CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11808	**Date: January 24, 2023**
	Change Request 12865

Transmittal 11739 issued December 09, 2022, is being rescinded and replaced by Transmittal 11808, dated January 24, 2023, to add business requirements (BRs) 12865.6 and 12865.7 to now include provider education with this instruction. This correction also revises BRs requirements 12865.2, 12865.3, 12865.4 and 12865.5 changing the NSC to NPEAST and NPWEST. All other information remains the same.

SUBJECT: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to incorporate into Chapter 10 of Pub. 100-08 certain provider enrollment policies included in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Final Rule.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

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	10/10.1/10.1.1/Definitions
R	10/10.2/10.2.1.14/Skilled Nursing Facilities (SNFs)
R	10/10.4/10.4.2.2/Denial Reasons
R	10/10.4/10.4.7.3/Revocation Reasons
R	10/10.6/10.6.15/Risk-Based Screening
R	10/10.6/10.6.21/Miscellaneous Enrollment Topics

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If

the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 11808	Date: January 24, 2023	Change Request: 12865

Transmittal 11739 issued December 09, 2022, is being rescinded and replaced by Transmittal 11808, dated January 24, 2023, to add business requirements (BRs) 12865.6 and 12865.7 to now include provider education with this instruction. This correction also revises BRs requirements 12865.2, 12865.3, 12865.4 and 12865.5 changing the NSC to NPEAST and NPWEST. All other information remains the same.

SUBJECT: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

I. GENERAL INFORMATION

A. Background: The CY 2023 PFS Final Rule contains provisions concerning Medicare provider enrollment. These principally involve the following: (1) Moving skilled nursing facilities (SNFs), various provider enrollment ownership changes, and certain other providers and suppliers into the "high" level of categorical screening; and (2) expanding several of our provider enrollment denial and revocation reasons. This CR instructs contractors on the implementation of these provisions. The new instructions in this CR apply to provider enrollment applications received on or after January 1, 2023.

B. Policy: This CR does not contain any legislative, statutory, or regulatory policies

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12865.1	The contractor shall follow the instructions in Chapter 10 of Pub. 100-08 regarding the processing of SNF enrollment applications at the "high" level of categorical screening.	X								
12865.2	The contractor	X	X	X						NPEAST

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	shall follow the instructions in Chapter 10 of Pub. 100-08 regarding the processing of certain provider/supplier ownership changes at the "high" level of categorical screening.									, NPWEST
12865.3	The contractor shall follow the instructions in Chapter 10 of Pub. 100-08 regarding the elevation of certain providers and suppliers to the "high" screening category pursuant to 42 Code of Federal Regulations Section 424.518(c)(4).	X	X	X						NPEAST, NPWEST
12865.4	The contractor shall observe the provider enrollment regulatory changes made in the CY 2023 PFS Final Rule and as described in Section 10.6.21 in Chapter 10 of Pub. 100-08.	X	X	X						NPEAST, NPWEST
12865.5	The contractor shall implement	X	X	X						NPEAST,

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	the new policies in this CR for enrollment applications received on or after January 1, 2023.									NPWEST
12865.6	The contractor shall perform the provider education described in this CR.	X	X	X						NPEAST, NPWEST

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12865.7	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X	X		

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Frank Whelan, 410-786-1302 or frank.whelan@cms.hhs.gov

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. 11808; Issued: 01-24-23)

10.1.1 – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Final adverse legal action means the following:

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

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

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

(3) Revocation or suspension by an accreditation organization;

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

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

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

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

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

Exclusions, Revocations, or Suspensions

1. Any current or past revocation, suspension, or voluntary surrender of a medical license in lieu of further disciplinary action.

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

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

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

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

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier.

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

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

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

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

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

Other eligible professional – as defined in 1848(k)(3)(B) of the Social Security Act – means: (i) a physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) a qualified

audiologist (as defined in section 1861(ll)(3)(B)). (For (ii), "practitioner" is defined in section 1842(b)(18)(C) as a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.2.1.14 - Skilled Nursing Facilities (SNFs)

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

A. General Background Information

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

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

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

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

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

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

1. Receipt of Application

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

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

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

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

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

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

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

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

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

2. Conclusion of Initial Contractor Review

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

a. Approval Recommendation

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

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

b. Denial

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

3. Completion of State Review

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

a. Approval Not Recommended

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

b. Approval Recommended

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

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

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

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

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

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

C. SNF Distinct Parts

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

- A hospital may have only one SNF distinct part.

