2 owner. Per Example 2:

- Company C owns 60% of the *Enrolling Provider*, and Individual X (Level 3) owns 5% of Company C. Multiplying 60% (.60) by 5% (.05) results in .03. This means that Individual X owns 3% of the *Enrolling Provider* and need not be reported as an owner.
- Repeat this process for Company B, which owns 40% of the *Enrolling Provider*. Individual Y (Level 3) owns 30% of Company B. Multiplying 40% (.40) by 30% (.30) results in .12, or 12%. Since Individual Y owns 12% of the *Enrolling Provider*, Individual Y must be reported (in Section 6: Individuals).

This process is continued until all owners in LEVEL 3 have been accounted for. This process must be repeated for Levels 4 and beyond.

2. <u>5 percent or greater mortgage or security interest</u>

For purposes of enrollment, ownership also includes "financial control." Financial control exists when:

(a) An organization or individual is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the *Enrolling P*rovider or any of the property or assets of the *Enrolling P*rovider, and

(b) The interest is equal to or exceeds 5 percent of the total property and assets of the *Enrolling P*rovider.

All entities with at least a 5 percent mortgage, deed of trust, or other security interest in the *Enrolling P*rovider must be reported in the Organizational Ownership and/or Managing Control section. This frequently will include banks, other financial institutions, and investment firms. To calculate whether this interest meets the 5% threshold, divide the dollar

amount of the mortgage/deed of trust/other obligation secured by the *Enrolling P*rovider or any of the property or assets of the *Enrolling P*rovider <u>by</u> the dollar amount of the total property and assets of the *Enrolling P*rovider.

EXAMPLE: Two years ago, *an Enrolling P*rovider obtained a \$20 million loan from Entity X to add a third floor to its facility. Various assets of the provider secure the mortgage. The total value of the provider's property and assets is \$100 million.

Using the above formula, divide \$20 million (the dollar amount of the secured mortgage) by \$100 million (the total property and assets of the Enrolling Provider). This results in .20, or 20%. Because Entity X's interest represents at least 5% of the total property and assets of the Enrolling Provider, Entity X must be reported in this section.

3. Partnerships

(a) General partnerships - Any general partnership interest in the *Enrolling P*rovider, regardless of the percentage.

(b) For limited partnerships: All general partnership and limited partnership interests, regardless of the percentage.

Only partnership interests in the Enrolling Provider need be disclosed in the Organizational Ownership and/or Managing Control section. Partnership interests in the *Enrolling P*rovider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the Enrolling Provider, this indirect ownership interest would have to be disclosed in this section.

See section 10.6.4(C) of this chapter for more information on the differences between general and limited partnerships.

4. Managing control of the provider

A managing organization is one that exercises operational or managerial control over the provider or conducts the day-to-day operations of the *Enrolling P*rovider. The organization need not have an ownership interest in the *Enrolling P*rovider to qualify as a managing organization; for instance, the entity could be a management services organization under contract with the *Enrolling P*rovider to furnish management services for one of the provider's practice locations.

The organizations referred to above generally fall into one or more of the following categories:

- Corporations
- Partnerships and limited partnerships
- Limited liability companies
- Charitable and religious organizations
- Governmental/tribal organizations
- Banks and financial institutions
- Investment firms
- Holding companies
- Trusts and trustees
- Medical providers/suppliers
- Consulting firms
- Management services companies

- Medical staffing companies
- Non-profit entities
- Private equity companies
- Real estate investment trusts

In the Organizational Ownership and/or Managing Control section of the Form CMS-855 and CMS-20134, the provider must indicate the type(s) of organizational categories the reported entity falls into.

B. Special Requirements for Governmental and Tribal Entities

If a federal, state, county, city or other level of government, or an Indian tribe, will be legally and financially responsible for Medicare payments received (including any potential overpayments), the name of that government or Indian tribe should be reported as an owner. The provider must submit a letter on the letterhead of the responsible government (e.g., government agency) or tribal organization attesting that the government or tribal organization will be legally and financially responsible for any outstanding debt owed to CMS. This letter must be signed by an appointed or elected official of the government or tribal organization who has the authority to legally and financially bind the government or tribal organization to the laws, regulations, and program instructions of the Medicare program. This governmental or tribal official, however, need not be an authorized or delegated officials listed in the Certification Statement Section of the Form CMS-855 or Form CMS-20134. The only requirement is that the individual have the binding authority described above, and the contractor shall assume such authority exists unless there is evidence to indicate otherwise.

In addition, governmental and tribal entities:

- Must be identified in the Organizational Ownership and/or Managing Control section even if they are already listed in the Identifying Information section.
- Governmental and tribal entities need not submit a copy of an IRS 501(c)(3) form if it is otherwise obvious to the contractor that the entity is a governmental or tribal entity. The contractor can assume that the governmental or tribal entity is non-profit. (See section 10.6.7(D)(3) below and section 10.6.4(G) of this chapter for more information on non-profit entities.)

C. Submission of Diagram

In addition to completing the Organizational Ownership and/or Managing Control section, the provider must submit an organizational structure diagram/flowchart identifying (1) all the entities listed in this section; and (2) the relationships they have with the provider and each other. (This applies to the Form CMS-855A, CMS-855B, CMS-855S and CMS-20134.) If the provider is a skilled nursing facility or opioid treatment program, it must also include in the diagram/flowchart all entities and individuals that have less than a 5 percent direct or indirect ownership interest (and were thus not required to otherwise be listed in the Organizational or Individual Ownership and/or Managing Control sections).

The above-mentioned diagram/flowchart must be submitted for Form CMS-855 and CMS-20134: (1) initial enrollments; (2) revalidations; (3) reactivations; (4) certified provider and certified supplier changes of ownership based on the principles of 42 § CFR 489.18; and (5) upon any contractor request. Upon receiving the chart, the contractor shall review the data thereon to ensure it matches what the provider/supplier is reporting on the Form CMS-855/20134. If the data is inconsistent, the contractor shall develop for revised Form CMS-

855/20134 data and/or a revised chart, as applicable. If the data remains inconsistent after development, the contractor may reject the application.

