CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12639	**Date: May 16, 2024**
	Change Request 13551

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to address several provider enrollment topics, including certified provider/supplier enrollment and revised model letters.

EFFECTIVE DATE: June 17, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 17, 2024
Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/Table of Contents
R	10/10.1/10.1.1/Definitions
D	10/10.1/10.1.1.1/Additional Definitions
R	10/10.1/10.1.4/General Overview of Medicare Enrollment Application Forms
R	10/10.2/10.2.1.3/End-Stage Renal Disease Facilities (ESRDs)
R	10/10.2/10.2.1.4/Federally Qualified Health Centers (FQHCs)
R	10/10.2/10.2.1.11/Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.2.5/Intensive Cardiac Rehabilitation (ICR)
R	10/10.2/10.2.3.9/Occupational Therapists in Private Practice
R	10/10.2/10.2.3.10/Physical Therapists in Private Practice
R	10/10.2/10.2.3.12/Physician Assistants
R	10/10.2/10.2.3.18/Mental Health Counselors (MHCs)
R	10/10.2/10.2.7/Opioid Treatment Programs
R	10/10.3/10.3.1.1.2/Section 2 (Identifying Information) - Form CMS-855A
R	10/10.3/10.3.1.1.4/Section 4 (Practice Location Information) - Form CMS-855A
R	10/10.3/10.3.1.3/Form CMS-855I – Medicare Enrollment Application for Physicians and Non-Physician Practitioners
R	10/10.3/10.3.1.3.1/Section 1 (Basic Information) – Form CMS-855I
R	10/10.3/10.3.1.3.2/Section 2 (Personal Identifying Information) – Form CMS-855I
R	10/10.3/10.3.1.3.4/Section 4 (Business Information) - Form CMS-855I
R	10/10.3/10.3.1.4/Reassignment of Medicare Benefits Via the Form CMS-855I
D	10/10.3/10.3.1.4.1/Sections 1 through 5 of the Form CMS-855R
D	10/10.3/10.3.1.4.2/Section 6 (Certification Statements and Signatures) - Form CMS-855R
D	10/10.3/10.3.1.4.3/Additional Form CMS-855R Policies and Processing Alternatives
R	10/10.3/10.3.2.1/CMS-20134 (Section 1 - Basic Information)

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.4/10.4.1.2/Receipt of Application
R	10/10.5/Timeliness and Accuracy Standards
R	10/10.6/10.6.1.2/Changes of Information – Transitioned Certified Providers and Suppliers
R	10/10.6/10.6.2/Establishing Effective Dates
R	10/10.6/10.6.7.1/Organizational Owning and Managing Information
R	10/10.6/10.6.7.2/Individual Owning and Managing Information
R	10/10.6/10.6.9/Contact Persons
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.6/10.6.21/Miscellaneous Enrollment Topics
R	10/10.6/10.6.21.1/Additional Miscellaneous Enrollment Topics
R	10/10.7/10.7.19/ESRD Approval Letters

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: 12639	Date: May 16, 2024	Change Request: 13551

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

EFFECTIVE DATE: June 17, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 17, 2024

I. GENERAL INFORMATION

A. Background: Chapter 10 of Pub. 100-08 outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR clarifies several provider enrollment topics, including certified provider/supplier enrollment, reassignments, and model letters.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13551.1	The contractor shall observe and adhere to the applicable policy changes outlined in this CR.	X	X	X						NPEAST, NPWEST
13551.2	The contractor shall observe the edits to the various model letters included in this CR.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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

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. 12639; Issued: 05-16-24)

Transmittals for Chapter 10

10.1.1 – Definitions

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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. *For purposes of this definition only, the term "organization" means the enrolling entity as identified by its legal business name and tax identification number.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Final adverse legal action means the following:

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

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

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

(3) Revocation or suspension by an accreditation organization;

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

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

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

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

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

Exclusions, Revocations, or Suspensions

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

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

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

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier; or

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

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. For purposes of this definition of managing employee, this includes, but is not limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director.

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

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

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

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

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

Other eligible professional – as defined in 1848(k)(3)(B) of the Social Security Act – means: (i) a physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) a qualified audiologist (as defined in section 1861(ll)(3)(B)). (For (ii), "practitioner" is defined in section 1842(b)(18)(C) as a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional.)