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

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

D. Site Visits

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

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

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

E. Additional Information

For more information on SNFs, refer to:

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

10.4.2.2 - Denial Reasons

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

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 subpart P (of Part 424) 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.

ix. The provider or supplier does not meet standards specific to their supplier type (e.g., MDPP supplier standards outlined in 42 CFR § 424.205(d)).

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

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

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

"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—

(i) 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

(ii) 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."

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

(i) 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.

(ii) 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.

(iii) 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.

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

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

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

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

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

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

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

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

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

F. Denial Reason 6– Existing Overpayment at Time of Application (42 CFR § 424.530(a)(6))

1. Background

Consistent with 42 CFR § 424.530(a)(6), an enrollment application may be denied if the provider, supplier, or owner thereof has an existing Medicare overpayment that is equal to or

exceeds a threshold of $1,500 and has not been repaid in full at the time the application was filed. More specifically:

"(A) The enrolling provider, supplier, or owner (as defined in § 424.502) thereof has an existing Medicare debt.

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

(1) 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.

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

(3) 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:

(a) The amount of the Medicare debt.

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

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

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

(e) 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) 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

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

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

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

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

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

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

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))

"The provider, supplier or any owning and managing employee or organization of the provider or supplier is currently under a Medicare or Medicaid payment suspension at the time the denial is issued, as defined in § 405.370 through §405.372."

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

An HHA submitting an initial application for enrollment:

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

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

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

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

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

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

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

K. Denial Reason 11– DEA Certificate/State Prescribing Authority Suspension or Revocation (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.)

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 an termination or suspension from another program.

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.

10.4.7.3 – Revocation Reasons

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

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

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

"The provider or supplier is determined not to be in compliance with the enrollment requirements in subpart P (of Part 424) 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."

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.

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

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

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

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

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

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

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

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

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

"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:

(i) 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.

(ii) 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."

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."

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:

- Where the beneficiary is deceased.

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

- 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:

- The percentage of submitted claims that were denied during the period under consideration.

- 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.

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

- 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." 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."*

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."

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

"The provider or supplier has an existing 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) The reason(s) for the failure to fully repay the debt (to the extent this can be determined);

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

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

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

(v) The amount of the debt; and

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

(NOTE: With respect to (a)(17), PEOG – rather than the contractor – will make all determinations regarding whether a provider/supplier has an existing debt that has been referred to the Department of Treasury.)

P. 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.)

Q. 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.)

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

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

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

S. 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).

T. 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.)

U. 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.

10.6.15 – Risk-Based Screening

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

Consistent with 42 CFR § 424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, revalidates its enrollment information, *or, in certain circumstances, changes all or part of its ownership.*

A. Specific Screening Categories

1. Limited Risk

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- Home infusion therapy suppliers
- Hospitals (including critical access hospitals, *rural emergency hospitals,* Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Organ procurement organizations
- Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics

For providers and suppliers in the "limited" category, the contractor shall process initial, revalidation, and new location applications in accordance with existing instructions.

2. Moderate Risk

a. General Information

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations

- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Newly Enrolling Opioid Treatment Program (OTP) that were SAMSHA certified prior to October 24, 2018
- Revalidating home health agencies (HHAs)
- Revalidating DMEPOS suppliers
- Revalidating MDPP suppliers
- Revalidating OTP providers
- *Revalidating SNFs*

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 10.6.15(A)(4) of this chapter or another CMS directive applies): *(1)* process initial, revalidation, and new location applications in accordance with existing instructions; and (2) order an *NSVC* site visit through *PECOS consistent with subsection 2(b)* below. *(U*nless stated otherwise in this chapter, the scope of the site visit *shall* be consistent with existing instructions.)

b. Provider/Supplier-Specific Information

(i) Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups

If the supplier submits an initial application, revalidation application, or application to add a new practice location, the contractor shall order a site visit. *(For new location additions,* the site visit shall be of the new location.) The contractor shall not make a final decision regarding the application *(or, for initial applications,* shall not convey Medicare billing privileges*)* prior to the completion of the NSVC's site visit and the contractor's review of the results.