D. Supporting Data/Contractor Request and Additional Information

1. IRS CP-575

Owning/managing organizations need not furnish an IRS CP-575 document unless requested by the contractor (e.g., the contractor discovers a potential discrepancy between the organization's reported legal business name and tax identification number).

2. Proof of Owning/Managing Control and Percentages

Proof of ownership interest, partnership interest, managerial control, security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

In addition, the percentage of managing control need not be reported.

3. Non-Profit, Charitable and Religious Organizations

As mentioned in section 10.6.4(G) of this chapter, many non-profit organizations are charitable or religious in nature and are generally typically operated and/or managed by a board of trustees or other governing body. The actual name of the board of trustees or other governing body must be reported in the Organizational Ownership and/or Managing Control. (Individual board members should be listed in the Individual Ownership and/or Managing Control section.)

Non-profit organizations typically do not have owners, and thus the latter would not need to be listed as such on the application. To confirm its non-profit status, the provider must submit an IRS 501(c)(3) document. If the non-profit entity does have owners, however, they would need to be disclosed in the Ownership and/or Managing Control section consistent with the instructions in section 10.6.7 et seq.

4. Duplicate Listing

Any entity listed as the provider in the Identifying Information section of the Form CMS-855A, CMS-855B and CMS-20134 need not be reported in the Organizational Ownership and/or Managing Control section. The only exception involves governmental entities, which must be identified in the Organizational Ownership and/or Managing Control section even if they are already listed in the Identifying Information section.

5. Disregarded Entities

In general, a "disregarded entity" is a term the IRS uses for an LLC that – for federal tax purposes only – is effectively indistinguishable from its single owner/member. The LLC's income and expenses are shown on the owner's personal tax return. The LLC itself does not pay taxes.

If an enrolling provider claims that it is a disregarded entity, the contractor need not obtain written confirmation of this from the provider notwithstanding the instruction in the Supporting Documents section of the Form CMS-855 or CMS-20134 that such confirmation is required. As a disregarded entity does not receive a CP-575 form from the IRS confirming its legal business name (LBN) and tax identification number (TIN), the contractor may accept

from the enrolling provider any government form (such as a W-9) that lists its LBN and TIN. The disregarded entity's LBN and TIN shall be listed in the Identifying Information/Business Information section of the Form CMS-855.

6. Ownership Disclosures

Consistent with the foregoing policies in this section 10.6.7.1, CMS re-emphasizes the following:

(i) The provider/supplier must disclose ALL persons and entities that meet the definition of "owner" in section 10.1.1 of this chapter

(ii) The applicable ownership percentage must be disclosed for each owner listed(iii) There cannot be indirect owners without direct owners (i.e., the provider/supplier cannot list only indirect owners and no direct owners)

(iv) The combined disclosed ownership percentages for the provider/supplier's organizational and individual direct owners cannot be greater than 100 percent

(Requirements (ii) and (iv) are inapplicable to applications that do not capture percentages of ownership.)

If the provider/supplier's ownership data does not meet the above-mentioned requirements, the contractor shall develop for the correct/complete data (e.g., the direct ownership total is greater than 100 percent) consistent with the instructions in this chapter.

7. PECOS Entry

The new and revised data elements on the 09/23 version of the Form CMS-855A will be included in PECOS 2.0. Most of them, however, will not be incorporated into the current version of PECOS. Accordingly, and until PECOS 2.0 is operational, the contractor need only enter the following new or revised 09/23 data elements into existing PECOS when processing a paper version of the 09/23 application:

- Private equity company (PEC) checkbox responses
- Real estate investment trust (REIT) checkbox responses
- Responses to the following question: "Is this organization itself owned by any other organization or by any individual?" (See subsection (D)(8) below for more information on this data element.)

The provider <u>must</u> respond to all three of these data requests on its application. The contractors shall develop for this information if the provider fails to do so. (PECs and REITs are defined in 42 CFR § 424.502.)

8. Indirect Owner Checkbox

For each entity listed in Section 5(A) of the Form CMS-855A, the provider must indicate whether the organization is itself owned by another organization or individual. A "Yes" or "No" checkbox response is required for each entity, regardless of whether the submitted organizational chart (or any other previously or presently submitted data) already indicates the response (e.g., the chart shows that Indirect Owner A is Owned by Indirect Owner B).

9. Type of Entity

For each entity listed in Section 5(A), the provider must indicate in Section 5(B) the type of organization involved. A "Yes" or "No" checkbox response is required for each listed entity type, regardless of whether the submitted organizational chart (or any other previously or presently submitted data) already indicates the response.

10.6.7.2 – Individual Owning and Managing Information

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

(See section 10.6.7.1 for more detailed information on ownership/managerial disclosures.)

A. Owning and Managing Individuals Who Must Be Listed in this Section

All individuals who have any of the following must be listed in this section:

- (i) **Ownership** A 5 percent or greater direct or indirect ownership interest in the provider.
- (ii) Mortgage/Security Interest A 5 percent or greater mortgage or security interest in the provider.

(iii) Partnership Interests

(a) General partnerships - Any general partnership interest in the provider, regardless of the percentage.

(b) For limited partnerships: All general partnership and limited partnership interests, regardless of the percentage.

(iv) Managing Control of the Provider - For purposes of enrollment, such a person is considered a "managing employee." A managing employee is any individual, including a general manager, business manager, office manager or administrator, who exercises operational or managerial control over the provider's business, or who conducts the day-to-day operations of the business. A managing employee also includes any individual who is not an actual W-2 employee but who, either under contract or through some other arrangement, manages the day-to-day operations of the business.

Hospice and SNF medical directors and administrators are considered managing employees under § 424.502. If a hospice or SNF fails to list its medical director and administrator on an initial, revalidation, reactivation, or CHOW Form CMS-855A application, the contractor shall develop for this information. This includes listing "medical director" or "administrator" in the "Title" box.