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

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

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

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

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

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

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

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

health center that has in effect a similar agreement but only to furnish partial hospitalization services.

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

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

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

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

Supplier *means (for purposes of 42 CFR Part 424, subpart P) all the following:*

(1) The individuals and entities that qualify as suppliers under § 400.202
(2) Physical therapists in private practice
(3) Occupational therapists in private practice
(4) Speech-language pathologists

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.

10.1.4 - General Overview of Medicare Enrollment Application Forms

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

The enrollment applications are available online as well as in paper form:

A. General Overview of Form CMS-855 and CMS-20134

Each Form CMS-855 application is used to enroll a specific provider or supplier type for a specific purpose.

1. CMS-855A – Medicare Enrollment Application for Institutional Providers

This application should be completed by institutional providers (e.g., hospitals) that will furnish Medicare Part A services to beneficiaries.

2. CMS-855B –Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers

This application should be completed by supplier organizations (e.g., ambulance companies) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.

3. CMS-855I - Medicare Enrollment Application for Physicians and Non-Physician Practitioners

This application should be completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries. (This includes a physician or practitioner who is: (1) the sole owner of a professional corporation, professional association, or limited liability company and will bill Medicare through this business entity; or (2) a sole proprietor.) (See section 10.6.4 of this chapter for more information on the business types discussed in this paragraph.) *The CMS-855I captures reassignment information that was previously collected via the CMS-855R, which has been discontinued.*

***4*. CMS-855S – Medicare Enrollment Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers**

This application should be completed by DMEPOS suppliers.

***5*. CMS-855O – Medicare Enrollment Application for Eligible Ordering, Certifying Physicians, and other Eligible Professionals**

This form is used for physicians and other eligible professionals who wish to register in Medicare solely for the purpose of ordering and certifying the items and services described in 42 CFR § 424.507. These physicians and other eligible professionals do not and will not send claims to a MAC for any services they furnish.

***6*. CMS-20134 – Medicare Enrollment Application for Medicare Diabetes Prevention Program (MDPP) Suppliers**

This application should be completed by any supplier organizations that will furnish and bill Medicare Part B for the MDPP services furnished to Medicare beneficiaries.

B. General Overview of Additional Enrollment Forms

The following forms or form types are routinely submitted with an enrollment application:

1. CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement

The EFT Agreement authorizes CMS to deposit Medicare payments directly into a provider/supplier's bank account.

For Form CMS-855S enrollments, CMS only requires collection of the Form CMS-588 with initial enrollment applications.

2. CMS-460 – Medicare Participating Physician or Supplier Agreement

This agreement establishes that the Medicare provider/supplier accepts assignment of the Medicare Part B payment for all services for which the participant is eligible to accept assignment under the Medicare law and regulations and which are furnished while the agreement is in effect. The contractor shall explain to the provider or supplier the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to suppliers that complete the Forms CMS-855B, CMS-855I and CMS-855S.)

3. CMS Standard Electronic Data Interchange (EDI) Enrollment Form

See CMS Publication 100-04, Medicare Claims Processing Manual, chapter 24, sections 30 - 30.5 for further information.

4. State-Specific Forms for Certified Providers/Certified Suppliers

If the applicant is a certified supplier or certified provider, it will need to contact the state agency for any state-specific forms and to begin preparations for a state survey. (This does not apply to those certified entities, such as federally qualified health centers, that do not receive a state survey.)

10.2.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

(In this section 10.2.1.3, the terms "ESRD" and "ESRD facility" have the same meaning and will be used interchangeably).

A. General Background Information

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

The provider-based rules for ESRD facilities are outlined in 42 CFR § 413.174 and are slightly different than those in the main provider-based regulation (42 CFR § 413.65). (For instance, § 413.174 uses the term "hospital-based" as opposed to "provider-based.")

The ESRD Network is a group of organizations under contract with CMS that serve as liaisons between the agency and ESRD providers. The organizations oversee the care that ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

B. Types of ESRD Facilities

Pub. 100-07, State Operations Manual, lists several classifications of ESRD facilities. They are summarized as follows:

1. Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that (1) is an outpatient department of a hospital and (2) meets the ESRD conditions of coverage at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CCN and be separately enrolled.