(ii) CMHCs, CORFs, Hospices and PXRSs

For site visits regarding these four provider/supplier types, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.1, 10.2.1.2, 10.2.1.7, and 10.2.2.8 of this chapter.

(iii) IDTFs

Initial applications - The NSVC will conduct site visits of initially enrolling IDTFs consistent with section 10.2.2(O)(15) of this chapter.

Revalidations - The NVSC will conduct site visits of revalidating IDTFs (prior to the contractor's final decision regarding the revalidation application) consistent with section 10.2.2(I)(15) of this chapter.

IDTF Code Changes - The NSVC will conduct site visits for IDTF code changes as specified in section 10.2.2(I)(17) of this chapter.

(iv) Revalidating HHAs and SNFs

For site visits regarding revalidating HHAs and SNFs, the contractor shall adhere to the site visit instructions in, respectively, sections 10.2.1.6 and 10.2.1.14 of this chapter.

(v) Revalidating DMEPOS Suppliers

A site visit of the DMEPOS supplier shall be conducted prior to the NSC making a final decision regarding the revalidation application.

(vi) Revalidating MDPP Suppliers

If an MDPP supplier submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

(vii) Revalidating OTP Providers

If an OTP provider submits a revalidation application, the contractor shall order a site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

3. High Risk

a. General Information

Pursuant to 42 CFR § 424.518, the "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs (including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))
- Newly enrolling MDPP suppliers
- Newly enrolling OTP providers that were SAMSHA certified after October 24, 2018
- *Newly enrolling SNFs*
- *DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, and SNFs submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42.*

For newly enrolling providers and suppliers in the "high" level of categorical screening:

(i) The contractor shall process the application in accordance with existing instructions.

(ii) The NSVC will perform a site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the site visit and the contractor's review of the results.

(iii) *Their 5 percent or greater direct and indirect owners must undergo* fingerprint-based criminal background checks. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of fingerprinting and the contractor's review of the results.

(iv) The contractor shall, upon switching the provider's or supplier's enrollment record to "Approved," enter the provider's risk category as "moderate" into PECOS.

b. Additional Considerations

(i) Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes.

(ii) The addition of a new HHA branch falls within the "moderate" level of categorical screening. *A site visit of the branch shall thus be performed consistent with the instructions in this chapter (including those in section 10.2.1.6).*

(iii) The addition of a new MDPP supplier administrative location that does not result in a new PTAN does not require an additional site visit. Any additional MDPP supplier administrative location that results in a new PTAN, either due to being in a new jurisdiction or because of a new CDC organizational code, the contractors shall order a site visit of the location through PECOS. This is to ensure that the *supplier* is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 15.19.2.2(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. Changes of/in Ownership

As explained above and in more detail in section 10.6.21(E)(3), the "high" screening category includes DMEPOS suppliers, HHAs, MDPP suppliers, OTP providers that were SAMSHA certified after October 24, 2018, and SNFs submitting either: (i) a change of ownership application pursuant to 42 CFR § 489.18; or (ii) an application to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42. Accordingly, any change of/in ownership that meets all of the following criteria would fall under (i) or (ii) above:

- *Does not involve the triggering of an initial enrollment (e.g., an HHA change in majority ownership for which no exception applies requires a new enrollment); and*
- *The change reports either:*
  - *For partnerships: A new partner (general or limited) who owns any percentage (even 1 percent) of the provider/supplier; or*
  - *Excluding partnerships: A new direct or indirect owner of at least 5 percent of the provider/supplier.*

Upon receipt of an application described above, the contractor shall process it consistent with the instructions in this chapter and this section 10.6.15. This includes requesting fingerprints from the new owner(s) if the owner has a 5 percent or greater direct or indirect ownership interest. However, the contractor need not also solicit them from the provider/supplier's existing owners; only the new owner(s) need be fingerprinted.

(Note that if a new partner is being reported but the partner owns less than 5 percent of the provider/supplier, the provider/supplier's application must still be processed at the high screening level. However, the new partner need not be fingerprinted. This is because fingerprinting only applies to 5 percent or greater direct or indirect owners. It is therefore possible that, in such a change of ownership transaction, no fingerprinting will have to be conducted at all.)