(v) Corporate Officers and Directors/Board Members

Officers and directors/board members must be listed in the Individual Ownership and/or Managing Control section if – and only if - the applicant is a corporation. (For-profit and non-profit corporations must list all their officers and directors. If a non-profit corporation has "trustees" instead of officers or directors, these trustees must be listed in this section of the Form CMS-855A, CMS-855B, CMS-855S and CMS-20134.)

Only the enrolling provider's officers and directors must be reported. Board members of the provider's indirect owners need not be disclosed to the extent they are not otherwise required to be reported (e.g., as an owner or managing employee) in this section. However, there may be situations where the officers and directors/board members of the enrolling provider's corporate owner/parent also serve as the enrolling provider's officers and directors/board members. In such cases – and again assuming that the provider is a corporation – the indirect owner's officers and directors/board members would have to be disclosed as the provider's officers and directors/board members in this section.

With respect to corporations, the term "director" refers to members of the board of directors. If a corporation has, for instance, a Director of Finance who nonetheless is not a member of

the board of directors, he/she would not need to be listed as a director/board member in this section. However, he/she may need to be listed as a managing employee in this section.

(See sections 10.6.7.1(A) of this chapter for more information on direct and indirect ownership, mortgage and security interests, and partnerships.)

Officers and directors can also include persons who serve in a voluntary or ceremonial capacity. CMS re-emphasizes, however, that officers and directors apply only to <u>corporations</u>.

B. Specific Reporting Policies

- 1. <u>Proof of Owning/Managing Control and Percentages</u> Proof of ownership interest, partnership interest, managerial control (including W-2s and other proof of employment), security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.
- 2. <u>Government Entities</u> Government entities need only report their managing employees, for they do not have owners, partners, corporate officers, or corporate directors.
- 3. <u>Minimum Number of Managing Employees</u> The provider must report all managing employees but must have at least one if it is completing the Form CMS-855A, CMS-855B, CMS-855S, or CMS-20134. An individual completing the Form CMS-855I need not list a managing employee if he/she does not have one.
- 4. <u>Practice Locations on the Form CMS-8551</u> All managing employees at all practice locations listed in the Business Information/Practice Location Information section of the Form CMS-8551 must be reported in the Managing Employee Information section. The only exceptions to this are individuals who are (a) employed by hospitals, health care facilities, or other organizations shown in the Business Information/Practice Location Information section (e.g., the chief executive officer of a hospital listed in this section) or (ii) managing employees of any group/organization to which the practitioner will be reassigning his/her benefits; these persons need not be reported.
- 5. <u>Partnership Interests Involving Indirect Owners</u> Only partnership interests in the enrolling provider need be disclosed. Partnership interests in the provider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the enrolling provider, this indirect ownership interest would have to be reported.
- 6. <u>Ownership Disclosures</u> Concerning ownership disclosures, the contractor shall adhere to the instructions in section 10.6.7.1(D)(6).

10.6.21.1 – Additional Miscellaneous Enrollment Topics

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

(The instructions in this section 10.6.21.1 take precedence over all other contrary instructions in this chapter, including, but not limited to, the existing guidance in sections 10.3.1 et al. The policies in this section will eventually be incorporated into the sections of this chapter that are applicable to the subject matter.)

A. Type of Practice Location

For Form CMS-855A, CMS-855B, and CMS-855I applications, the contractor may collect the practice location type in Section 4 of the application via telephone or---if the practice location type is otherwise apparent---may forgo development altogether.

B. Voluntary Terminations for Non-Certified Suppliers

If a non-certified supplier wishes to voluntarily withdraw from Medicare (including deactivating all active PTANs), the supplier must submit the applicable Form CMS-855/20134 to do so. It cannot make this request via letter, phone, etc.

C. Initial Enrollments with Multiple Locations

(This section 10.6.21.1(C) takes precedence over all other instructions in this chapter excluding section 10.3.)

If a high or moderate-risk provider or supplier (hereafter "provider") is initially enrolling in Medicare and has multiple practice locations, the SVC will conduct a site visit of each location rather than simply one selected location. In such instances, the contractor shall note the following:

- 1. Certified Providers/Suppliers If, per this chapter, the site visits are to be performed after the contractor receives a recommendation of approval from the state, the contractor shall wait until all site visits are completed before taking the next required step (e.g., referring the application to PEOG to final review).
- 2. Site Visit Failure If one of the locations fails its site visit, the contractor shall follow existing guidance for handling such situations (e.g., approving the application but without the failed location).

D. Verification of Telephone Numbers

Except when the provider or supplier has a regulatory supplier standard regarding maintenance of a telephone number (e.g., § 410.33(g)(5) for IDTFs), the contractor need not verify the provider's or supplier's phone number listed on the application. *though the provider or supplier must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.*

If a regularly supplier standard concerning telephone numbers is implicated, the contractor shall not call the supplier's phone number as a means of verification. However, all other applicable means of validating the phone number remain intact.

E. Sales Agreement

For any reported <u>direct</u> ownership change in Section 5 or 6 of the Form CMS-855A – and except as otherwise directed by CMS -- the provider must submit a copy of the legal document(s) that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1(B) of chapter 10 for more information on such documents.) This requirement, however, does not apply to: (1) indirect ownership changes; and (2) ownership changes that are not otherwise required to be reported (e.g., less than 5 percent owner of a corporation).

10.7 – Model Letters (*Rev. 12717; Issued: 07-18- 24; Effective: 08-19-24; Implementation: 08-19-24*)

The contractor shall use the following letters when rejecting, returning, approving or denying an application, or when revoking an entity's Medicare billing privileges. Any exceptions to this guidance shall be approved by the contractor's CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL), unless specified otherwise. The contractor shall document approval received by its PEOG BFL for QASP purposes.

As stated in section 10.3, PECOS will automatically generate and send some of the letters described in this section 10.7 et seq. If any modifications or additions to a certain PECOS-generated letter are required pursuant to the instructions in this section 10.7 et seq. or elsewhere in this chapter, the contractor shall, of course, ensure that such edits are made before the letter is sent. This includes situations where a particular party is typically copied on a letter but the circumstances of the transaction do not require the party to be copied.

In the event of a conflict between the instructions in section 10.3 and section 10.7, et al, the instructions in section 10.3 take precedence.

