CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11154	**Date: December 10, 2021**
	Change Request 12502

Transmittal 11142, dated December 2, 2021, is being rescinded and replaced by Transmittal 11154, dated December 10, 2021, to include section 10.6.13, which was accidently removed by another CR. 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 new and revised provider enrollment policies included in the Calendar Year (CY) 2022 Home Health Prospective Payment System (HH PPS) and Physician Fee Schedule (PFS) Final Rules.

EFFECTIVE DATE: January 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2022

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	10/10.2/10.2.1.4/Federally Qualified Health Centers (FQHCs)
R	10/10.2/10.2.1.6/Home Health Agencies (HHAs)
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.3.12/Physician Assistants
R	10/10.4/10.4.1.4.2/Returns
R	10/10.4/10.4.1.4.3/Rejections
R	10/10.4/10.4.2.2/Denial Reasons
R	10/10.4/10.4.2.3/Additional Denial Policies
R	10/10.4/10.4.6/Reactivations
R	10/10.4/10.4.7.3/Revocation Reasons
R	10/10.4/10.4.7.4/Reenrollment Bar
R	10/10.4/10.4.8/Deactivations
R	10/10.4/10.4.8.1/Deactivation Rebuttals
R	10/10.6/10.6.2/Establishing Effective Dates
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.6/10.6.13/Ordering/Certifying Suppliers
R	10/10.6/10.6.14/Application Fees

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:	Date:	Change Request: 12502

Transmittal 11142, dated December 2, 2021, is being rescinded and replaced by Transmittal 11154, dated December 10, 2021, to include section 10.6.13, which was accidently removed by another CR. 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, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2022

I. GENERAL INFORMATION

A. Background: The CY 2022 HH PPS and PFS Final Rules (FR) (respectively, 86 FR 62240 and 86 FR 64995) contained provisions concerning Medicare provider enrollment. Some of these provisions merely incorporated certain longstanding sub-regulatory policies into regulation. Other provisions, however, represent new or modified provider enrollment policies. This CR will incorporate the latter into Chapter 10 of Pub. 100-08 and instruct the contractors on the implementation of these policies. In addition, this CR also clarifies an outstanding policy matter concerning the processing of Federally Qualified Health Center (FQHC) enrollment applications.

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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12502.1	If the contractor receives an Exhibit 177 that was signed prior to the FQHC's listed effective date, the contractor shall develop for an Exhibit 177 signed on or after said effective date.	X								
12502.2	The contractor shall observe and, as applicable, abide by the instructions in Section		X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	10.2.2.4(A)(2) in Chapter 10 of Pub. 100-08 regarding "indirect" independent diagnostic testing facilities.									
12502.3	The contractor shall observe and, as applicable, abide by the new and revised guidance and instructions in this CR concerning application returns, rejections, denials, revocations, reactivations, effective dates, deactivations, and deactivation rebuttals.	X	X	X						
12502.4	The contractor shall observe that the new and revised policies in this CR apply to enrollment applications that are pending, in process, or received on or after January 1, 2022.	X	X	X						
12502.5	The contractor shall observe and, as applicable, adhere to the revised opt-out guidance in Section 10.6.12(C)(3) in Chapter 10 of Pub. 100-08.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12502.6	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.11154; Issued-12-10-21)

10.1.1 – Definitions

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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.

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.

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

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

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

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.

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Statutory Background

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

B. Requirements

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

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

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

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

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

C. Initial FQHC Applications

1. Contractor Review and Required Documents

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

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

- One signed and dated copy of the attestation statement (Exhibit 177). In order to attest to being in compliance, the facility must be open and operating when the attestation is signed. Since FQHCs must sign an agreement stipulating that they will comply with § 1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC benefit (or provider/supplier) agreement when it is also signed and dated by PEOG. (See Pub. 100-07, chapter 2, section 2826B.)

- HRSA Notice of Grant Award or FQHC Look-Alike Designation that includes an address for the site of the applicant which matches the practice location reported on the Form CMS-855A. A Notice of Grant Award by HRSA verifies that the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies look-alike status.

- Form CMS-588; Electronic Funds Transfer (EFT) Authorization Agreement.

- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostics test. Pub. 100-07, chapter 6, section 6002 provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the FQHC's responsibility to review the CLIA requirements and obtain a CLIA certificate if needed. Neither the contractor nor CMS determines whether the FQHC needs to obtain and submit a CLIA certificate.

- Copy of state license (if applicable).

2. General Processing Concepts

(A) Practice Locations - An FQHC cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own CCN.

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

(C) Date on Exhibit 177 - The contractor shall ensure that the date on which the Exhibit 177 was signed is on or after the date the FQHC listed as its effective date on the Form CMS-855A application. If the Exhibit 177 was signed prior to the listed effective date, the contractor shall *(using the development procedures outlined in this*

chapter) develop for an Exhibit 177 signed on or after the FQHC's listed effective date; the FQHC should be providing services in order to meet the regulations noted in Exhibit 177.

(D) Date Application Complete - When reviewing an initial FQHC application, the contractor shall verify the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing, so the contractor requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its approval letter as the effective date of the FQHC.

(E) Site Visits - Site visits for FQHCs are performed by HRSA prior to enrollment.

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

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

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

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

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

3. Determination

a. Approval

The contractor shall contact PEOG via email at MedicareProviderEnrollment@cms.hhs.gov if it believes that the FQHC's initial application should be approved. The contractor shall provide to PEOG: (1) a copy of the draft approval letter (see section 10.7.19 of this chapter for a model FQHC approval letter); (2) the Form CMS-855A application or PECOS Application Data Report (ADR) and all supporting documentation; (3) a copy of the FQHC's HRSA documentation; and (4) Exhibit 177.

While awaiting PEOG's final determination---and beginning on the date following the sending of the aforementioned e-mail---the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

b. Denial

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

4. Post-PEOG Review and Response to Contractor

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

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

5. Post-Approval Contractor Action

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

D. Location Changes

1. Verification

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

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

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

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

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

2. Approval

If approving the location change, the contractor does not issue a recommendation of approval to the SOG Location, notwithstanding any instruction to the contrary in this chapter; rather, the contractor shall approve the location change in PECOS and issue an approval letter to the FQHC (with an e-mailed copy to PEOG at MedicareProviderEnrollment@cms.hhs.gov; PEOG will update ASPEN accordingly). Beginning on March 15, 2021, tie-in notices will not be issued for address changes.

3. Denial

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

E. Timeframes and Alternatives

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

F. Revocations and Other Transactions

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

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

Upon revalidation or reactivation, an FQHC need not submit a new HRSA Notice of Award (NoA) (unless HRSA made an update and issued the FQHC a new one) or new Exhibit 177; new provider agreements are not required for either transaction.

G. Complaint Investigations

CMS SOG Locations investigate complaints that raise credible allegations of an FQHC's noncompliance with health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR

491 Subpart A (except for 42 CFR § 491.3). The contractor shall refer such complaints to the SOG Location that has jurisdiction over the FQHC.

For additional general information on FQHCs, refer to:

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

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

10.2.1.6 - Home Health Agencies (HHAs)

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. General Background Information

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

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

B. Site Visit Requirements

See sections 10.6.20(A) and 10.6.20(B) of this chapter for more information on HHA site visit requirements.

C. HHA Components

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

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

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

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

D. Out-of-State HHA Operations

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

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

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

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

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

E. Verification of HHA Sites

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

F. Nursing Registries

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

G. HHA Ownership Changes

1. Background

Effective January 1, 2011, and in accordance with 42 CFR § 424.550(b)(1), if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of § 424.510, and

- Obtain a state survey or an accreditation from an approved accreditation organization.

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

2. Exceptions

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

- The HHA has submitted 2 consecutive years of full cost reports *since initial enrollment or the last change in majority ownership, whichever is later*. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)

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

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

- An individual owner of the HHA dies.

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

3. Timing of 36-Month Period

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

- Example 1 – Smith HHA initially enrolled in Medicare effective July 1, 2009. Smith underwent a change in majority ownership effective September 1, 2011. The provisions of § 424.550(b)(1) applied to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.

- Example 2 – Jones HHA initially enrolled in Medicare effective July 1, 2007. Jones underwent a change in majority ownership effective February 1, 2019. Section 424.550(b)(1) did not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, that Jones underwent another change in majority ownership effective February 1, 2020. Section 424.550(b)(1) applied to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2019).

- Example 3 – Davis HHA initially enrolled in Medicare effective July 1, 2012. It underwent its first change in majority ownership effective December 1, 2015. This change was not affected by §424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis underwent another change in majority ownership effective July 1, 2019. This change, too, was unaffected by § 424.550(b)(1), for it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on December 1, 2015). Davis underwent another majority ownership change on July 1, 2020. This change was impacted by § 424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on July 1, 2019).

4. Determining the 36-Month Rule's Applicability

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

Step 1 – Change in Majority Ownership

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

- The ownership change was a direct ownership change and not a mere indirect ownership change, and

- The change involves a party assuming a greater than 50 percent ownership interest in the HHA.

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

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

Step 2 – 36-Month Period

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

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

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

Step 3 – Applicability of Exceptions

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

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

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

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

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

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

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

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

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

5. Determination

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

If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor apply the 36-month rule to the HHA and require an initial enrollment based thereon without the prior approval of PEOG. If PEOG agrees with the contractor's determination, the contractor shall send a letter to the HHA notifying it that, as a result of § 424.550(b)(1), the HHA must:

- Enroll as an initial applicant; and

- Obtain a new state survey or accreditation survey after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the state/SOG Location.

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. The effective date of the deactivation shall be the date the HHA is notified that it must enroll as an initial applicant. If the sale has not occurred, the contractor shall alert the HHA that it must submit a Form CMS-855A voluntary termination application.

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

6. Additional Notes

The contractor is advised of the following:

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

ii. If the contractor determines, under Step 3 above, that one of the § 424.550(b)(2) exceptions applies, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It underwent a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from § 424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA underwent another change in majority ownership that did not qualify for an exception. The HHA thus had to enroll as a new HHA under § 424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from § 424.550(b)(1).