The contractor shall also order a site visit of the provider/supplier consistent with existing instructions. In terms of the timing of the HHA or SNF site visit, however, the contractor shall adhere to the following:

- *No State/SOG Location Approval Required – If the ownership change does not require state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1 of this chapter for more information on this topic), the*

site visit shall be ordered and performed prior to the contractor's final decision regarding the application.

- *State/SOG Location Approval Required - If the ownership change requires state or SOG Location approval under existing CMS instructions, the site visit shall be ordered and performed no later than 5 business days after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.*

(See section 10.6.21(E)(3) of this chapter for more information.)

4. Elevating Existing Providers and Suppliers into the High-Risk Screening Category

a. Criteria for Raising Providers/Suppliers to High-Risk

Under § 424.518(c)(3), CMS may adjust *(or "bump up")* a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

(ii) The provider or supplier:

- Has been excluded from Medicare by the Office of Inspector General;
- Had its billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by: *(A)* enrolling as a new provider or supplier; or *(B)* obtaining billing privileges for a new practice location;
- Has been terminated or is otherwise precluded from billing Medicaid;
- Has been excluded from any federal health care program; *or*
- Has been subject to any final adverse action (as defined in § 424.502) within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

b. Extension of Application of a Provider/Supplier's "Bump-Up"

Effective January 1, 2023 (and pursuant to § 424.518(c)(4)), any screening level adjustment under § 424.518(c)(3) also applies to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification number (TIN) as the provider or supplier for which the screening level under § 424.518(c)(3) was originally raised. To illustrate, suppose an entity is enrolled as an ambulance supplier, a CORF, and a home infusion therapy (HIT) supplier. All three providers/suppliers are under the entity's TIN and LBN. The HIT supplier is under a payment suspension and is thus bumped-up to "high." Pursuant to § 424.518(c)(4), the ambulance supplier and CORF will also be moved to "high" because they have the same LBN and TIN as the HIT supplier.

c. List of Bumped-Up Providers/Suppliers

CMS makes available to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that have been "bumped-up" pursuant to *§ 424.518(c)(3) and (c)(4)*. Upon receipt of an initial or revalidation application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor

shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions. If the provider or supplier is on the list, the contractor shall process the application using the procedures in the "high" screening category unless the provider is on the list solely because he/she/it was revoked for failing to timely respond to a revalidation request. If such is the case, the contractor shall contact its CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance as to how the situation should be handled.

d. Post-Moratorium Applications

If the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

B. Changes of Information *(Including Additions and Changes of Practice Locations)*

(This subsection (B) does not apply to ownership changes that qualify as a mere change of information (e.g., reporting a new 10 percent owner).) These transactions are addressed in subsection (C) below.)

1. Limited

Changes of information (including additions of practice locations) submitted by providers/suppliers in the "limited" level of categorical screening shall be processed *consistent* with existing instructions.

2. Moderate

Changes of information submitted by providers/suppliers in the *"moderate"* level of categorical screening shall be processed *consistent* with existing instructions, *although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15.* The site visit shall be performed consistent with the applicable instructions in this chapter *(e.g., section 10.2.1.2 for CORFs).* The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

3. High

*Except as stated below, c*hanges of information submitted by providers/suppliers in the "*high"* level of categorical screening shall be processed *consistent* with existing instructions, *although practice location additions and changes in a practice location's physical location also require a site visit as described in this section 10.6.15.* The site visit shall be performed consistent with the applicable instructions in this chapter. The contractor shall not make its final decision regarding the application prior to the completion of the site visit and the contractor's review of the results.

For purposes of this requirement:

- A change of location includes situations in which the provider/supplier is switching suite numbers or floors within a building. A site visit is required.

- If the provider/supplier's physical location is not changing (e.g., the provider's street name is changing but its actual office space is not), no site visit is required.

- A DMEPOS supplier that is adding a new practice location falls within the "high" screening category. *This is because each location must be separately enrolled. The enrollment of a new location thus constitutes an initial enrollment.*

- *A DMEPOS supplier undergoing* a change in TIN with no change in ownership falls within the "moderate screening category.

C. Change of Ownership

1. Limited

Changes of ownership (regardless of whether a new TIN is triggered) shall be processed consistent with existing instructions.