A. Issuing Letters - Model Letter Guidance

All letters sent by contractors to providers and suppliers shall contain and/or adhere to the formats/requirements addressed in sections 10.7(A) and (B). Note, however, the following:

(i) For certified provider/supplier types and transactions that have formally "transitioned" as described in section 10.7.5.1, the requirements (e.g., data elements) of the model letters in section 10.7.5.1 take precedence over any contrary instruction in section 10.7. For example, if section 10.7 requires a data element that a specific letter in section 10.7.5.1 pertaining to the same enrollment transaction/situation does not, the section 10.7.5.1 letter requirements supersede the former. Likewise, if section 10.7 requires the removal/addition of language that is/is not in the applicable section 10.7.5.1 letter, the latter controls.

(ii) For certified provider/supplier types and transactions that have not transitioned (and except as otherwise stated in section 10.7 (e.g., subsection (A)(2)(n)), the contractor shall continue to follow the existing instructions in section 10.7 and utilize the letters in section 10.7.5.

1. General Guidance

(a) The CMS logo (2012 version) displayed per previous CMS instructions.

(b) The contractor's logo shall be displayed however the contractor deems appropriate. There are no restrictions on font, size, or location. The only restriction is that the contractor's logo must not conflict with the CMS logo.

(c) All dates in letters, except otherwise specified, shall be in the following format: month/dd/YYYY (e.g., January 26, 2012).

(d) Letters shall contain fill-in sections as well as static, or "boilerplate" sections. The fill-in sections are delineated by words in brackets in italic font in the model letters.

(e) The static sections shall be left as-is unless there is specific guidance for removing a section (e.g., removing a CAP section for certain denial and revocation reasons; removing state survey language for certain provider/supplier types that do not require a survey). If there is no guidance for removing a static section, the contractor must obtain approval from its PEOG BFL to modify or remove such a section.

2. Approval Letters

(a) Part A/B certified provider and supplier paper/web COI and revalidation "referral to state" shall detail the requested changes (e.g., practice location changed to 123 Main Street, Baltimore MD 21244).

(b) For COI and revalidation applications that do not require a tie-in or recommendation but require notification to the SOG Location as a cc, the contractor shall add the additional fields applicable to the letter (e.g., cc the state/SOG Location). The contractor should itemize the changes if it is beneficial to the SOG Location.

(c) Part A/B and DME provider and supplier paper/web COI and revalidation letters shall only list the section title (at the sub-section level) from the paper/web Form CMS-855 and Form CMS-20134 application (e.g., Correspondence Mailing Address, Final Adverse Legal Actions, Remittance Notices/Special Payments Mailing Address, etc.).

(d) If, as part of a revalidation, the provider/supplier only partially revalidates (i.e., a provider has multiple PTANs, and one PTAN is revalidated with the others end-dated), the contractor shall notate the reassignments that were terminated due to non-response and the effective date of termination (i.e., the revalidation due date or the development due date).

(e) If the provider is submitting a change as part of a voluntary termination application (e.g. special payment address, EFT, authorized official), the contractor shall enter the applicable fields into the Medicare Enrollment information table.

(f) Approval letters may include a generic provider enrollment signature and contact information (e.g. customer service line). However, all development letters shall include a provider enrollment analyst's name and phone number for provider/supplier contacts.

(g) Participation status shall only be included in initial and reactivation letters for Part B sole proprietors, Part B sole owners, any Part B organizations and DME suppliers. Change of information approval letters shall only include the participation status if it was changed as part of the application submission.

(h) The contractor shall add lines to the enrollment information tables on any reactivation letter if the provider/supplier has reactivated following non-response to a revalidation and enrollment information was changed on the application.

(i) The contractor shall enter an effective date on all change of information approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality).

(j) The contractor shall add appeal rights to all change of information and revalidation approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality; a new reassignment is created).

(k) If the provider/supplier is revalidating multiple reassignments to different groups, the contractor shall add additional lines to the grid to identify the separate groups and PTANs.

(1) If the provider/supplier revalidates both reassignments and one or more sole proprietorship locations, the contractor shall indicate on the appropriate letter that the approval covers the reassignments and sole proprietorship locations.

(m) In the Part B non-certified supplier letters, the contractor shall populate 42 CFR§ 424.205 for MDPP suppliers or § 424.516 for all other providers/suppliers with the following

paragraph: "Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR § 424.516 or 42 CFR§ 424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617."

(n) For all pre-transition and post-transition seller CHOWs (both HHA and non-HHA), the contractor shall use the "M. Approval – Seller CHOW (Part A/B Certified Org") letter in section 10.7.5.1 when voluntarily terminating the seller's enrollment in a 42 CFR § 489.18 CHOW (which includes mergers, acquisitions, and consolidations). The contractor shall use the effective date of the CHOW as the "Effective Date of Enrollment Termination" in the letter.

(o) The contractor shall remove the following language when issuing the Approval – Voluntary Termination (Part B Non-Certified Org or Part B Sole Owner) letter in section 10.7.6(V) for a Part B non-certified supplier: "Reassignments and any physician assistant employment arrangements are also deactivated", unless other active reassignments/employment arrangements exist on the enrollment.

3. Denial/Revocation Letters

(a) The contractor shall populate the fill-in sections with the appropriate information, such as primary regulatory citation, specific denial and revocation reasons, names/addresses, etc.

(b) The fill-in sections shall be indented $\frac{1}{2}$ inch from the normal text of the letter.

(c) All specific or explanatory reasons shall appear in bold type and shall match the federal registry heading. This applies to headings. For example, if the revocation letter contains the following specific explanatory language, the heading should be in bold type and the explanation should be in normal type as shown in the excerpt below:

42 CFR § 424.535(a)(8)(i) – Abuse of Billing Privileges

Data analysis conducted on claims billed by [Dr. Ambassador], for dates of service [Month XX, XXXX], to [Month XX, XXXX], revealed that [Dr. Ambassador] billed for services provided to [XX] Medicare beneficiaries who were deceased on the purported date of service.

(d) There may be more than one primary reason listed.