H. Capitalization

1. Background

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

2. Points of Review

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

- Prior to making its recommendation for approval;

- After a recommendation for approval is made but before the SOG Location review process is completed;

- After the SOG Location review process is completed but before the contractor conveys Medicare billing privileges to the HHA; and

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

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

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

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

3. Determining Initial Reserve Operating Funds

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

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

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

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

4. Proof of Operating Funds

As described further in section 10.2.1.6(H)(5) and (7) below, the HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For purposes of the capitalization requirement, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify as meeting the initial reserve operating funds requirement. Examples of cash equivalents for purposes of the capitalization requirement are Treasury bills, commercial paper, and money market funds.

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

5. Borrowed Funds

a. General Information

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA. As part of this, and except as stated in section 10.2.1.6(H)(5)(b) below, the HHA must (at a minimum) furnish: (1) a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds; and (2) an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds; this could include furnishing an attestation from a financial institution or other source (as may be appropriate) to establish that such funds will remain available until a date when the HHA will have been surveyed by the state agency or by an approved accrediting organization.

b. Inability to Obtain Attestation Statements

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

6. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

7. Documents

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

- A document outlining the HHA's projected budget – preferably, a full year's budget broken out by month
- A document outlining the number of anticipated visits - preferably a full year broken out by month
- An attestation statement from an officer of the HHA defining the source of funds
- Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)
- Except as stated in section 10.2.1.6(H)(5)(b) above, a letter from an officer of the bank attesting that funds are available
- If available, audited financial statements

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

I. Additional HHA Review Activities

As stated in section 10.2.1.6(H) of this chapter, the contractor must verify that a newly enrolling HHA has the required amount of capitalization after the SOG Location review process is completed but before the contractor conveys Medicare billing privileges to the HHA. Accordingly, the HHA must submit proof of capitalization during this "post-SOG Location" period.

To confirm that the HHA is still in compliance with Medicare enrollment requirements prior to the issuance of a provider agreement and conveyance of Medicare billing privileges, the contractor during the post-SOG Location review period shall ensure that each entity and individual listed in sections 2, 5 and 6 of the HHA's Form CMS-855A application is again reviewed against the Medicare Exclusion Database (MED) and the System for Award Management (SAM) (formerly the General Services Administration (GSA) Access Management System). This activity applies: (1) regardless of whether the HHA is provider-based or freestanding; and (2) only to initial enrollments.

The capitalization and MED/SAM re-reviews described above shall be performed once the SOG Location notifies the contractor via e-mail that the SOG Location's review is complete. (Per sections 10.6.20(A) and 10.6.20(B) of this chapter, a site visit will be performed after the contractor receives the tie-in/approval notice from the SOG Location but before the contractor conveys Medicare billing privileges to the HHA.) If:

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

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

ii. The SOG Location will: (1) CCN; (2) sign a provider agreement; and (3) send a tie-in notice or approval letter to the contractor.

iii. Upon receipt of SOG Location's notification, the contractor will perform the capitalization reviews discussed in section 10.2.1.6(H) and MED/SAM reviews discussed in section 10.2.1.6(I) of this chapter.

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

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

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

iii. Upon receipt of SOG Location's notification, the contractor will perform capitalization reviews discussed in section 10.2.1.6(H) and MED/SAM reviews discussed in section 10.2.1.6(I) of this chapter.

J. Recommendation before New HHA Location Established

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

K. Additional Information

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act
- 42 CFR Part 484
- 42 CFR § 489.28 (capitalization)
- Pub. 100-07, chapter 2
- Pub. 100-04, chapter 10
- Pub. 100-02, chapter 7

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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

A. ***Introduction***

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

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

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

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

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

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

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

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

In addition. 42 CFR § 410.33(c) previously stated in full: "Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in

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

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

iii. Synopsis

In sum:

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

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

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

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

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

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

- *Unless there is evidence that the IDTF only performs indirect tests, the contractor may assume that the supplier is not an "indirect IDTF."*
- *If the contractor determines that the IDTF performs both indirect and direct tests, it shall follow the instructions described in this subsection (A)(2).*
- *If the contractor does not believe the supplier is an indirect IDTF but the supplier states that it is, the contractor shall contact its PEOG BFL for guidance.*

B. IDTF Standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual

beneficiary by telephone or via door-to-door sales.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Leasing and Staffing

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

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

D. Sharing of Space and Equipment

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

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

E. Multi-State IDTFs

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

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

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

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

F. One Enrollment per Practice Location

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

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

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

G. Interpreting Physicians

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

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

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare

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

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

the interpretations; that is, the physicians may be billing for the interpretation themselves.

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

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

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

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

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

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

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

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

J. IDTF Technician Licensure and Certification Requirements

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

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

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

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

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

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

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

M. IDTF - Information about Supervising Physicians

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

In addition:

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

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

- If the contractor knows that a reported supervising physician has been listed with several other IDTFs, the contractor shall check with the physician to determine whether he or she is still acting as supervising physician for these other IDTFs.

- If the supervising physician is enrolling in Medicare and does not intend to perform medical services outside of his/her role as a supervising physician: (1) the contractor shall still send the physician an approval letter (assuming successful enrollment) and issue a PTAN; (2) the physician shall list the IDTF's address as a practice location; and (3) the space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

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

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

P. IDTF - Changes of Supervising Physicians

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

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

Q. Desk and Site Reviews

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

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

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

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

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

R. Mobile Units

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

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

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

- What their responsibilities are; and

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

S. Addition of Codes

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

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

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

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

T. IDTF That Performs Diagnostic Mammography

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

U. IDTF Ownership of CLIA Laboratory

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

10.2.3.12 – Physician Assistants

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

(The physician assistant (PA) enrollment instructions in this section 10.2.3.12 supersede all other PA-specific instructions in this chapter.)

A. *PA* Requirements Under § 410.74

Current federal regulations at 42 CFR §§ 410.74 discuss the requirements that a PA must meet.

Among the requirements for coverage of PA services outlined in 42 CFR §§ 410.74(a) are that the PA (as listed in §§ 410.74(a)(2)):

(i) Meets the qualifications set forth in § 410.74(c);

(ii) Is legally authorized to perform the services in the state in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and PAs (including explicit supervisory or collaborative practice requirements) describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Social Security Act. For states with no explicit state law and scope of practice rules regarding physician supervision of a PA's services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physician(s) when furnishing professional services*; and*

(v) Performs the services: (A) in all settings in either rural and urban areas; or (B) as an assistant at surgery.

Section 410.74(c), meanwhile, states that for Medicare Part B coverage of his or her services, a PA must meet all of the following conditions:

(1) Have graduated from a PA educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(2)(i) Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and (ii) be licensed by the state to practice as a PA.

B. PA Employer

Prior to January 1, 2022, payment for the PA's services *could* only be made to the PA's employer, not to the PA himself/herself. *That is,* the PA *could* not individually enroll in Medicare to receive direct payment for his or her services. This also mean*t* that the PA *could* not reassign his or her benefits to the employer, for the employer must receive direct payment anyway. *Pursuant to the CY 2022 Physician Fee Schedule Final Rule, however, a PA may:*

- *Individually enroll in Medicare (e.g., as a sole proprietorship, professional corporation)*
- *Receive direct payment for his/her services*
- *Establish PA groups (e.g., LLCs)*
- *Reassign his/her benefits to his/her employer.*

The previous requirement that the PA's employer must bill for his/her services has hence been eliminated.

C. PA Enrollment Information

With the aforementioned change concerning PA employers (and except as stated in this subsection (C)), the contractor is advised of and/or shall adhere to the below policies, which are effective January 1, 2022. Although these policies can be applied to PA applications that are pending or in process as of January 1, 2022, it is important that the contractor adhere to the effective date instructions in subsection (C)(2)(e) below.

1. Newly enrolling, revalidating, and reactivating PAs shall complete the applicable Form CMS-855I sections to the same extent as would any other individual practitioner who is able to individually enroll in and bill Medicare.

2. Transactions

a. Initial Enrollment - If a PA is initially enrolling in Medicare and does not intend to reassign his/her benefits, he/she need not complete Section 2(I) of the Form CMS-855I. (The PA's practice location information, however, shall be furnished.)

b. Initial Enrollment - If a PA is initially enrolling in Medicare and intends reassign his/her benefits, the PA shall complete Section 2(I) with the name, PTAN (if assigned), NPI, and EIN of the employer/entity/supplier to which benefits will be reassigned. With PECOS unable to accommodate Form CMS-855R PA reassignments at this time, Section 2(I) will effectively constitute a reassignment application in the interim. (For purposes of this section 10.2.3.12, such situations will be labeled "PA payment arrangements.") Reassigned payments can therefore be made to the employer/entity/supplier listed in Section 2(I), similar to how employers have previously been paid for PA services.

Regarding verification, the contractor:

- *Shall follow this chapter's existing instructions for validating PA employer information rather than those for Form CMS-855R submissions*
- *Shall apply the Form CMS-855I's effective date to the PA payment arrangement*
- *Consistent with existing policy concerning PA employers, shall confirm that the employer/entity/supplier is enrolled in Medicare*
- *Need not secure the employer/entity/supplier's signature to effectuate the PA payment arrangement (as occurs with Form CMS-855R reassignees)*
- *If Section 2(I) is blank, the contractor can assume that the PA seeks direct payment. If there is evidence to the contrary, however, the contractor can (via any means) ask the PA whether reassignment is or is not desired. If it is, the contractor shall develop for the completion of Section 2(I).*

c. Change Request Involving Section 2(I)

On and after January 1, 2022, the contractor shall continue to pay the employer/entity/supplier listed in Section 2(I) unless or until the PA submits a Form CMS-855I that removes or changes the employer/entity/supplier. The contractor need not contact every enrolled PA upon the January 1, 2022 effective date to determine whether the PA wishes to continue his/her existing payment arrangement or instead receive payment directly. It is the PA's responsibility to report or change this data, if applicable, via the Form CMS-855I.

Form CMS-855Rs shall not be submitted to establish, change, or terminate a PA payment arrangement. If a Form CMS-855R is nonetheless submitted, the contractor shall not return

the form; instead, the contractor shall place it in the provider file and develop with the PA for a Form CMS-855I change request that updates Section 2(I).