2. Moderate

If a provider or supplier is undergoing a change of ownership resulting in a new TIN, the contractor shall:

a. Process the application *consistent* with existing instructions, and

b. Order a site visit through PECOS in accordance with the following:

- For ownership changes that must be approved by the *state or SOG Location* under current CMS instructions *(see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1) of this chapter)*, the site visit shall be ordered and performed after the contractor receives notice of approval from the *state or SOG Location* but before the contractor switches the provider/supplier's enrollment record to an "Approved" status. The contractor shall not switch the provider/supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

- For ownership changes that do not require *state or SOG Location* approval under current CMS instructions, the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.

3. High

See subsection (A)(3)(c) for information on processing changes of/in ownership applications from DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, and SNFs.

D. Reactivations

a. Limited

Form CMS-855 reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

b. Moderate

Form CMS-855 reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening – including existing *DMEPOS suppliers, HHAs, MDPP suppliers, OTPs that have not been continuously SAMSHA-certified since October 24, 2018, and SNFs* – shall be processed in accordance with the screening procedures for this

category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

c. High

Form CMS-855 reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be needed prior to the contractor's final decision regarding the application.

10.6.21 – Miscellaneous Enrollment Topics

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

This section 10.6.21 addresses additional provider enrollment policies. Except as otherwise stated, the instructions in this section supersede any other instructions to the contrary in this chapter. *It is anticipated that the provisions in this section 10.6.21 will eventually be moved to those sections of this chapter most applicable to their respective subject matter. For organizational reasons, section 10.6.21 is merely a placeholder section of chapter 10.*

A. Group and Reassignment Reactivation

If a group practice submits a reactivation application after being deactivated for non-response to a revalidation request, the contractor shall reactivate the group's reassignments when the group's reactivation application has been approved; Form CMS-855I and/or CMS-855R applications for the reassignments are not required. The effective dates assigned to the reassigned providers shall align with the group's effective date per existing reactivation instructions.

This section 10.6.21(A) only applies to deactivations based on a non-response to a revalidation request.

B. Specialty Changes

When a Form CMS-855 enrollment application is submitted to report a change to a physician's or non-physician practitioner's primary or secondary specialty, the contractor shall not contact the physician, non-physician practitioner, or contact person directly to confirm either the change itself or the individual's intent to change his/her specialty.

C. Reassignments Related to Revoked or Deactivated Reassignee

The contractor shall end-date in PECOS all reassignment associations and the associated Provider Transaction Access Numbers (PTANs) when revoking or deactivating an individual or organization (reassignee) that is receiving reassigned benefits from an individual practitioner. The end-date shall be the same as the effective date of the revocation or deactivation; this will ensure the appropriate end-date in the Multi-Carrier System (MCS) and prevent improper use of those PTANs. However, the contractor shall not deactivate the individual practitioner's (reassignor's) enrollment record even if (1) the reassigned PTAN is the only PTAN on the individual's enrollment record and/or (2) no other active locations exist (private practice locations or reassignments); the contractor shall allow the practitioner's/reassignor's enrollment record to remain in an approved status.

When sending a deactivation, revocation, or voluntary withdrawal letter to the deactivated or revoked non-certified Part B supplier, said letter shall include the following language: "Please notify all physician assistants and/or group members who reassign benefits to your organization that, in accordance with 42 CFR §424.540(a)(2), their Medicare enrollment

status may be deactivated if they fail to update their enrollment record within 90 calendar days

D. Interstate License Compacts

A new trend in medicine has arisen involving interstate license compacts. While physician compacts streamline the licensure process for physicians who want to practice in multiple states, a separate license from each state in which the physician intends to practice is still issued (if all requirements are met). CMS will continue to rely on the license issued by the state medical board to help confirm compliance with federal requirements.

In a similar vein, certain non-physician practitioner (NPP) compacts allow the NPP to work in a compact member state (other than their home state) without going through the normal process for licensure in the remote state. NPPs working under the authorization of such a compact must meet both the licensure requirements outlined in the primary state of residence and those established by the compact laws adopted by the legislatures of the interstate compact states.

At present, there are interstate compacts involving physicians, physical therapists, occupational therapists, speech language pathologists, and psychologists (though none for nurse practitioners). More are possible.