(e) This subsection (A)(3)(e) applies to certified provider and certified supplier denial or revocation letters that meet both of the following requirements:

- The provider enrollment denial or revocation also requires the denial or termination of the corresponding provider or supplier agreement (e.g., Form CMS-1561, Form CMS-370, etc.)
- The SOG Location is responsible for handling the reconsideration/appeal of the provider/supplier agreement denial or termination.

If these requirements are met -- and notwithstanding any instruction to the contrary in this chapter -- the contractor shall insert the following language into the provider enrollment denial or revocation letter (preferably at the conclusion of the letter's discussion/outline of appeal rights):

"Note that the provider enrollment appeal rights addressed in this letter are unrelated to any appeal rights concerning the [denial or termination, as applicable] of your [provider or supplier, as applicable] agreement. The two processes are separate and distinct, and a

successful appeal of your enrollment [denial or revocation, as applicable] does not automatically restore your [provider or supplier] agreement. Any such restoration of the latter is handled by the Survey Operations Group Location and not by CMS' Provider Enrollment & Oversight Group."

4. Voluntary Terminations

If a provider/supplier (certified or non-certified) is voluntarily terminating their enrollment, the contractor shall use the applicable voluntary termination letter.

5. No PEOG Approval

The following letter revisions do not require prior PEOG BFL approval. (Notwithstanding the language in subsection 10.7(A)(i), this includes the letters in section 10.7.5.1 et seq.)

(a) If the contractor cannot format the enrollment information table as provided in these model letters, the contractor may provide the information in a similar non-table format.

(b) Placing a reference n umber or numbers between the provider/supplier address and the salutation. (For Internet-based PECOS applications, the contractor can include its document control number and the Web Tracking ID in this field.)

(c) The contractor shall enter "N/A" or leave blank a data element in an enrollment information table if said field is inapplicable (e.g., doing business as (DBA), effective date for changes).

(d) The contractor shall include the applicable PTAN and NPI for the application submission on the letter. If multiple PTANs or NPIs apply, the contractor should: (1) enter "multiple" in the PTAN and NPI fields; (2) copy and add additional PTAN/NPI rows to the enrollment information tables; or (3) attach a list of any and all PTAN and NPI combinations that apply in the letter.

(e) For individual revalidations in which multiple PTANs may be revalidating from multiple reassignments or individual associations, the contractor may also list the group's LBN and PTAN effective date in connection with the appropriate individual NPI-PTAN combinations. The contractor has flexibility in relaying these fields when multiplicities exist, ensuring they meet the template's reporting requirements.

(f) Appropriate documents attached to specific letters as needed.

(g) Placing language in any letter regarding self-service functions, such as the Provider Contact Center Interactive Voice Response (IVR) system and Electronic Data Interchange (EDI) enrollment process.

6. Rural Emergency Hospitals (REHs)

The contractor shall replace all appeal rights language in any REH initial enrollment denial letter with the following: "In accordance with Title 42, United States Code (U.S.C.) § 1395x(kkk)(9), no administrative or judicial review under Section 1395ff or 1395oo or otherwise is granted based upon a determination of whether a hospital meets the requirements of a rural emergency hospital." This language will notify the facility that it cannot appeal its enrollment denial.

B. Sending Letters

The contractor shall note the following:

1. Except as stated otherwise in this chapter (e.g., certain applications from alreadytransitioned certified provider/supplier types), the contractor shall issue approval letters within 5 business days of approving the application in PECOS.

2. For all applications other than the Form CMS-855S, the contractor shall send development/approval letters, etc., to the contact person if one is listed. Otherwise, the contractor may send the letter to the provider/supplier at the e-mail, mailing address, or fax provided in the correspondence address or special payments address sections.

3. The contractor may insert an attention field with the contact's name as part of the mailing address, but the letter should still be addressed to the provider/supplier. As applicable, the contractor shall continue to send letters to the DMEPOS supplier's correspondence address until their automated process can be updated to include the contact person as a recipient of the letters.

4. For initial, change of information, revalidation, and voluntary termination applications submitted by sole owners, the contractor should issue one approval letter. However, the Medicare enrollment information table shall distinctly list the individual and sole owner information.

5. If, as part of revalidation, a physician assistant is adding and terminating an employment relationship, one letter shall be issued (approving the revalidation). However, the termination and additional employment relationship shall be noted in the approval letter.

6. The contractor shall issue all denial and revocation letters via certified mail.

7. Notwithstanding any other instruction to the contrary in this chapter, the contractor shall copy via email the applicable accrediting organization (AO) (along with, as currently required, the state agency) on a recommendation for approval letter or final provider/supplier notification letter (e.g., final approval, denial, etc.) letter if: (1) the provider/supplier lists the AO on the Form CMS-855 or ADR application; (2) PEOG notifies the contractor of the AO's involvement; or (3) the contractor otherwise becomes aware of the provider/supplier's AO affiliation.

8. Notwithstanding any other instruction to the contrary in this chapter, DMEPOS suppliers shall send all applicable rebuttals, CAPs, and reconsideration requests to Chags Health Information Technology LLC (C-HIT). The contact information is:

Chags Health Information Technology LLC P.O. Box 45266 Jacksonville, FL 32232 Phone: (800) 245-9206 E-mail: <u>PEARC@c-hit.com</u> Fax: (866) 410-7404

The NPEs shall ensure that all previous section 10.7 et seq. references to the National Supplier Clearinghouse as the destination for rebuttals, CAPs, and reconsideration requests be replaced with C-HIT consistent with prior CMS guidance.

10.7.5.1 – Part A/B Certified Provider and Supplier Letter Templates – Post-Transition

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

The model letters in this section 10.7.5.1 pertain to certain enrollment transactions involving certified providers and certified suppliers. Except as otherwise stated, the contractor shall begin utilizing these letters (instead of those in section 10.7.5) upon completion of the transition of the applicable CMS Survey & Operations Group (SOG) function to the contractor and the CMS Provider Enrollment & Oversight Group (PEOG). In other words, once a provider specialty, provider agreement, or provider enrollment transaction type (for example, voluntary terminations) has been transitioned, the contractor shall commence using the section 10.7.5.1 letter(s) pertaining to said transaction. CMS will notify contractors once a particular transition has occurred.