A hospital-based ESRD facility is discussed at 42 CFR § 413.174(c) and must meet the criteria listed therein (e.g., ESRD facility and hospital have a common governing body and are financially integrated). Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

2. Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility: (1) is separately certified and surveyed; (2) must independently meet the ESRD conditions of coverage; (3) is assigned its own CCN; and (4) be separately enrolled. Satellite renal dialysis facilities (hospital-based) are assigned CCNs in the 3500-3699 series.

3. Independent Renal Dialysis Facility

An independent renal dialysis facility is any outpatient ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but it is not owned and/or administered by the hospital. Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series and are individually enrolled.

4. Special Purpose Renal Dialysis Facility (SPRDF) (§ 494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e., up to 8 months in any 12-month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area. The SOG Location must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications. The special locations for SPRDF fall into two categories:

(A) Vacation Camps - Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding interruption of the camping experience. Vacation camps may be approved for the duration of the camp but up to a maximum of 8 months in any 12-month period.

(B) Emergency Circumstance SPRDFs - These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their geographical area resulting from a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location. The CMS SOG Location may extend the time-period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

SPRDFs are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities. Although they are individually enrolled, they cannot convert to a permanent ESRD facility (i.e., to a non-SPRDF). They must instead reapply as a brand new ESRD facility and receive an initial certification survey.

C. Processing Instructions for ESRD Initial Form CMS-855A Applications

An ESRD facility is separately and individually certified and does not have any branch, multiple, or parent locations. As such, each type of ESRD facility/location must independently and separately enroll as such via the Form CMS-855A; multiple sites cannot be listed on a single application.

Note that the instructions in this section 10.2.1.3(C) apply to all ESRD facility types except for SPRDFs. This ESRD type is not "transitioning" as that term is described in this chapter. Accordingly, the contractor shall continue to process initial applications from SPRDFs consistent with longstanding instructions rather than those described in this section 10.2.1.3(C) (e.g., receiving the final approval from the SOG location rather than the state; no need to send the application to PEOG after final SOG location approval).

1. Receipt of Application

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

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

(B) Ensure that the application(s) is complete consistent with the instructions in this section 10.2.1.3 and this chapter.

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

- Part I of the Form CMS-3427A (End Stage Renal Disease Application and Survey and Certification Report) (See Pub. 100-07, chapter 2, section 2274B for more information on this form.)

- A certificate of need (CON) if required by state law (though SPRDFs need not submit a CON)

(The ESRD must complete and submit Part I of the Form CMS-3427A, though the ESRD need not complete those sections of the form reserved for CMS. For organizational ESRDs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign. Note that there is no provider agreement for ESRD facilities; the Form CMS-3427A is a survey and certification document, not a provider/supplier agreement.)

Notwithstanding the foregoing, if Part I of the Form-CMS-3427A and/or CON evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon. (Nor need the contractor: (1) research individual state laws to ascertain whether the state requires a CON; or (2) review the data on the CON.) The contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.3(C) prohibits the contractor from returning or rejecting the ESRD application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.3(C) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4) contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the ESRD, however, the timeframe is 15

business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof----typically via the Form CMS-1539, although the contractor may accept any notification that is in writing (e-mail is fine). No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.1.3(C)(2)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

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

(As required per section 10.6.21 of this chapter, the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.))

PEOG will review the documentation. Based on the information received from the contractor, PEOG will also (1) assign an effective date, (2) assign a CCN, and (3) enter the relevant data into the applicable national database, and (4) approve (with possible edits) the approval letter. Within 5 business days of receiving from PEOG the effective date, and CCN the contractor shall: (1) send the approval letter to the ESRD provider, with a copy to the state and/or AO (as applicable); and (2) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

D. Additional/Changed Stations

If an enrolled ESRD seeks to add/change services or stations (e.g., add ESRD services in SNFs, additional modalities), the ESRD need not submit a Form CMS-855A application to do so, for these services and stations do not constitute practice locations and cannot otherwise be reported on the application. Instead, the ESRD contacts the state or accreditation organization (AO) to request these changes. The ESRD must complete a Form CMS-3427 and submit it to the state or AO (as applicable). A survey may be performed, and the state will update the applicable national database with any administrative changes.