If, after a change request or other Form CMS-855I transaction, no employers/entities/suppliers are left in Section 2(I), payments shall be made directly to the PA.

d. Form CMS-855B

Effective January 1, 2022, PAs can establish PA group practices and be enrolled via the Form CMS-855B. The contractor shall process the Form CMS-855B in the same fashion it would any other group practice application, and the application shall be completed to the same extent as would any other such application. PA payment arrangements to the group (e.g., Section 2(I)) shall be processed consistent with the instructions in this subsection (C).

e. Effective Date

The effective date under § 424.520(d) and § 424.521(a) for PAs enrolling as sole proprietors/solely-owned entities and/or PA groups shall be on or after January 1, 2022 -- even if the application was received prior to that date and the effective date might thus otherwise be before January 1, 2022. In this latter situation, an effective date of January 1, 2022 is appropriate.

10.4.1.4.2 - Returns

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Reasons/Grounds for Return

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

Notwithstanding any other directive to the contrary in this chapter or another CMS directive, the contractor (including the NSC) may immediately return the enrollment application to the provider only in the instances described below and which are outlined in *§ 424.526(a)(1) through (13). Except as otherwise indicated in the specific return reason, t*his policy applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations, etc.):

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

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

(*3*) *The seller or buyer* in a CHOW submitted its *Form CMS-855A or Form CMS-855B* application more than *9*0 days prior to the anticipated date of the sale.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Procedures for Returning the Application

If the contractor returns the application, the following apply:

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

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

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

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

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

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

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

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

D. Reactivations

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

E. Revalidations

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

the contractor returns it again, rejects it, or denies it, the contractor shall – absent another CMS instruction to the contrary - deactivate the provider's billing privileges, assuming the applicable time period has expired.

10.4.1.4.3 - Rejections

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Background

1. Rejection Reasons

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

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

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

(ii) *The application is* unsigned *or* undated.

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

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

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

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

(vii) *The paper application is* completed in pencil.

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

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

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

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

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

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

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

2. Applicability

a. Development

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

b. Transaction and Form Types

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

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

B. Timeframe

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

C. Incomplete Responses

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

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

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

D. Creation of L & T Record

If the contractor cannot create an L & T record in PECOS because of missing data and the application is subsequently rejected, the contractor shall document the provider file accordingly. If the contractor can create an L & T record for a rejected application, it shall flip the status to "rejected" in PECOS.

E. Other Impacts of a Rejection

1. Changes of Information and CHOWs

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

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

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

F. Reactivations

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

G. Revalidations

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

H. Additional Rejection Policies

1. Resubmission after Rejection

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

2. Applicability

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

3. Physicians and Non-Physician Practitioners

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

4. Notice

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

5. Copy of Application

If the contractor rejects an application, it shall either (1) keep the original application and all supporting documents or (2) make a copy or scan of the application and documents and return the originals to the provider. If the contractor chooses the former approach and the provider requests a copy of its application, the contractor may fax or mail it to the provider.

10.4.2.2 - Denial Reasons

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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, 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 or managing employee 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.

2. Contractor's Determination of Overpayment

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

3. Examples

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

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

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

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

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

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

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

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

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

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

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

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

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

"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.

10.4.2.3 – Additional Denial Policies

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Post-Denial Submission of Enrollment Application

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

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

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

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

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

B. 30-Day Effective Date of Denial

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

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

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

1. Expiration of Timeframe for Reporting Changes

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

2. Timeframe Not Yet Expired

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

3. Second Rejection, Return, or Denial

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

D. Reactivations

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

E. Revalidations

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

F. Appeals of Denials

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

10.4.6 – Reactivations

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Form CMS-855 or CMS-20134 Reactivations – Screening Levels

1. Limited

The contractor shall process reactivation applications from providers in the "limited" level of categorical screening in accordance with existing instructions.

2. Moderate

The contractor shall process reactivation applications from providers in the "moderate" level of categorical screening (including existing HHAs and DMEPOS suppliers) in accordance with the screening procedures for this category. A site visit is thus needed prior to the contractor's final decision regarding the application.

3. High

The contractor shall process reactivation applications from providers in the "high" level of categorical screening in accordance with the screening procedures for this category. A site visit is thus needed prior to the contractor's final decision regarding the application.

B. Form CMS-855B and CMS-855I Non-Certified Supplier Reactivations

If the contractor approves a Part B non-certified supplier's reactivation application, the reactivation effective date shall be the date the contractor received the application that was processed to *approval.* In addition, upon reactivating a Part B non-certified supplier, the contractor shall issue a new PTAN.

C. Form CMS-855A or CMS-855B Certified Provider or Supplier Reactivations

With the exception of HHAs, reactivation of a certified provider/supplier does not require a new state survey, provider agreement, or participation agreement. Per 42 CFR § 424.540(b)(3)(i), an HHA must undergo a new state survey or obtain accreditation by an approved accreditation organization before it can be reactivated.

D. Reactivations - Deactivation for Reasons Other Than Non-Submission of a Claim

To reactivate its billing privileges, the provider or supplier must submit a complete Medicare enrollment application if the provider or supplier was deactivated*: (i)* for failing to timely notify the contractor of a change of information; *or (ii) under § 424.540(a)(4) and (a)(5).*

E. Reactivation Effective Date

Per 42 CFR § 424.540(d)(2), the effective date of a reactivation of billing privileges under this section is the date on which the contractor received the provider's or supplier's reactivation submission that the contractor processed to approval. Under 42 CFR § 424.540(e), however, the provider or supplier may not receive payment for services or items furnished while deactivated. This means that the contractor shall not add a retroactive back-

billing period (e.g., 30 days) to the reactivation effective date. To illustrate, suppose the contractor establishes a reactivation effective date under § 424.540(d)(2) of October 30, the date the contractor received the ultimately approved reactivation submission. The contractor under § 424.540(e) cannot establish an effective date earlier than October 30 to allow for additional retroactive billing.

F. Miscellaneous Policies

1. Previous Withdrawn Status

A provider that voluntarily withdraws (or, in the case of a certified provider/supplier, voluntarily or involuntarily withdraws from Medicare enrollment) is ineligible for reactivation. Such a provider must complete an initial enrollment application and, if applicable, pay an application fee.

2. Deactivation for Non-Billing

For providers deactivated for non-billing, the provider must submit a complete Form CMS-855 or CMS-20134 enrollment application via paper or PECOS Web.

3. Contractor Timeliness Standards

For Form CMS-855 or CMS-20134 reactivation applications, the timeliness requirements in section 10.5 et seq. of this chapter pertaining to initial enrollment applications apply. Except as otherwise stated in this chapter or another CMS directive, the contractor shall validate all of the information on the application as it would with an initial application.

10.4.7.3 – Revocation Reasons

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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, 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 or managing employee 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."

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;

(i) Business structure; or

(ii) 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.

10.4.7.4 – Reenrollment Bar

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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

A. Background

As stated in 42 CFR § 424.535(c), if a provider/supplier has their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar. The reenrollment bar begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation. In addition, CMS may impose a reenrollment bar of up to 20 years if the provider/supplier is being revoked from Medicare for the second time.

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

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

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

B. Establishment of Length

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

- § 424.535(a)(1) (Noncompliance) -- For licensure issues, 1 year if no billing after loss of license
- §424.535(a)(6) (Grounds Related to Screening) – 1 year
- §424.535(a)(11) (Initial Reserve Operating Funds) – 1 year

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

- §424.535(a)(17) (Debt Referred to the United States Department of Treasury)
- §424.535(a)(18) (Revoked Under a Different Name, Numerical Identifier or Business Identity)
- §424.535(a)(19) (Affiliation that Poses an Undue Risk)
- §424.535(a)(20) (Billing from a Non-Compliant Location, §424.535(a)(21) (Abusive Ordering, Certifying, Referring, or Prescribing of Part A or B Services, Items or Drugs)
- §424.535(a)(22) (Patient Harm) will receive reenrollment bar lengths per CMS' discretion.

C. Applicability of Bar

In general, and unless stated otherwise above, any reenrollment bar at a minimum applies to: (1) all practice locations under the provider's PECOS or legacy enrollment record; and (2) any effort to reestablish any of these locations (i) at a different address and/or (ii) under a different business or legal identity, structure, or TIN. If the contractor receives an application and is unsure whether a revoked provider is attempting to reestablish a revoked location, it

shall contact its PEOG BFL for guidance. Instances where the provider might be attempting to do so include - but are not limited to – the following:

SCENARIO 1 - John Smith was the sole owner of Group Practice X, a sole proprietorship. Six months after X was revoked under § 424.535(a)(9), the contractor receives an initial application from Group Practice Medicine, LLC, of which John Smith is the sole owner/member.

SCENARIO 2 - Jack Jones and Stan Smith were 50 percent owners of World Home Health Agency, a partnership. One year after World Home Health was revoked under § 424.535(a)(7), the contractor receives an initial application from XYZ Home Health, a corporation owned by Jack Jones and his wife, Jane Jones.

SCENARIO 3 - John Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ's lone location was at 1 Jones Street. XYZ's billing privileges were revoked after it was determined that the site was non-operational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has two locations in the same city in which 1 Jones Street is located. John Smith is listed as a 75 percent owner.