For certified provider/supplier transactions (and transaction outcomes) not specifically addressed in this section 10.7.5.1, the contractor shall continue to use the existing model letters in section 10.7 et seq. (even after the above-mentioned transition).

In addition:

(i) Most of the documents in this section 10.7.5.1 identify parties that must receive a copy of the letter in question. If an inconsistency exists between said copied parties and those listed elsewhere in this chapter concerning a particular letter, the parties identified in this section 10.7.5.1 take precedence. To illustrate, suppose another section of this chapter requires X, Y, and Z to be copied on a certain letter while section 10.7.5.1 only requires X to be copied. The contractor in this situation need only copy X.

(ii) The contractor need only copy an accrediting organization (AO) on a particular letter if the provider/supplier has an AO for the identified provider/supplier specialty. The contractor can typically ascertain this by checking PECOS (for currently enrolled providers/suppliers) or reviewing the application (for initial enrollments) to see if an AO is disclosed. Also, PEOG will often identify an AO (if one exists) in cases where it must review the transaction before notifying the contractor of its final approval (e.g., CHOWs, certain changes of information, voluntary termination).

(iii) See section 10.7.5.1(P) below for the applicable e-mail addresses of the SOG Locations. The contractor shall insert the relevant e-mail address into any letter in section 10.7.5.1 that addresses the provider/supplier's right to a reconsideration of a provider agreement determination.

(iv) Any data element boxes that the contractor cannot complete because the information is unavailable or inapplicable (e.g., CMS Certification Number (CCN) in certain instances) can be: (1) left blank; (2) denoted with "N/A," "Not applicable," or any similar term; or (3) removed altogether.

(v) The Provider Transaction Access Number (PTAN) box should contain the CCN for all provider/supplier types other than ASCs and PXRSs; the PTAN for the latter two supplier types will be that which the contractor assigns or has assigned.

(vi) The Primary Practice Location Address box shall include the suite number if one was/is listed on the application.

(vii) For the Denial letter in section 15.7.5.1(H), the contractor shall indicate (in any manner it chooses) whether the denial pertains to the buyer's or the seller's application if a prospective CHOW was involved.

(viii) In cases where provider/supplier data has changed and the contractor must list "detailed information or application section titles (as applicable)", the contractor has the discretion to list either (i.e., the info or the section titles).

(ix) Note that some provider/supplier types, such as PXRSs, do not have provider/supplier agreements. In such cases, and as shown in the section 10.7.5.1 model letters, the contractor shall remove references to provider/supplier agreements from these letters. For example, if no provider/supplier agreement is involved, the contractor shall:

- Change the data box heading "Provider/Supplier Agreement-Specific Information" to "Other Information".
- *Remove the section regarding provider/supplier agreement appeal rights.*

(Quotation marks, of course, should be removed.)

A. Approval – Change of Information (Part A/B Certified Org; No Referral to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has approved your Change of Information (COI) application.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Changed Information	Include detailed changes or application	
	section titles, as applicable.	

["Provider/Supplier Agreement-Specific" OR "Other", as applicable]		
Information		
CMS Certification Number (CCN)		
CCN Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services

Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [& Accrediting Organization (AO), if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

B. Approval - State Agency Approved Change of Information (Part A/B Certified; Referral to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the Medicare State Agency. Your change of information application is now approved.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Changed Information	Include detailed changes or application	
	section titles, as applicable	

["Provider/Supplier Agreement Specific" OR "Other", as applicable]		
Information		
CMS Certification Number (CCN)		
CCN Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

C. Approval - State Agency Approved Change of Ownership (Part A/B Certified Excluding FQHCs)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip] Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the State Agency. Your change of ownership application is now approved. *[If the provider/supplier type has a provider/supplier agreement, insert* "The corresponding executed [insert provider/supplier agreement type] *is enclosed/attached*"]. Your enrollment and [insert provider/supplier agreement-specific *OR* "other", as applicable] information is outlined below:

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	

Provider Transaction Access Number	
(PTAN)	

["Provider/Supplier Agreement Specific" OR "Other", as applicable]		
Information		
CMS Certification Number (CCN)		
CCN Effective Date (use effective date		
of seller's CCN)		
CHOW Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

If you are also requesting a reconsideration of the provider/supplier agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to: [Insert: Name and e-mail address of CMS Location Office]/

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

D. Approval - State Agency Approved Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]

[Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency. Your initial enrollment application *[if applicable to the provider/supplier type, insert "and [provider/supplier agreement"]]* [is */are]* approved. *[If applicable, insert "Your executed [if applicable, insert provider/supplier agreement name]* is enclosed/attached."] The effective date is the date you met all federal requirements.

Medicare Enrollment and /insert "Provider/Supplier Specific Participation Agreement" *OR "Other"* Information/

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Enrollment Effective Date	

["Provider/Supplier Agreement Specific" OR "Other", as applicable] Information	
CMS Certification Number (CCN)	
CCN Effective Date	
Medicare Year-End Cost Report Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and

include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to: <u>ProviderEnrollmentAppeals@cms.hhs.gov</u>

[Insert the following language if provider/supplier type has a provider/supplier agreement:

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

E. Forwarded to State - Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your initial enrollment application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As (DBA)	
National Provider Identifier (NPI)	
Provider/Supplier Type	
Medicare Year-End Cost Report Date (Part A only)	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

F. Forwarded to State – Change of Information, Change of Ownership, Revalidation, or Reactivation Containing Changed New/Changed Data that the State Must Review (if applicable) (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

This letter updates you on the status of your [list type of transaction] enrollment application. Your application is required to go through a multi-step review process.

[Contractor Name] is a CMS Medicare Administrative Contractor (MAC) charged with enrolling providers and suppliers in the Medicare program. We have assessed your enrollment application and forwarded it to the [Enter State Agency] for the next step in the process. The State Agency will conduct a review for further compliance with the applicable Federal, State, and local requirements. Once the State Agency's review is complete, CMS will conduct a final review and issue a decision.