Licenses obtained through an interstate license compact for the above supplier types shall be treated as valid, full licenses for the purposes of meeting federal requirements. The contractor shall thus accept Form CMS-855 applications from applicants reporting a license obtained via an interstate license compact. In addition, the contractor shall attempt to verify the interstate license obtained through the compact using the state licensing board website(s) or compact website (if one exists); if neither technique can confirm the interstate license, the contractor shall request documentation from the supplier that validates said data.

E. Provisions in CMS-1770-F

The CMS Calendar Year 2023 Physician Fee Schedule Final Rule (CMS-1770-F) included a number of revisions to our provider enrollment regulations. This subsection 10.6.21(E) addresses these matters. Effective January 1, 2023, the contractor shall apply and execute the policies in this subsection 10.6.21(E) notwithstanding any other instruction to the contrary in this chapter.

1. Managing Organizations, Officers, and Directors

a. Definitions

CMS-1770-F finalized definitions of managing organization, officer, and director in 42 CFR § 424.502. These definitions are consistent with those commonly understood in the provider enrollment arena and are as follows:

- *Managing organization - An entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.*
- *Officer - An officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.*
- *Director - A director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member; said body could be a board of directors, board of trustees, or similar body.*

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

Managing organizations, officers, and directors have long been reported in Section 5 or 6 (as applicable) of the Form CMS-855 and on the Form CMS-20134. The contractor shall continue to follow existing instructions in this chapter for: (1) ensuring that these parties and all required data pertaining thereto are disclosed, such as EINs/SSNs and any adverse legal history; and (2) performing all required verifications (e.g., reviewing against the OIG excluded parties list).

b. Expansion of § 424.530(a)(2)/(3) and § 424.535(a)(2)/(3)

Managing organizations, officers, and directors have been added to the scope of the denial/revocation reasons at §§ 424.530(a)(2), 424.530(a)(3), 424.535(a)(2), and 424.535(a)(3). This means that a felony conviction within the past 10 years, an OIG exclusion, or a SAM debarment against an officer, director, or managing organization can serve as the basis for the provider/supplier's denial/revocation. The contractor shall continue to follow existing instructions in this chapter for handling potential denial and revocation situations with the understanding that officers, directors, and managing organizations now fall within the aforementioned denial and revocation reasons. Thus, for example, if an officer of the provider has a current OIG exclusion, the contractor shall handle the matter in the same fashion it would if a supervising physician were excluded.

Note that CMS-1770-F also formally incorporated into § 424.530(a)(2)/(3) and § 424.535(a)(2)/(3) the policy that the individuals and entities listed within these regulatory provisions include W-2 employees and contracted individuals and organizations of the provider/supplier.

c. Expansion of § 424.530(c) and § 424.535(e)

As mentioned in sections 10.4.2.3(B) and 10.6.18(C)(7) of this chapter, §§ 424.530(c) and 424.535(e) state that if a denial or revocation, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider/supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, the denial or revocation may be reversed if the provider/supplier terminates (and submits proof that it has terminated) its business relationship with that party within 30 days of the denial/revocation notification. CMS-1770-F added officers, directors, and managing organizations to §§ 424.530(c) and 424.535(e).

2. Clarification of § 424.535(a)(12)

As stated in § 424.535(a)(12) and in section 10.4.7.3(L) of this chapter, CMS may revoke a provider or supplier that is terminated, revoked, or otherwise barred from participation in a state Medicaid program or any other federal health care program. Under § 424.535(a)(12)(ii), CMS cannot revoke unless and until the provider or supplier "has exhausted all applicable appeal rights." However, CMS-1770 added the following to the end of this quoted language in § 424.535(a)(12)(ii): "or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal." This merely incorporated into regulation CMS' existing policy that § 424.535(a)(12) can be applied if the provider or supplier fails to file an appeal within the prescribed timeframe.