D. Discussing Provider Enrollment Appeals Process in Revocation Letter

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

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

	CAP requests should be sent to:		**Reconsideration request should be sent to:**	
Revocation Regulation	**Institutional***	**Non-institutional**	**Institutional***	**Non-Institutional**
424.535(a)(1) related to an enrollment requirement (i.e., 425.516)	Alone or in combination: CMS	MAC	CMS	MAC
424.535(a)(1) Licensure	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(1) DME or IDTF	CAP rights (to CMS)	CAP rights (to the MAC)	CMS	MAC
424.535(a)(2) Exclusion	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(2) Debarment	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(3)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(4)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(5)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(6)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(7)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(8)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(9)	No CAP rights	No CAP rights	CMS	MAC
424.535(a)(10)	No CAP rights	No CAP rights	CMS	CMS

424.535(a)(11)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(12)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(13)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(14)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(17)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(18)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(19)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(20)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(21)	No CAP rights	No CAP rights	CMS	CMS
424.535(a)(22)	No CAP rights	No CAP rights	CMS	CMS

* Institutional providers:
  - Ambulance Service Supplier
  - Ambulatory Surgery Centers
  - CLIA Labs
  - Community Mental Health Center
  - Comprehensive Outpatient Rehabilitation Facilities (CORFs)
  - Critical Access Hospitals
  - End Stage Renal Disease (ESRDs)
  - Federally Qualified Health Careers (FQHCs)
  - Histocompatibility Laboratories
  - Home Health Agencies
  - Hospices
  - Hospitals and Hospital Units
  - Independent Diagnostic Testing Facilities (IDTFs)
  - Intensive Cardiac Rehabilitation
  - Indian Health Service Facility
  - Mammography Screening Centers
  - Mass Immunization/Flu Roster Billers
  - Medicare Diabetes Prevention Programs (MDPPs)
  - Opioid Treatment Centers (OTPs)
  - Organ Procurement Organizations (OPOs)
  - Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
  - Pharmacies
  - Portable X-Ray Suppliers (PXRSs)
  - Radiation Therapy Centers
  - Rehabilitation Services
  - Religious Non-Medical Health Care Institutions (RNCHIs)
  - Rural Health Clinics (RHCs)
  - Skilled Nursing Facilities (SNFs)

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

10.4.8 – Deactivations

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Bases for Contractor Action

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

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

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

(iii) The provider/supplier is enrolled in an approved status with *neither* an active reassignment *n*or practice location for 90 days or longer. *(The deactivation basis shall be 42 CFR § 424.540(a)(4), which permits deactivation if the provider/supplier is not in compliance with all enrollment requirements. See sections 10.4.8(B) and (D) below for more information on this new deactivation ground.)*

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

(v) The provider/supplier is deceased, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the provider's/supplier's death; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(6) below.)

(vi) The provider or supplier is voluntarily withdrawing from Medicare, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the voluntary withdrawal; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(7) below.)

The contractor shall not take deactivation action except as specified *and permitted* in this chapter or other CMS directives.

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

Section 424.540(a) lists *eight* deactivation grounds:

Section 424.540(a)(1) - The provider/supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12-month period will begin the 1st day of the 1st month without a claim submission through the last day of the 12th month without a submitted claim.

Section 424.540(a)(2) - The provider/supplier *does not* report a change *to the information supplied on the enrollment application within the applicable time period required under Title 42. (For example,* a provider/supplier *type falling within the purview of § 424.516(e)(1) and (2)* failed to report a change in ownership or control within (*i*) 30 calendar days of when the change occurred, or (b) 90 calendar days of when the change occurred for all other information on the enrollment application.

If the provider/supplier submits a change of information *and (a) it appears the* change was not reported within 90 days of the change, (*b*) the contractor did not previously take administrative action against the provider/supplier, and (*c*) no revocation action is applicable, the contractor should process the change of information without deactivating the provider/supplier's enrollment.

Section 424.540(a)(3) - The provider/supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

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

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

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

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

Section 424.540(a)(8) - The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

C. Effective Dates

(See § 424.540(d) for regulations concerning deactivation effective dates.)

The effective dates of a deactivation are as follows:

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

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

c. Section 424.540(a)(5) – Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider's/supplier's practice location became non-operational or otherwise invalid.

d. Section 424.540(a)(6) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of death of the provider/supplier.

e. Section 424.540(a)(7) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/supplier voluntarily withdrew from Medicare.

f. Section 424.540(a)(8) - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of the sale. (Note that PEOG will *ultimately* determine *this* effective date during its review of the case *per subsection (E)(2) below.)*

D. *Sections 424.540(a)(4) and (a)(5)*

(This section 10.4.8(D) is inapplicable to the situations described in section 10.4.8(A)(iii) and (iv). These two scenarios do not require any referral to PEOG; the contractor can take deactivation action on its own volition.)

The grounds for deactivation under § 424.540(a)(4) and (a)(5) mirror the revocation reasons described in, respectively, § 424.535(a)(1) and (a)(5). When sending a potential §

424.535(a)(1) and (a)(5) revocation case to PEOG for review per section 10.4.7.1(A) of this chapter, PEOG will determine whether a revocation or a deactivation (under § 424.540(a)(4) and (a)(5)) is appropriate. The contractor shall not deactivate a provider or supplier under § 424.540(a)(4) or (a)(5) unless PEOG specifically directs the contractor to do so. Moreover, the contractor need not refer a potential § 424.540(a)(4) and (a)(5) deactivation case to PEOG outside of the situation described in per section 10.4.7.1(A).

***E*. Miscellaneous**

1. The deactivation of Medicare billing privileges does not affect a provider/supplier's participation agreement.

2. Prior to deactivating an HHA's billing privileges for any reason (including under the "36-month rule"), the contractor shall refer the matter to its PEOG BFL for review and approval. The only exception for PEOG BFL review and approval is deactivations due to failure to comply with a revalidation request.

10.4.8.1 – Deactivation Rebuttals

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Background

Pursuant to 42 CFR § 424.54*6*, a provider/supplier whose Medicare billing privileges have been deactivated under 42 CFR § 424.540(a) may file a rebuttal. A rebuttal is an opportunity for the provider/supplier to demonstrate that it meets all applicable enrollment requirements and that its Medicare billing privileges should not have been deactivated. Only one rebuttal request may be submitted per deactivation. Additional rebuttal requests shall be dismissed.

If an application is received for a deactivated provider/supplier while a rebuttal submission is pending or during the rebuttal submission timeframe, the contractor shall process the application consistent with current processing instructions. If the rebuttal determination is issued and overturns the deactivation prior to an application being approved, the contractor shall return the application received while the rebuttal determination was pending unless: (1) the submitted application is required to reactivate the provider/supplier's enrollment; or (2) if there are new changes being reported. If an application (1) is received while a rebuttal submission is pending, (2) is approved prior to the issuance of a rebuttal determination, and (3) results in the provider's/supplier's enrollment being reactivated without a gap in billing privileges, the contractor shall stop processing the rebuttal submission and issue an applicable moot letter.

B. Notification Letters for Deactivations

If a basis is found to deactivate a provider/supplier's Medicare billing privileges under one of the regulatory authorities in 42 CFR § 424.540, the contractor shall deactivate the provider/supplier unless another CMS direction applies. If a revocation authority is applicable, the contractor shall follow the instructions in section*s* 10.4.7 *and 10.4.8* et seq. of this chapter in lieu of deactivating the enrollment. If no revocation authority applies, the contractor shall send notification of the deactivation using the applicable model deactivation notice. The contractor shall ensure the deactivation notice contains sufficient details so it is clear why the provider/supplier's Medicare billing privileges are being deactivated. The contractor shall send the deactivation notification letter via hard-copy mail and via e-mail (if a valid email address is available); the contractor should also send the notice via fax if a valid fax number is available. All notifications shall be saved in PDF format, and all notification letters shall be mailed on the same date listed on the letter.

C. Rebuttal Submissions

1. Requirements and Submission of Rebuttals

The rebuttal submission:

a. Must be received by the contractor within *15* calendar days from the date of the deactivation notice. The contractor shall accept a rebuttal submission via hard-copy mail, e-mail, and/or fax;

b. Must specify the facts or issues with which the provider/supplier disagrees, and the reasons for disagreement;

c. Should include all documentation and information the provider/supplier would like to be considered in reviewing the deactivation;

d. Must be submitted in the form of a letter that is signed and dated by the individual provider, supplier, the authorized or delegated official, or a legal representative (as defined in 42 CFR § 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider/ supplier*; t*his statement is sufficient to *constitute* notice *of said authority*. If the legal representative is not an attorney, the provider/supplier must file written notice of the appointment of a representative with the contractor. This notice of appointment must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative.

If the rebuttal submission is not appropriately signed or if a statement from the attorney or written notice of representation is not included in the submission, the contractor shall send a development request for a proper signature or the missing statement/written notice (using the applicable model letter) before dismissing the rebuttal submission. The contractor shall allow 15 calendar days from the date of the development request letter for the rebuttal submitter to respond to the development request.

If a rebuttal submission (1) is not appropriately signed and no response is received to the development request (if applicable), (2) is untimely (as described above), (3) does not specify the facts or issues with which the provider/supplier disagrees and the reasons for disagreement, or (4) is a duplicative submission, the contractor shall dismiss the rebuttal submission using the applicable model rebuttal dismissal letter. The contractor may make a good cause determination to accept any rebuttal that has been submitted beyond the *15* calendar-day filing timeframe. Good cause may be found where there are circumstances beyond the provider/supplier's control that prevented the timely submission of a rebuttal. (These uncontrollable circumstances do not include the provider/supplier's failure to timely update its enrollment information, specifically its various addresses.) If the contractor believes good cause exists to accept an untimely rebuttal submission, the contractor shall send a request approval email to ProviderEnrollmentAppeals@cms.hhs.gov within 5 calendar days of making the good cause determination. This email shall detail the contractor's reasoning for finding good cause. Processing timeliness standards shall begin on the date the contractor receives a response from CMS.

2. Time Calculations for Rebuttal Submissions

If the *15th* calendar day from the date on the deactivation notice falls on a weekend or federally-recognized holiday, the rebuttal shall be accepted as timely *if the contractor received it* by the next business day.

It is the provider/supplier's responsibility to timely update its enrollment record to reflect any changes to the provider/supplier's enrollment information including, but not limited to, its correspondence address. Failure to timely update a correspondence address or other addresses included in its Medicare enrollment record does not constitute an "in fact" showing that the deactivation notice was received after the presumed receipt date (as described above).

3. Processing Rebuttal Submissions

The contractor shall send an acknowledgement letter via hard-copy mail to the return address on the rebuttal submission within 10 calendar days of receipt of the accepted rebuttal request using the model rebuttal acknowledgment letter, including a rebuttal tracking number. The acknowledgement letter shall also be sent via email if a valid email address is available. It is optional for the contractor to send the acknowledgement letter via fax if a valid fax number is available.

The contractor shall process all accepted rebuttal submissions within 30 calendar days of the date of receipt. If, while reviewing the rebuttal submission, the provider/ supplier wishes to withdraw its rebuttal, the request to withdraw must be submitted to the contractor in writing before the rebuttal determination is issued.

The contractor's review shall only consist of whether the provider/supplier met the enrollment requirements and if billing privileges were deactivated appropriately. All materials received by the provider/supplier shall be considered by the contractor in its review.