We will contact you when your application has completed all stages of review and a decision has been made.

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	

["Provider/Supplier Agreement-Specific" OR "Other" Information [as applicable]]		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or	Existing	Seller
Revalidation; remove if inapplicable)	New	Buyer
	Effective Date	

For questions concerning the application's review at this stage, contact [Insert State] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

G. Approval Revalidation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your revalidation application [include if the application was sent to the state: "and forwarded it to the State Agency. The State Agency review has also been completed"]. Your Medicare enrollment information is provided below.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or application
	section titles, as applicable.

["Provider/Supplier Agreement-Specific" OR "Other" Information [as applicable]]		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or	Existing	Seller
Revalidation; remove if inapplicable)	New	Buyer
	Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services

Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

H. Denial Letter – Post-1539 (Or Other Similar Notice) Received from State Agency for the following application types—Initials, COIs, CHOWs, Revalidations, and Reactivations

(This letter only applies in cases where:

A recommendation to the state was required per the instructions in this chapter (e.g., the application contained information/changes requiring state review), and
 The state sends notification to the contractor (e.g., via the 1539 or other notice) that the application should be denied and/or, if applicable, the provider/supplier agreement should be terminated.

As explained in this chapter, certain changes of information and revalidation applications can result in an enrollment revocation and provider agreement termination, though most do not. Accordingly, the contractor shall insert the applicable review result language (e.g., see bracketed options below) in the first paragraph of the letter.)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[The [insert name of State Agency] completed its evaluation of your [initial application] or [change of information] or [change of ownership] or [revalidation] or [reactivation]. [Insert the following language based on the situation involved and the specific result of the state's review:

[INITIAL ENROLLMENT: Your participation in the Medicare Program and your enrollment in the Medicare Program is [denied] for the following reasons]:

[NO REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION INVOLVED: Your application for [insert] is denied for the following reasons]:

[REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION RESULTING FROM THE APPLICATION SUBMISSION. As a result of the state's review, your provider/supplier agreement for participation in the Medicare program is terminated and your enrollment in the Medicare program is revoked for the following reason(s]:

[INSERT DENIAL OR TERMINATION REASON GIVEN BY THE STATE AGENCY]

Information about your *[if applicable, "provider/supplier agreement" and your]* Medicare enrollment *[are/is]* are outlined in the text box below.

Medicare Administrative Contractor Name &	
Contractor Number	
Medicare Enrollment	Determination
Status	DENIED [OR REVOKED]
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Provider/Supplier Agreement Determinati elements below only if the provider/s	-
provider/supplier of	agreement]
Provider/Supplier Agreement	DENIED [OR TERMINATED]
CMS Certification Number (CCN)	

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

RECONSIDERATIONS REQUEST—MAILING ADDRESSES:

Requests for Reconsideration: Medicare Provider Enrollment: The reconsideration request regarding your Medicare enrollment may be submitted electronically via e-mail to: <u>ProviderEnrollmentAppeals@cms.hhs.gov</u> or addressed as follows:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

[Insert the following language if provider/supplier type has a provider/supplier agreement:

And

<u>Requests for Reconsideration: Medicare Provider/Supplier Agreement</u>: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

[If a failed survey was involved, the contractor shall include the following language here: "Note that any survey deficiencies may only be addressed as part of the provider/supplier agreement reconsideration process."]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

I. Approval – Voluntary Termination (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are voluntarily terminating your provider/supplier agreement **or** [Insert Contractor name [and Contractor number]] has completed processing your application [or letter] to voluntarily disenroll from the Medicare program. Therefore, *[if applicable to the provider/supplier type, insert "your provider/supplier agreement has been voluntarily terminated and"*] your enrollment in the Medicare program has been voluntarily terminated effective on the date[s] shown below.

Medicare Enrollment *[if applicable to the provider/supplier type, add "and Provider/Supplier Agreement"]* Information

Medicare Enrollment Termination and Deactivation of Billing Privileges	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Termination and Deactivation	

Provider/Supplier Agreement Termination <i>[include this title and</i>	
the three data elements below only if the provider/supplier type is one that has a	
provider/supplier agreement]	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following: [Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

J. Approval – Reactivation (Part A/B Certified Org)

(This letter should be used for reactivation approvals regardless of whether the application was referred to the state agency for review.)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your reactivation enrollment application.

Medicare Enrollment Information

["Provider/Supplier Agreement Specific" OR "Other" Information [as	
applicable]]	
CMS Certification Number (CCN)	
CCN Effective Date	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

<u>ProviderEnrollmentAppeals@cms.hhs.gov</u> [Insert the following language if provider/supplier type has a provider/supplier agreement:

And

Requests for Reconsideration: Medicare Provider/Supplier Agreement: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

(Note: No CC: to State Agency/AO required. Deactivations do not impact certified provider CCN participation status.)

K. Voluntary Termination: Failure to Respond to Request for Information

Month, Day, Year

PROVIDER/SUPPLIER NAME ADDRESS CITY, STATE, ZIP

Reference # Application ID

Dear Provider Name (LBN),

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are no longer operational. We have not received a response to the request sent on Month DD, YYYY to update your enrollment information. Therefore, we have disenrolled you from the Medicare program. *[Include if provider/supplier type has a provider/supplier agreement:* "Your [provider/supplier agreement] has also been terminated."]

Medicare Enrollment [add if applicable "and Provider/Supplier Agreement"] Information

Medicare Enrollment Termination and Deactivation of Billing Privileges Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type/Specialty	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Deactivation	

["Provider/Supplier Agreement" OR "Other", as applicable] Termination Information		
CMS Certification Number (CCN)		
Effective Date of CCN Termination		

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number] If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

L. Voluntary Termination Cessation of Business

[Month, Day, Year]

PROVIDER/SUPPLIER NAME ADDRESS CITY, STATE, ZIP

Reference Number:

Dear Provider/Supplier Name:

[Insert Contractor name [and Contractor number]] was notified by State Agency Name that on MONTH DD, YYYY, the State Agency attempted to verify if your Type of Provider is operational. The State Agency has reported that your facility was closed, not operational, and/or ceased business at your address of record.