3. Expansion of Providers and Suppliers Undergoing High-Risk Screening

CMS-1770-F also expanded the number and types of providers and suppliers that are subject to high-risk level screening under § 424.518. This generally involves, but is not limited to: (1) moving skilled nursing facilities (SNFs) from the "limited" screening category to the "high" screening category; and (2) including certain changes in ownership as among the types of enrollment transactions subject to the "high" screening category under § 424.518. These regulatory changes and the associated contractor instructions for effectuating them are described in (a) through (c) below.

a. Changes in Ownership

i. General Policy

As stated in § 424.518 and as described in section 10.6.15 of this chapter, the following three application types are subject to § 424.518's screening requirements: (1) initial applications; (2) revalidations; and (3) applications to add a new practice location. CMS-1770-F added the following two transaction types to the purview of § 424.518:

(i) Change of ownership applications pursuant to 42 CFR § 489.18
(ii) Applications to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42.

The foregoing means that an application under (i) or (ii) must be processed at the high screening level if it is submitted by:

- *An enrolled OTP that has not been fully and continuously certified by SAMHSA since October 24, 2018*
- *A DMEPOS supplier*
- *An MDPP supplier*
- *An HHA*
- *A SNF (described further below)*

(For purposes of this subsection (E)(3)(a), these five provider/supplier types will be collectively referred to as the "affected providers.")

Categories (i) and (ii) above would include, for instance:

- *A SNF CMS-855A CHOW, acquisition, merger, and consolidation application (as those terms are described on the CMS-855A and in section 10.6.1.1 of this chapter).*

- *An HHA CHOW under 42 CFR § 489.18. (See section 10.2.1.6.1 of this chapter for information on these types of CHOWs.) Note that a change in majority ownership under 42 CFR § 424.550(b) that requires a new enrollment would not fall under (i) or (ii) above because it would generate an initial enrollment, though, for this latter reason, it would still be processed at the high screening level (as all HHA initials are).)*

- *A DMEPOS supplier reporting a 15 percent new owner.*

In sum, any change of/in ownership that meets all the following criteria would fall under (i) and (ii) above:

- *Does not involve the triggering of an initial enrollment (e.g., an HHA change in majority ownership and no exception applies, thus warranting a new enrollment); and*
- *The change reports either:*

- *For partnerships: A new partner (general or limited) that owns any percentage (even 1 percent) of the affected provider; or*
- *Excluding partnerships: A new direct or indirect owner of at least 5 percent of the affected provider.*

Changes of ownership involving providers/suppliers other than the five aforementioned affected provider categories (e.g., ambulance suppliers, CORFs) shall continue to be processed consistent with existing instructions.

ii. Processing Instructions

Upon receipt of an application described in subsection (E)(3)(a)(i) above, the contractor shall process it consistent with the instructions in this chapter and, in particular, with section 10.6.15. This includes requesting fingerprints from any new direct or indirect owner of 5 percent or more of the provider, though the contractor need not also solicit them from the provider/supplier's existing owners; only the new owner(s) need be fingerprinted.

The contractor shall also order a site visit of the affected provider consistent with existing instructions. In terms of the timing of the HHA or SNF site visit, however, the contractor shall also adhere to the following:

- *No State/SOG Location Approval Required – If the ownership change does not require state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1 of this chapter for more information), the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.*
- *State/SOG Location Approval Required - If the ownership change requires state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1), the site visit shall be ordered and performed no later than 5 business days after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.*

All clock stoppages permitted under this chapter (e.g., fingerprinting per section 10.5(C)(1)) apply to the situations described in this subsection (E)(3)(a). In addition, since a site visit and fingerprinting are required, the contractor shall adhere to the timeliness standards in section 10.5(A)(1)(a) for paper applications and those in section 10.5(A)(3)(a) for web-based applications.

b. SNFs

As already mentioned, SNFs are now in the "high" screening category under § 424.518(c). Accordingly, SNF initial applications require a site visit as well as the fingerprinting of the SNF's 5 percent or greater owners. In executing this policy, the contractor shall follow existing instructions in this chapter regarding the collection and processing of fingerprints, including those in subsection (E)(3)(a) above for SNF ownership changes. As for site visits, the contractor shall follow the instructions in section 10.2.1.14 for initial and revalidation applications and subsection (E)(3)(a) above for change in ownership applications.

c. "Bump-Ups"

Effective January 1, 2023 (and pursuant to CMS-1770-F), any screening level adjustment under § 424.518(c)(3) also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the

provider or supplier for which the screening level under § 424.518(c)(3) of this section was originally raised. See section 10.6.15(A)(4) of this chapter for more information.