4. Reason-Specific Instructions

a. § 424.540(a)(1)

For deactivations under § 424.540(a)(1), the contractor shall review submitted documentation and internal systems to confirm whether billing occurred during the 12-month period preceding the date of deactivation, starting with the 1st day of the 1st month 12 months prior to the date of deactivation. If it is confirmed that billing occurred within 12 months, the contractor shall issue a favorable rebuttal determination. If no billing occurred during the 12-month period prior to the date of deactivation, the contractor shall issue an unfavorable rebuttal determination. Consider the following illustration:

EXAMPLE: Dr. Awesome has been enrolled in Medicare since 2010. A review of billing data reveals that Dr. Awesome has not submitted any Medicare claims since January 2016. Dr. Awesome's enrollment is deactivated effective January 1, 2018. Dr. Awesome timely submits a rebuttal statement regarding the deactivation. Upon the contractor's review of the submitted documentation and internal records, it is confirmed that Dr. Awesome had not submitted claims since January 2016. An unfavorable determination would therefore be appropriate in this scenario, for the deactivation was justified.

b. § 424.540(a)(2)

For deactivations under 42 CFR § 424.540(a)(2), the contractor shall review the submitted documentation and internal records to determine whether the change of information was properly submitted within 90 calendar days of when the change occurred. If information was submitted properly and timely, the contractor shall approve the rebuttal request and reinstate the provider/supplier's Medicare billing privileges to an approved status. If it was not submitted properly and timely, the contractor shall deny the rebuttal request, for the deactivation was justified. In making this determination, the contractor shall consider, at minimum, the following.

- Whether the deactivation was implemented after 90 days of when the change of enrollment information occurred.
- Whether the letter notifying the provider/supplier of the deactivation was sent to the correct address as instructed in section 10.7 et seq. of this chapter.
- Whether the enrollment changes were received in an enrollment application that was processed to completion within 90 days of when the change of enrollment occurred.

Consider the following illustration:

EXAMPLE: Dr. Happy has reassigned his benefits to physician group Smile, LLC. Smile, LLC is Dr. Happy's only reassignment and only practice location. Smile, LLC's billing privileges are revoked effective January 1, 2018. Dr. Happy's enrollment is deactivated on April 15, 2018 for failing to update his enrollment record with respect to his practice location. Dr. Happy timely submits a rebuttal to the deactivation. Upon the contractor's review of the submitted documentation and internal records, it is discovered that Dr. Happy submitted a change of information application received on February 28, 2018 that sought to update his practice location. However, this application was ultimately rejected due to his failure to timely respond to a development request.

In this scenario, the deactivation was correctly implemented after 90 days of the change of enrollment information – the change in practice location. However, an enrollment application updating Dr. Happy's practice location that was processed to completion was not received within 90 days of the change of enrollment information. Though an application was received within 90 days of the change of enrollment information, that application was not processed to completion. Thus, an unfavorable rebuttal determination would be appropriate in this scenario, as the deactivation was justified.

c. § 424.540(a)(3)

For deactivations under 42 CFR § 424.540(a)(3), the contractor shall review all submitted documentation and internal records to determine whether the provider/ supplier furnished complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information. In making this determination, the contractor shall consider, at minimum, the following:

- Whether the deactivation was implemented after 90 days of the revalidation request.
- Whether the letter notifying the provider or supplier of the requirement to revalidate was sent to the correct address as instructed in section 10.7 of this chapter.
- Whether a revalidation application was timely received that was processed to completion.

Consider the following scenario:

EXAMPLE: On January 1, 2018, the contractor appropriately and timely informs Dr. Great that the contractor must receive a revalidation application from Dr. Great by April 15, 2018. The contractor receives a revalidation application from Dr. Great on March 1, 2018. The contractor requests that Dr. Great furnish further information needed to process the revalidation application. Dr. Great does not respond to the development request within 30 days as requested. The contractor rejects the March 1, 2018 revalidation application and subsequently deactivates Dr. Great's enrollment on April 16, 2018. Dr. Great timely files a rebuttal in response to the deactivation. Upon review of the submitted documentation and

internal records, the contractor confirms that Dr. Great was appropriately and timely notified of the requirement to revalidate and that it did not receive a revalidation application within 90 days of the revalidation request that could be processed to completion. Accordingly, an unfavorable rebuttal determination would be appropriate in this scenario, as the deactivation was justified.

d. § 424.540(a)(4) and (5)

For a deactivation under 42 CFR § 424.540(a)(4) or (a)(5), the contractor shall review all submitted documentation and internal records to determine whether: (1) the provider/supplier was, in fact, compliant with all enrollment requirements at the time of the deactivation (for § 424.540(a)(4) deactivations); or (2) the provider's/supplier's practice location was operational or otherwise valid at the time of the deactivation (for § 424.540(a)(5) deactivations).

If the provider/supplier was indeed compliant at the time of the deactivation, the contractor shall approve the rebuttal request and reinstate the provider/supplier's Medicare billing privileges to an approved status; prior PEOG review of the rebuttal or approval of the rebuttal request is not required. If the rebuttal was not submitted properly and timely, the contractor shall dismiss the rebuttal request.

e. § 424.540(a)(6), (a)(7), and (a)(8)

Although rebuttals under these three deactivation grounds are uncommon, the provider/supplier may submit one. Upon receipt thereof, the contractor shall review all submitted documentation and internal records to determine whether the deactivation pursuant to the regulatory basis in question was, in fact, proper. If it was not, the contractor shall approve the rebuttal request and reinstate the provider/supplier's Medicare billing privileges to an approved status; prior PEOG review of the rebuttal or approval of the rebuttal request is not required. If the rebuttal was not submitted properly and timely, the contractor shall dismiss the rebuttal request.

D. Determination

The contractor shall render a determination regarding a rebuttal submission using the appropriate model rebuttal decision letter. If the contractor is unable to render a determination, the contactor shall use the appropriate model letter for the specific situation. All determinations (including dismissals and withdrawals) related to rebuttal submission*s* shall be sent via hard-copy mail to the return address on the rebuttal submission and by e-mail (if a valid e-mail address is available). The contractor may also send via fax if a valid fax number is available. All documentation shall be saved in PDF format, and all notification letters shall be mailed on the same date listed on the letter.

If the contractor issues a rebuttal determination favorable to the provider/supplier, it shall make the necessary modification(s) to the provider/supplier's Medicare billing privileges within 10 business days of the date the favorable determination is issued. This may include the elimination of the deactivation altogether so that there is no gap in billing privileges or a change in the deactivation effective date. If the contactor issues a rebuttal determination unfavorable to the provider/supplier, the provider/ supplier's Medicare billing privileges shall remain deactivated until a reactivation application is received and processed to completion.

If a rebuttal determination overturns the deactivation, the contractor shall return any application(s) received while the rebuttal submission was being reviewed or during the rebuttal submission timeframe that ha*s* not been processed to completion, unless the application is needed to reactivate the enrollment or if there are new changes being reported.

If the contractor confirms that the application is not needed and that no new changes are being reported, the contractor shall use the following return reason in the Returned Application Model Letter found at 10.7.7.A of this chapter in response to the scenario described above: "A rebuttal decision has been issued; therefore, the submitted Form CMS [855/588/20134] is not needed."

If additional information/documentation is needed prior to reinstating the provider/supplier (e.g., deactivation due to non-response to revalidation and a complete application or missing information is needed to finalize the revalidation), the contractor shall document these next steps in its rebuttal determination letter. The contractor shall not reinstate the provider/supplier until the requested information is received and processed. If the additional information/documentation is not received within 30 calendar days of the date of the rebuttal determination, the contractor shall contact the provider/supplier to again request the additional information/documentation within 10 calendar days of not receiving a response. If no response is received within 30 calendar days of the second request for additional information/documentation, the contractor shall contact ProviderEnrollmentAppeals@cms.hhs.gov within 10 calendar days for further instruction.

E. No Further Review

Pursuant to 42 CFR *§ 424.546(f),* a determination made regarding a rebuttal request is not an initial determination and is not subject to further review. Thus, no additional appeal rights shall be included on any rebuttal determination letter.

10.6.2 – Establishing Effective Dates

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

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

A. Date of Enrollment/Approval

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

B. Establishing Effective Dates of Billing *Privileges* for Certain Suppliers Under *42 CFR § 424.520(d)*

1. Applicability

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

a. *P*hysicians; physician assistants; nurse practitioners; audiologists; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; certified nurse- midwives; clinical social workers; clinical psychologists; independently billing psychologists, registered dietitians or nutrition professionals; physical therapists; occupational therapists; speech-language pathologists; *and* physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified above.

b. Ambulance suppliers

c. Part B hospital departments

d. CLIA labs

e. Opioid treatment programs.

f. Mammography centers

g. Mass immunizers/pharmacies

h. Radiation therapy centers

i. Home infusion therapy suppliers

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

2. Background

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

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

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

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

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

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

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

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

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

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

The contractor shall interpret the *aforementioned* phase "circumstances precluded enrollment" to mean that the supplier meets all program requirements (including state licensure) during the 30-day period before an application was submitted and no final adverse action (as *that term is defined in § 424.502)* precluded enrollment. If a final adverse action

precluded enrollment during this 30-day period, the contractor shall only establish an effective billing date the day after the date that the final adverse action was resolved--*so* long as it is not more than 30 days prior to the date on which the application was submitted.

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

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

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

C. Effective Date *of* Reassignment

Per 42 CFR § 424.522(a), the effective date of the reassignment is 30 days before the Form CMS-855R is submitted if all applicable requirements during that period were otherwise met. The contractor shall apply this policy in the following manner:

1. Form CMS-855R submitted as "stand-alone" without Form CMS-855I – The effective date in § 424.522(a) applies to the reassignment unless the effective date that the supplier listed on the Form CMS-855R is later than what the § 424.522(a) date is, in which case the Form CMS-855R-listed effective date controls.

2. Form CMS-855R submitted with Form CMS-855I either simultaneously or as part of development (e.g., physician only submits Form CMS-855I and contractor develops for Form CMS-855R) – The contractor shall apply the Form CMS-855I effective date (per 42 CFR §§ 424.520(d) and 424.521(a)) to the Form CMS-855R. When one or both of these forms requires the contractor to develop for information – and for purposes of establishing the §§ 424.520(d)/424.521(d) effective date -- the contractor may apply the receipt date of the first application that is submitted as complete (i.e. no further development is necessary).