Pursuant to 42 CFR § 489.52(b)(3), CMS considers a cessation of business and providing services to the community to constitute a voluntary withdrawal from the Medicare program.

If you believe that our determination is incorrect and your Type of Provider facility remains operational, you must notify the State Agency and copy this office within 10 days from your receipt of this notice that your facility is still operational and participating in the Medicare program. You must provide the State Agency and this office with information to clarify why your facility was not functional at the address of record at the time the State Agency performed the site survey.

STATE AGENCY NAME ADDRESS CITY, STATE, ZIP

We request that you complete and submit a CMS-855 or an application via the Internet-Based Provider Enrollment Chain and Ownership System (PECOS) for a change of information to indicate that your facility/practice location remains open and operational or to request a voluntary termination of your enrollment.

If we do not hear from you, your Medicare enrollment *[add if applicable* "and corresponding provider/*supplier* agreement"] will be terminated pursuant to 42 CFR § 489.52(b)(3). With this termination, your billing privileges will also be deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

If you have any questions, please contact our office at:

Sincerely,

[Name] [Title] [Company]

M. Approval – Seller CHOW (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the [use "State Agency" or "CMS Survey & Operations Group Location", as appropriate] that the change of ownership involving [insert seller name] is now approved. Therefore, you have been disenrolled from the Medicare program effective on the date shown below.

Medicare Enrollment *[add if applicable "and Provider/Supplier Agreement"]* Termination Information

Medicare Enrollment Termination	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Termination	

["Provider/Supplier Agreement" OR "Other"] Information	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

N. Federally Qualified Health Centers (FQHCs) – Initial Enrollment Approval Letter

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use this letter (which was formerly in section 10.7.19 of this chapter) for all FQHC initial enrollment approvals. For all other FQHC transactions (e.g., revalidations), the contractor may use the applicable letters in either 10.7.5 or 10.7.5.1.

[Month, Day, Year]

[FQHC Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [FQHC],

[Insert Contractor] has approved your enrollment as a federally qualified health center (FQHC).

Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)/CMS Certification Number	
(CCN)	
PTAN/CCN Effective Date	
Medicare Year-End Cost Report Date	

Medicare Enrollment Information

Provider/Supplier Agreement Information	
CMS Certification Number (CCN)	
Effective Date of CCN	

Included with this letter is a copy of your "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes to, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

O. Approval – FQHC Change of Ownership

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip] Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your change of ownership application is now approved. The corresponding executed "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed, is enclosed/attached. Your enrollment and Exhibit 177 information is outlined below:

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		

Provider Agreement Specific Information		
CMS Certification Number (CCN)		
CCN Effective Date (use effective date		
of seller's CCN)		
CHOW Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at <u>https://pecos.cms.hhs.gov</u>.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

<u>Right to Submit a Reconsideration Request:</u>

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must--

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement; and
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

You may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted; and
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

P. 36-Month Rule Voluntary Termination Letter

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City] ST [Zip]

Reference # (Application Tracking Number)

Dear [HHA or Hospice Seller],

[Insert Contractor name] has [Insert appropriate situation (e.g., reviewed [insert HHA's *or hospice's* current name] change of ownership application; learned that [insert HHA's *or hospice's* current name] may have undergone a change in majority ownership pursuant to 42 C.F.R. § 424.550(b)(1); etc.]. After our review, [Insert Contractor name] has determined that [insert HHA's or hospice's current name] has undergone a change in majority ownership under 42 C.F.R. § 424.550(b)(1) and that none of the exceptions described in 42 C.F.R. § 424.550(b)(2) apply to this situation. Pursuant to 42 C.F.R. § 424.550(b)(1), therefore, [insert HHA's or hospice's current name] provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of [insert HHA's or hospice's current name] must instead:

- Enroll in the Medicare program as a new (initial) [*insert* home health agency *or hospice, as applicable*] under the provisions of 42 C.F.R § 424.510; and
- Obtain a state survey or an accreditation from an approved accreditation organization.

Consistent with the foregoing, [insert HHA's or hospice's current name] provider agreement [will be/has been] voluntarily terminated and its Medicare billing privileges [will be/have been] deactivated pursuant to 42 C.F.R § 424.540(a)(8) effective [Insert date(s)].

Medicare Enrollment Deactivation		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		

Medicare Enrollment and Provider Agreement Information

Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Deactivation	

Provider Agreement Termination	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:

[Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]

CC: State Agency [and AO, if applicable]

Q. Applicable SOG Location E-mail Boxes

CMS Locations Corporate Email Addresses		
CMS LOCATION	BRANCH	EMAIL Address
CMS Boston	ACC & LTC	BostonRO-DSC@cms.hhs.gov
Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont		
CMS Philadelphia	ACC & LTC	ROPHIDSC@cms.hhs.gov
Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia		
CMS New York	ACC & LTC	RONYdsc@cms.hhs.gov
New Jersey, New York, Puerto Rico, Virgin Islands		
CMS Atlanta	ACC & LTC	ROATLHSQ@cms.hhs.gov
Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee		
CMS Chicago	ACC & LTC	ROCHISC@cms.hhs.gov
Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin		
CMS Kansas City	ACC & LTC	ROkcmSCB@cms.hhs.gov
Iowa, Kansas, Missouri, Nebraska		
CMS Denver	ACC & LTC	<u>CMSKC DEN SOG@cms.hhs.gov</u>
Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming	Ace a Lie	<u>CMSRC_DDIV_SOO(wems.mis.gov</u>
CMS Dallas	ACC & LTC	RODALDSC@cms.hhs.gov
Arkansas, Louisiana, New Mexico, Oklahoma, Texas		
CMS San Francisco	ACC & LTC	ROSFOSO@cms.hhs.gov
Arizona, California, Hawaii, Nevada, Pacific Territories		

CMS Seattle	ACCB	CMS RO10 CEB@cms.hhs.gov
Alaska, Idaho, Oregon, Washington	LTC	Seattle LTC@cms.hhs.gov