3. Form CMS-855R submitted with Form CMS-855B either simultaneously or as part of development – The contractor shall apply the Form CMS-855B effective date (per 42 CFR §§ 424.520(d) and 424.521(a)) to the Form CMS-855R. When one or both of these forms requires the contractor to develop for information – and for purposes of establishing the §§ 424.520(d)/424.521(d) effective date -- the contractor may apply the receipt date of the first application that is submitted as complete (i.e. no further development is necessary).

D. Effective Date for Certified Providers and Certified Suppliers

Note that 42 CFR § 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Section 489.13 has been revised to state that: (1) the date of a Medicare

provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met; and (2) such requirements include the contractor's review and verification of an application to enroll in Medicare.

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

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

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

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

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

F. Form CMS-855O Effective Dates

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

G. Effective Date for M*edicare* D*iabetes* P*revention* P*rogram (*MDPP*)* Suppliers

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

- The date the supplier filed an enrollment application that was subsequently approved,
- The date the supplier filed a corrective action plan that was subsequently approved by a Medicare contractor, or
- The date the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number.

Under no circumstances should an effective date for billing privileges be prior to April 1, 2018. For any Form CMS-20134 submitted prior to April 1, 2018 and subsequently approved, the contractor shall note April 1, 2018 as the MDPP supplier's effective date, even if this date is in the future.

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

H. Future Effective Dates

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

10.6.12 – Opting-Out of Medicare

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

Physicians and practitioners are typically required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. They are also not permitted to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare-covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to CMS Pub. 100-02, Chapter 15, sections 40 - 40.39 for more information regarding the maintenance of opt-out affidavits and the effects of improper billing of claims during an opt-out period.

The instructions in this section 10.6.12 address the contractor's processing of opt-out affidavits. (See Pub. 100-02, chapter 15, section 40.8 for private contract definitions and requirements.)

A. Who May Opt-Out of Medicare

Only the following physicians and practitioners (sometimes collectively referenced as "eligible practitioners" in this section) can "opt-out" of Medicare:

Physicians who are:

- Doctors of medicine or osteopathy,
- Doctors of dental surgery or dental medicine,
- Doctors of podiatry, or
- Doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the state in which such function or action is performed.

Non-physician practitioners who are

- Physician assistants,
- Nurse practitioners,
- Clinical nurse specialists,
- Certified registered nurse anesthetists,
- Certified nurse midwives,
- Clinical psychologists,
- Clinical social workers, or
- Registered dietitians or nutrition professionals who are legally authorized to practice by the state and otherwise meet Medicare requirements.

(Organizations are not permitted to opt-out of Medicare.)

This means that neither the eligible practitioner nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the eligible practitioner out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the eligible practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. (The contract, though, must be signed before the services are provided so the beneficiary is fully aware of the eligible practitioner's opt-out status.) Moreover, the eligible practitioner must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The contractor's provider enrollment unit must process these affidavits.

Eligible practitioners who opt-out of Medicare are not the same as non-participating physicians/suppliers. The latter are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment-related basis as required by law (e.g., for drugs, ambulance services, etc.). Non-participating physicians/suppliers must therefore comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Opt-out eligible practitioners, on the other hand, are excused from the mandatory claim submission, assignment, and limiting charge rules, though **only** when they maintain compliance with all of the requirements for opting out.

In an emergency care or urgent care situation, an eligible practitioner who has opted-out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the eligible practitioner must complete a Form CMS-855 application.

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, chapter 15, section 40.9, the affidavit shall state that, upon signing the affidavit, the eligible practitioner agrees to the following requirements:

- Except for emergency or urgent care services, during the opt-out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;

- The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary;

- During the opt-out period, the eligible practitioner understands that he/she may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- An eligible practitioner who opts out of Medicare acknowledges that, during the opt-out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;

- On acknowledgment by the eligible practitioner to the effect that, during the opt- out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;

- Acknowledge that the eligible practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the eligible practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the eligible practitioner has not previously privately contracted) without regard to any payment arrangements the eligible practitioner may make;

- With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

- Acknowledge that the eligible practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services;

- Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and

- Be filed with all MACs that have jurisdiction over claims the eligible practitioner would otherwise file with Medicare; the initial two-year opt-out period will begin the date on which the affidavit meeting the requirements of 42 C.F.R. § 405.420 is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs his or her first private contract with a Medicare beneficiary.

(See Pub. 100-02, chapter 15, section 40.9 for more information on the requirements of opt-out affidavits. See also section 10.6.12(B)(5) below for acceptable opt-out formats.)

The contractor shall review initial opt-out affidavits to ensure that they contain the following information about the eligible practitioner in order to create an affidavit record in PECOS:

- Full name (first, middle and last),
- Birthdate,
- Address and telephone number,
- License information and
- NPI (if one has been obtained), and
- SSN (if no NPI has been issued, though note that this cannot be an individual tax identification number (ITIN)).

If, in order to create a PECOS affidavit record, the contractor needs to obtain data that is missing from an affidavit, it may (1) obtain this information from other sources (such as the state license board) or (2) contact the eligible practitioner only **one time** directly. The contractor shall **not** use Internet-based PECOS or the Form CMS-855 to secure the data from the eligible practitioner, for the eligible practitioner **is not** enrolling in Medicare. If the eligible practitioner is requested to submit missing information to permit the processing of the affidavit and fails to do so within 30 days, the contractor shall reject the opt-out affidavit.

2. Opting-Out and Ordering/Certifying/Referring

If an eligible practitioner who wishes to opt-out elects to order/certify/refer Medicare items or services, the contractor shall develop for the following information (if not provided on the affidavit):

- NPI (if one is not contained on the affidavit voluntarily);
- Date of birth, and;
- SSN (if not contained on the affidavit, though it cannot be an ITIN).

If this information is requested but not received, the eligible practitioner's affidavit can still be processed; however, he/she cannot be listed as an ordering/certifying/referring provider.

3. Adverse Actions

The contractor shall review the List of Excluded Individuals and Entities (LEIE) and the System for Award Management (SAM) for all eligible practitioners who submit opt-out affidavits. Excluded eligible practitioners may opt-out of Medicare but cannot order certify/refer.

As noted in 42 CFR § 405.425(i) and (j), individuals who are revoked from Medicare cannot order, certify, or refer Part A or B services or items to Medicare beneficiaries if they opt-out of Medicare after revocation.

4. No Dual Status

a. Form CMS-855O - Eligible practitioners cannot be enrolled via the Form CMS-855O and actively opted-out simultaneously. Prior to processing an initial Form CMS-855O or opt-out affidavit submission, therefore, the contractor shall confirm that an approved Form CMS-855O enrollment or valid opt-out affidavit does not exist in PECOS. If an approved enrollment or affidavit indeed exists, the contractor shall return the pending application.

b. Form CMS-855I – A Form CMS-855I enrollment can simultaneously exist with a valid opt-out affidavit **only** if the Form CMS-855I is to bill for emergency services. If a Form CMS-855I is received **and** an opt-out affidavit is active, the contractor shall contact the eligible practitioner (via any means) to clarify if he/she submitted the application to solely bill for emergency services provided to a beneficiary. If so, the application shall be processed via normal procedures. If not, the application may be returned. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

An eligible practitioner who has opted out of Medicare need not also enroll via the Form CMS-855O if he/she wishes to order/refer/certify (e.g., providing the necessary information on his/her affidavit per this section 10.6.12).

5. Acceptable Opt-Out Affidavit Formats

The contractor may provide a sample opt-out affidavit form for eligible practitioners to complete. The opt-out affidavit form must provide spaces for the eligible practitioners to furnish their personal information.

Eligible practitioners may also create their own affidavit. If he/she elects to do so, he/she should include information found in section 10.6.12(B)(1) to ensure timely processing of the opt-out affidavit.

The contractor and eligible practitioners may use the information below as an opt-out affidavit form.

I, {Enter Physician/Non-Physician Practitioner Name}, being duly sworn, depose and say:

- Opt-out is for a period of two years. At the end of the two year period, my opt-out status will automatically renew. If I wish to cancel the automatic extension, I understand that I must notify my Medicare Administrative Contractor (MAC) in writing at least 30 days prior to the start of the next two-year opt-out period.

- Except for emergency or urgent care services (as specified in the Medicare Benefit Policy Manual Publication 100-02, Chapter 15 §40.28), during the opt-out period I will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services.

- I will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will I permit any entity acting on my behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 40.28.

- During the opt-out period, I understand that I may receive no direct or indirect Medicare payment for services that I furnish to Medicare beneficiaries with whom I have privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under Medicare Advantage.

- I acknowledge that during the opt-out period, my services are not covered under Medicare and that no Medicare payment may be made to any entity for my services, directly or on a capitated basis.

- I acknowledge and agree to be bound by the terms of both the affidavit and the private contracts that I have entered into during the opt-out period.

- I acknowledge and understand that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by myself during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom I have not previously privately contracted) without regard to any payment arrangements I may make.

- I acknowledge that if I have signed a Part B participation agreement, that such agreement terminates on the effective date of this affidavit.

- I acknowledge and understand that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if I furnish such services.

- I have identified myself sufficiently so that the MAC can ensure that no payment is made to me during the opt-out period. If I have already enrolled in Medicare, I have included my Medicare PTAN, if one has been assigned. If I have not enrolled in Medicare, I have included the information necessary to opt-out.

- I will file this affidavit with all MACs who have jurisdiction over claims that I would otherwise file with Medicare and the initial two- year opt-out period will begin the date the affidavit meeting the requirements of 42 C.F.R. §405.420 is signed, provided the affidavit is filed within 10 days after the physician/practitioner signs his or her first private contract with a Medicare beneficiary.

Eligible practitioners should also be encouraged to include the following information (to complete an affidavit record in PECOS): NPI; Medicare Identification Number (if issued); SSN (not an ITIN); date of birth; specialty; e-mail address; any request to order/certify/refer.

C. Effective Date of an Opt-Out Period

As noted in Pub. 100-02, chapter 15, section 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

Eligible practitioners need not enroll prior to opting-out of Medicare. If a non-enrolled eligible practitioner submits an opt-out affidavit, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

2. Non-Participating Practitioners

If an eligible practitioner who is a non-participating provider decides to terminate his/her active Medicare billing enrollment and instead opt-out of Medicare, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

3. Participating Practitioners

If an eligible practitioner who is a participating provider (one who accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. *Per 42 CFR § 405.410(d), an eligible practitioner may opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in 42 CFR § 405.420 is submitted to the applicable contractor(s) at least 30 days before the beginning of the selected calendar quarter. (The contractor shall, however, add 5 calendar days to the 30-day period to allow for mailing.)* An opt-out affidavit must *therefore be submitted* at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is *submitted* within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, for the affidavit was not submitted *at least* 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain

enrolled as a participating supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, he/she must apply for enrollment via the Form CMS-855I. Once he/she receives his/her PTAN, he/she must submit the claim(s) for any emergency or urgent care service furnished. The contractor shall contact its PEOG BFL for additional guidance when this type of situation arises. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

E. Termination of an Opt-Out Affidavit

As noted in Pub. 100-02, chapter 15, section 40.35, an eligible practitioner who has not previously opted-out may terminate his/her opt-out period early. However, he/she must submit written notification thereof (with his/her signature) no later than 90 days after the effective date of the initial 2-year opt-out period. To properly terminate an affidavit, moreover, the eligible practitioner must:

1. Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of his/her opt-out);
2. Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;
3. Notify all beneficiaries (or their legal representation) with whom the eligible practitioner entered into private contracts of the eligible practitioner's decision to terminate his/her opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period and;
4. Refund to each beneficiary with whom the physician or practitioner has privately contracted all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.

For eligible practitioners who were previously enrolled to bill Medicare for services, the contractor shall reactivate the eligible practitioner's enrollment record in PECOS and reinstate his/her PTAN as if no opt-out affidavit existed. The eligible practitioner may bill for services provided during the opt-out period.

For eligible practitioners who were not previously enrolled to bill Medicare for services, the contractor shall remove the affidavit record from PECOS; this will help ensure that the eligible practitioner can submit the appropriate application(s) (via PECOS or paper Form CMS-855 for individual and/or reassignment enrollment) in order to establish an enrollment record in PECOS and thus bill for services rendered during the opt-out period.

F. Opt-Out Period Auto-Renewal and Cancellation of the Opt-Out Affidavit

1. General Policies

Eligible practitioners who initially opted-out or renewed an affidavit on or after June 16, 2015 need not submit a renewal of their affidavit. The opt-out will be automatically renewed for another 2-year period. Yet if the eligible practitioner decides to cancel his/her opt-out, he/she must submit a written notice to each contractor to which he or she would file claims (absent the opt-out) not later than 30 days before the end of the current 2 year opt-out period.

If the eligible practitioner decides to enroll in Medicare after his/her opt-out is canceled, he/she must submit a Form CMS-855I application. The effective date of enrollment, however, cannot be before the cancellation date of the opt-out period. (For example, suppose an eligible practitioner submits a cancellation of her opt-out to end the period on March 31, which is two years from the eligible practitioner's opt-out affidavit effective date. Her requested effective date of enrollment cannot be before April 1.)

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights.

2. Auto-Renewal Report and Opt-Out Renewal Alert

The contractor shall issue an Opt-Out Renewal Alert Letter (found in section 10.7.14(E) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. For this purpose, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The contractor shall access the report monthly through the Share Point Ensemble site. The contractor shall also review the opt-out report for opted-out eligible practitioners that will auto-renew in the next three-and-a-half months. In addition, the contractor shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date; the eligible practitioner will thus have at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide (1) the date on which the current opt-out period will be auto renewed and (2) the date by which the eligible practitioner will need to submit a cancellation request. The letter will also furnish the eligible practitioner appeal rights if he/she fails to submit a cancellation request and the opt-out renews.

The contractor shall (1) complete the Opt-Out Renewal Alert Letter Report to include the date the Alert Letter was issued, (2) post its reports no later than the 15th of the following month to the Share Point Ensemble site, and (3) email its PEOG BFL when the report has been posted.

If an opted-out eligible practitioner submits a Form CMS-855I and/or a CMS-855R without submitting a cancellation request of his or her opt-out, the contractor shall develop for the cancellation notice. Once the cancellation notice is received, the contractor shall then process the application(s).

If the eligible practitioner submits a cancellation request within 30 days of the end of the current opt-out period or after the opt-out period automatically renews, the contractor shall return the cancellation request to the eligible practitioner and provide appeal rights using the Late Cancellation Request return letter. In addition, if the eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date, the contractor shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

H. Failure to Properly Cancel or Terminate Opt-Out

Eligible practitioners who fail to properly cancel or terminate their opt-out may appeal the decision to continue (1) the auto-renewal of the opt-out or (2) the eligible practitioner's initial opt-out period.

Opt-out approval letters include appeal rights for eligible practitioners who initially opt-out and fail to properly terminate the opt-out within 90 days of the approval.

10.6.13 – Ordering/Certifying Suppliers

(*Rev.* 11154; *Issued: 12-10-21;* Effective: 11-13-20; Implementation: 11-13-20)

A. Ordering/Certifying Suppliers– Background

1. Who Can Order/Certify

Pursuant to CMS Final Rule 6010-F (published April 27, 2012), to order or certify for Medicare items and services, a provider or supplier must be enrolled (i.e., in an approved or valid opt-out status) in PECOS.

Generally, depending upon state law, the following physicians and non-physician practitioners are permitted to order or certify items or services for Medicare beneficiaries:

- Doctors of medicine or osteopathy
- Doctors of dental surgery or dental medicine
- Doctors of podiatry
- Doctors of optometry
- Physician assistants
- Certified clinical nurse specialists
- Nurse practitioners
- Clinical psychologists
- Certified nurse midwives
- Clinical social workers
- Residents meeting eligibility criteria (Pursuant to CMS Final Rule CMS-6010-F, residents (as defined in 42 CFR § 413.75 and which includes interns and fellows) who are enrolled in an accredited graduate medical education program in a state that licenses or otherwise enables such individual to practice or order these items or services may enroll in Medicare to order and certify).

Most physicians and non-physician practitioners enroll in Medicare so they can receive reimbursement for covered services to Medicare beneficiaries. However, some physicians and non-physician practitioners who are not enrolled in Medicare via the Form CMS-855I may wish to order or certify items or services for Medicare beneficiaries. These individuals can become eligible to do so by completing the Form CMS-855O via paper or the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) process.

NOTE: It is important to observe that physicians and non-physician practitioners that complete the Form CMS-855O do not and will not send claims to a Medicare contractor for services they furnish. They are not afforded Medicare billing privileges for the purpose of

submitting claims to Medicare directly for services that they furnish to beneficiaries. Such persons may be:

- Employed by the Department of Veterans Affairs (DVA)
- Employed by the Public Health Service (PHS)
- Employed by the Department of Defense (DOD) Tricare
- Employed by the Indian Health Service (IHS) or a tribal organization
- Employed by a federally qualified health center (FQHC), rural health clinic (RHC), or critical access hospital (CAH)
- Licensed residents and physicians in a fellowship (see subsection B)
- Dentists, including oral surgeons
- Pediatricians

B. Requirements for Suppliers to Maintain Ordering and Certifying Documentation

1. Background

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation (see next paragraph) for 7 years from the date of service, and
- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

In addition, under §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain the documentation described in the previous paragraph for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request.

If the provider, supplier, physician or eligible professional (as applicable) fails to maintain this documentation or to furnish this documentation upon request, the contractor may revoke enrollment under §424.535(a)(10).

2. Contractors Requests for Documentation of Ordering or Certifying

Absent a CMS directive to the contrary, the contractor shall request the documentation described in subsection (A) if it has reason to believe that the provider, supplier, physician or eligible professional (hereinafter collectively referred to as “provider”) is not maintaining the

documentation in accordance with §424.516(f)(1) or (2). Examples of when a request might be appropriate include, but are not limited to:

- The contractor has detected an unusually high number of denied claims involving the provider, or the Fraud Prevention System has generated an alert with respect to the provider.

- The provider has been the subject of a recent Unified Program Integrity Contractor referral.

- The provider maintains an elevated surety bond amount.

These are, of course, only examples of when a request could perhaps be warranted. Ultimately, the contractor would have to consider the surrounding circumstances of each case, including those involving situations not addressed in the aforementioned examples. The contractor may always contact its PEOG BFL if it is uncertain as to whether a particular documentation request should be made.

NOTE: Documentation cannot be requested for written orders and certifications dated prior to July 6, 2010.

3. Requirement for Providers and Suppliers to Maintain and Provide Access to Documentation

Under §424.516(f), CMS or a Medicare contractor may request access to documentation described in §424.516(f). The term "access to documentation" means that the documentation is actually provided or made available in the manner requested by CMS or a Medicare contractor. All providers and suppliers who either furnish, order, or certify the items described in section 10.6.13(B)(1) are subject to this requirement and are individually responsible for maintaining these records and providing them upon request.

For example, if a Medicare contractor requests copies of all orders for wheelchairs from an ordering physician for all beneficiaries with dates of service from November 1, 2014 through November 10, 2014, the ordering physician must provide the copies, in full, according to the specific request. If copies cannot be provided because the physician or eligible professional did not personally maintain the records or can only be partially provided, then the requirement to maintain this documentation and provide access to it will not have been met and the provider, supplier, physician, or eligible professional may be subject to the revocation basis set forth in §424.535(a)(10).

Examples of Sufficient and Deficient Access may include, but are not limited to:

Sufficient Access:

- All documentation requested

- Documentation specific to the order(s) or certification(s), as requested

- Documentation for the dates of service or billing periods requested

  Deficient Access

- Providing none of the requested documentation

- Providing none of the requested documentation

- Providing similar documentation that does not contain the order or certification requested

- Providing other documents NOT requested by CMS or a Medicare contractor and/or not specifically directing attention to the requested documentation

CMS recognizes that providers and suppliers often rely upon an employer or another entity to maintain these records on their behalf. However, it remains the responsibility of the individual or entity upon whom/which the request has been made to provide documentation. All individuals and entities subject to this documentation requirement are responsible for ensuring that documents are provided upon request and may ultimately be subject to the revocation basis associated with not complying with the documentation request.

4. Process to Request Documentation of Ordering or Certifying

If the contractor believes that a request for documentation is warranted, it shall prepare and send a request letter (refer to model letters at the end of this chapter) to the provider via certified mail. If the provider:

- Fails to respond within 30 calendar days of the contractor's request (i.e., a complete non-response), the contractor shall revoke enrollment using §424.535(a)(10) as the basis. Prior approval from the contractor's PEOG BFL is not necessary. A 1-year re-enrollment bar shall be imposed.

- Timely furnishes documentation that the contractor nevertheless deems inadequate, the contractor shall send a developmental letter via mail, e-mail or fax to the provider that requests more sufficient documentation. If the provider fails to submit such documentation (either via a complete non-response or by submitting additional inadequate documentation), the contractor shall refer the matter (including the documentation submitted to date) to its CMS PEOG BFL. CMS will determine whether a revocation is warranted and will notify the contractor via e-mail of its decision.

- Furnishes documentation that the contractor deems adequate, the contractor need not take further action other than to place the documentation and the documentation request letter(s) in the provider file.

5. Additional Guidance Regarding Documentation of Ordering or Certifying

The contractor shall also abide by the following:

a. When preparing the letter referred to in section 10.6.13(B)(4) above, the contractor shall use the appropriate model language in Section 10.7.17 and 10.7.17 (A) below. Note, however, that while the letters request copies of orders, the contractor has the discretion to ask for different or additional documentation (e.g., documentation that supports the legitimacy of a particular service or the payment of a particular claim). Copies of orders need not be requested in every situation. As alluded to in section 10.6.13(B)(2) above, the contractor would have to examine the facts of each case in determining the type(s) of documentation to be requested.

b. There may be situations in which CMS directs the contractor to request documentation in a particular case. The contractor shall follow the instructions in this section 10.6.13(B) with respect to doing so.

c. The contractor shall contact its CMS PEOG BFL if it has questions as to whether particular submitted documentation is adequate or legitimate – specifically, whether it falls within the category of documentation described in section 10.6.12(B)(3) above.

10.6.14 – Application Fees

(Rev. 11154; Issued: 12-10-21; Effective: 01-01-22; Implementation: 01-03-22)

A. Background

Pursuant to 42 CFR § 424.514 - and with the exception of physicians, non-physician practitioners, physician group practices, non-physician group practices, *and Medicare Diabetes Prevention Program (MDPP) suppliers* – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR § 424.515 (regardless of whether the revalidation application was requested by CMS or voluntarily submitted by the provider or supplier), must submit with their application:

- An application fee in an amount prescribed by CMS, and/or
- A request for a hardship exception to the application fee.

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR § 424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations), Form CMS-855S, or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. A physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

For a list of fee requirements broken out by provider/supplier and application type, refer to the Application Fee Matrix.

Except as otherwise noted, nothing in this section 10.6.14 supersedes any other CMS directive to the contractor pertaining to application fees.

(For purposes of this section 10.6.14, the term "provider" will be used in lieu of "institutional provider.")

B. Contractor Activities Upon Receipt

Upon receipt of a paper or Internet-Based PECOS application from a provider that is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

1. Determine whether the provider has: (1) paid the application fee via Pay.gov (all payments must be made via Pay.gov); and/or (2) included a hardship exception request with the application or certification statement.

2. Outcomes

a. The provider has neither paid the fee nor submitted the hardship exception request- - The contractor shall send a development letter to the provider notifying it that: (i) it has 30 days from the date of the letter to pay the application fee via Pay.gov and any other items that may be missing or needed; and (ii) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations).

b. The provider has submitted a hardship exception request but has not paid a fee - The contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. If CMS:

- Denies the hardship exception request – CMS will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall determine whether the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR § 424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR § 424.535(a)(6) (revalidations).

(If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.)

- Approves the hardship exception request - CMS will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall continue processing the application as normal.

c. Has submitted a hardship exception request and has paid a fee - The contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. As the fee has been paid, the contractor shall begin processing the application as normal.

C. Fee Amount

The application fee must be in the amount prescribed by CMS for the calendar year (1) in which the application is submitted (for Internet-based PECOS applications) or (2) of the postmark date (for paper applications). The current fee amount can be found via PECOS at the following link: https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do

Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year. CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

D. Non-Refundable

Per 42 CFR § 424.514(d)(2)(v), the application fee is non-refundable unless it was submitted with one of the following:

1. A hardship exception request that is subsequently approved;

2. An application that was rejected prior to the contractor's initiation of the screening process, or

3. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR § 424.570.

(For purposes of section 10.6.14(D) only, the term "rejected" includes applications that are returned.)

In addition, the fee should be refunded if: (i) it was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number); or (ii) it was not part of an application submission.

E. Format

The provider must submit the application fee electronically through https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do, either via credit card, debit card, or electronic check.

Should the provider submit an application with a paper check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in section 10.4(C) of this chapter (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via.Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.

F. Practice Locations

DMEPOS suppliers, federally qualified health centers (FQHCs), independent diagnostic testing facilities (IDTFs), and certain other provider and supplier types described in this chapter must individually enroll each site. The enrollment of each site thus requires a separate fee. For **all other providers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. (This includes the addition of a hospital unit – such as a psychiatric unit – in the Practice Location section of the Form CMS-855A.) If multiple locations are being added on a single application, however, only one fee is required; indeed, the fee for providers that are not required to separately enroll each location is based on the application submission, not the number of locations listed on a single application.

G. Other Application Fee Policies

1. PECOS Enrollment Records

The fee is based on the Form CMS-855 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In the Identifying Information/hospital type section of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.

2. Group Practices/Clinics

A physician/non-physician practitioner clinic or group practice enrolling via the Form CMS-855B is exempt from the fee even if it is tribally-owned/operated or hospital-owned. Yet if a hospital is adding a physician/non-physician practitioner clinic or group practice to its Form CMS-855A enrollment, a fee is required because the hospital is adding a practice location.

3. Change of Ownership via Form CMS-855B or Form CMS-855S

A provider or supplier need not pay an application fee if the application is reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

4. Reporting a Change in Tax Identification Number

A provider need not pay an application fee if the application is reporting a change in TIN for a Part A, Part B, or DMEPOS provider or supplier.

5. Requesting a Reactivation

A provider need not pay an application fee to reactivate Medicare billing privileges unless the provider/supplier was deactivated for failing to respond to a revalidation request, in which case the resubmitted application constitutes a revalidation (not a reactivation) application, hence requiring a fee.

6. Changing the Physical Location of an Existing Practice Location

A provider need not pay an application fee when changing the physical location of an existing practice location (as opposed to reporting an additional/new practice location).

The application fee requirement is separate and distinct from the site visit requirement and risk categories discussed in this chapter. Physicians, non-physician practitioners, physician groups, and non-physician practitioner groups are exempt from the application fee even if they fall within the "high" level of categorical screening per 42 CFR § 424.518. Likewise, physical therapists enrolling as individuals or group practices need not pay an application fee even though they fall within the "moderate" level of categorical screening and are subject to a site visit.

H. Refund Requests

Unless otherwise approved by CMS, the provider must request a refund no later than 150 days from the date it submitted its application. In its request, the provider shall include documentation acceptable to process the refund request. For credit card refunds, the provider shall include its Pay.gov receipt or the Pay.gov tracking ID number.

If a refund is requested and the fee was paid via ACH Debit, the contractor shall collect from the provider a completed "Authorization and Payment Information Form for Electronic Funds Transfer" form (previously furnished to contractors) and submit it to the PEMACReports@cms.hhs.gov mailbox. In the subject line of this e-mail, the contractor shall: (1) identify the provider's legal business name, National Provider Identifier (NPI), and the Pay.gov Tracking ID; and (2) include the completed, previously-mentioned form.

I. Institutional Provider and Fee: Year-to-Year Transition

There may be isolated instances where, at the end of a calendar year, a provider pays the fee amount for that year (Year 1) but the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider must pay the Year 2 fee. The contractor shall thus: (1) send an e-mail to its PEOG

BFL requesting a full refund of the fee and including any pertinent documentation in support of the request; and (2) send a letter to the provider notifying it that (i) it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) via Pay.gov and (ii) failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

J. Hardship Exception

1. Background

A provider requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via Internet-based PECOS, the hardship exception letter must accompany the certification statement. Hardship exception letters shall not be considered if they were submitted separately from the application or certification statement, as applicable. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider; and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee generally should not represent a significant burden for an adequately capitalized provider. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including furnishing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that may suggest that a hardship exception is appropriate include the following:

a. Considerable bad debt expenses,

b. Significant amount of charity care/financial assistance furnished to patients,

c. Presence of substantive partnerships (whereby clinical and/or financial integration are present) with those who furnish medical care to a disproportionately low-income population,

d. Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or

e. Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application or certification statement, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. CMS has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's

application. CMS will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 10.6.14(K) below.

If the provider fails to submit appropriate documentation to support its request, the contractor need not contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG BFL. It is ultimately the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

K. Appeals of Hardship Determinations

A provider may appeal CMS' denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with CMS' decision to deny a hardship exception request, it may file a written reconsideration request with CMS within 60 calendar days from receipt of the notice of initial determination (e.g., CMS' denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity. Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop: AR-18-50
Baltimore, MD 21244-1850

Notwithstanding the filing of a reconsideration request, the contractor shall still implement the post-hardship exception request instructions in this section 10.6.14(K). A reconsideration request, in other words, does not stay the implementation of section 10.6.14(K)'s instructions.

CMS has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be: (a) conducted by a CMS staff person who was independent from the initial decision to deny the hardship exception request; and (b) based on CMS' review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, CMS will send a letter to the provider to acknowledge receipt of its request. In its acknowledgment letter, CMS will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

If CMS denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If CMS approves the reconsideration request, it will notify the provider of this via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

i. If the application has already been rejected, request that the provider resubmit the application without the fee, or

ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request but the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request but the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail, or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such requests shall be filed within 60 days from receipt of the notice of the DAB's decision.