The state will also send a CMS-1539 or approval letter to the contractor as notification of the additional/change service(s) or station(s). When the contractor receives such a notice, it shall abide by the following:

- As applicable, and consistent with longstanding practice, the contractor shall enter all relevant data into PECOS. No referral to or prior approval from PEOG is necessary. However, the contractor may contact its PEOG BFL if it has questions regarding the Form CMS-1539 or the supplier's PECOS record.
- For situations involving new/expanded/changed ESRD stations, the contractor shall send to the supplier the "ESRD Service Station/Modality Changes" letter identified in section 10.7.19 of this chapter. (The state and, as applicable, the AO shall be copied on said letter.)

E. ESRD Location Changes

An ESRD facility that is changing its location must submit either a Form CMS-855A change of information application or an initial enrollment application. The specific transaction type involved (change request or initial) will depend on the particular situation. These situations include the following, and they will generally trigger the termination of the ESRD's existing CCN and the issuance of a new one.

(i) A hospital-based ESRD facility is relocating to an off-campus location in the same state.

In this situation, the ESRD's current CCN will be retired.

If the off-campus location will still function under a common governing body, operate under the hospital's policies and practices, continue to serve the same community, and utilize the same staff at this new location, the new CCN will be that of a renal satellite facility. The application can be processed as a change of information pursuant to the instructions in section 10.6.1.2(A).

If the off-campus location will no longer be operationally, administratively, or financially integrated with the hospital, the new CCN will be that of an independent dialysis facility. The hospital must voluntarily terminate this location from its enrollment, and the site must enroll as a new ESRD facility.

If the contractor has any questions as to whether the relocated location will still be sufficiently integrated with the hospital to permit a change of information application rather than an initial enrollment, the contractor may contact the state for guidance. The processing time clock stops while the contractor awaits the state's guidance.

(ii) An independent ESRD facility is relocating to become a hospital-based facility or a renal satellite facility of a hospital

Since the ESRD facility will be serving a different community under different policies, etc., the facility must terminate its existing enrollment and enroll as a new ESRD facility.

(iii) An independent ESRD facility is relocating to another location and will remain independent

If the ESRD facility will be serving a different community, the facility must terminate its existing enrollment and enroll as a new/initial ESRD facility. If it will serve the same community, the relocation can be processed as a change of information.

(iv) ESRD facility relocating out-of-state

If an ESRD facility of any type (e.g., independent, satellite) is relocating out-of-state --- and notwithstanding any other instruction to the contrary in this chapter ---- it must terminate its existing enrollment and enroll as an initial/new applicant.

F. CHOWs and Changes of Information

For ESRD CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter. For ESRD changes of information, the contractor shall follow the instructions in section 10.6.1.2 of this chapter.

G. New ESRD Model Letters

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use the applicable ESRD letters in section 10.7.19 of this chapter for initial enrollments and state-approved changes of ownership.

H. Beds and Services

A Form CMS-3427 from the state must be included with an initial or CHOW Form CMS-1539 that identifies, as applicable, the services or number of beds at issue. If, nonetheless, this data is not furnished by the state to the contractor for an initial or CHOW application, the contractor may secure it from the state (or, for CHOWs, and as applicable, the AO).

I. ESRD Survey, Certification, *and Modalities*

As previously indicated, the standard CMS survey and certification form used for ESRDs is the Form CMS-3427. *The modalities listed on the Form CMS-3427 are:*

- *In-center Hemodialysis (HD)*
- *In-center Peritoneal Dialysis (PD)*
- *In-center Nocturnal HD*
- *Home HD Training & Support*
- *HD in LTC*
- *Home PD Training & Support*
- *PD in LTC*
- *Dialyzer Reuse*

For further information on ESRD facilities, refer to:

- Section § 1881 of the Social Security Act

- 42 CFR Part 405, Subpart U

- Pub. 100-07, chapter 2, section 2270 – 2287B
- Pub. 100-02, chapter 11
- Pub. 100-04, Claims Processing Manual, chapter 8

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Statutory Background

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

B. Requirements

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

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

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

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

- Is receiving a grant under § 330 of the Public Health Service (PHS) Act;
- Is receiving funding under a contract with the recipient of a § 330 grant, and meets the requirements to receive a grant under § 330 of the PHS Act;
- Is an FQHC "Look-Alike" (i.e., HRSA), has notified it that it meets the requirements for receiving a § 330 grant, even though it is not actually receiving such a grant);
- Was treated by CMS as a comprehensive federally funded health center as of January 1, 1990; or

- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

C. Initial FQHC Applications

1. Contractor Review and Required Documents

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

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

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

2. General Processing Concepts

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

(B) Date on the NOA - The project period (*Line 26* of the NOA) *and budget period (Line 19 of the NOA)* must be valid through the date on which the FQHC's application was complete

(as determined by the contractor). *For the HRSA Look-Alike document, the designation period (Line 6) and Annual Certification Period (Line 7) must be valid through the date on which the FQHC's application was complete (as determined by the contractor).* The contractor shall develop for a correct NOA date(s) if *either* the project period or budget period *(or designation period and annual certification period)* do not meet the above-mentioned requirement. (In developing for this data, the contractor may (but is not required to) send the "Reminder and Assistance for Health Centers for CMS FQHC Site Enrollment" guidance to the FQHC.)

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

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

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

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

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

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

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

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

3. Determination

a. Approval

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

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

b. Denial

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

4. Post-PEOG Review and Response to Contractor

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

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

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

- Make any necessary revisions to the draft approval letter

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

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

5. Post-Approval Contractor Action

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

D. Changes of Information

1. Location Changes

a. Verification

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

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

(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 (NOA), IHS website, etc., must match that listed on the Form CMS-855A change request. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter. In addition, both the budget date and the project date on the NOA *(or designation period and annual certification period on the Look-Alike document)* must be valid through the date on which the FQHC's change request application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if *either* the project period and/or budget period *or the designation period and/or annual certification period* do not meet the *above*-mentioned requirement.

b. Approval

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

c. Denial

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

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

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

3. All Other Change Requests

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

E. Changes of Ownership (CHOWs)

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

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

- The "provider agreement" for FQHCs is the Exhibit 177.
- No recommendations to the state or SOG Location are involved. The contractor and PEOG alone will handle the transaction. In particular, the contractor---in lieu of making a recommendation to the state/SOG Location---will send its "final analysis" to PEOG. PEOG will then: (i) review the transaction; (ii) determine whether the CHOW should be approved; (iii) as needed, update ASPEN and perform any other related tasks; and (iv) notify the contractor of the results of its review and provide any required direction. The above-described process, in effect, combines a recommendation to the state/SOG Location and the contractor's post-recommendation e-mail to PEOG (described in section 10.6.1.1.3.3(B)) into a single step. For purposes of this section 10.2.1.4(E), the term "final analysis" (in the context of FQHC CHOWs) is roughly the equivalent of a recommendation to the state. Accordingly, when sending its "final analysis" to PEOG as described above, the contractor may—but is not required to—change the application's status in PECOS to "approval recommended."

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

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

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

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

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

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

1. Special Processing Steps

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

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

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

- Exhibit 177 containing the new owner's information.

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

b. Old and New Owner Applications

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

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

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

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

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

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

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

d. Intervening Change of Ownership

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

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

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

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

- Return the CHOW application.

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

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

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

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

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

2. Post-Initial Review Actions and Scenarios

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

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

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

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

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

F. Timeframes and Alternatives

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

G. Supporting Documentation

1. Revalidations

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

2. Initial Applications, CHOWs, and Location Changes

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

H. Revocations and Other Transactions

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

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

I. Complaint Investigations

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

J. FQHC DPV Errors

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

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

K. Additional Data

For additional general information on FQHCs, refer to:

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

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

10.2.1.11 - Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. General Background Information

Physical therapists and speech pathologists provide therapy targeting a person's ability to move and perform functional activities in their daily lives typically inhibited by illness or injury. Care is typically coordinated by therapists in conjunction with a physician and is based on an agreed upon plan of care.

As explained in Pub. 100-07, chapter 2 section 2292, there are three types of organizations that may qualify as providers of OPT and OSP services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CCN. The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability and to tailor a rehabilitation program to meet the specific rehabilitation needs of each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. Social/vocational services are no longer a requirement.

Note that:

- If an OPT/OSP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. An initial Form CMS-855A enrollment application, state survey, and CMS program approval are also required.

- Only those OTP/OSP providers covered under 42 CFR Part 485, Subpart H that furnish OPT/OSP services (as listed above) have provider agreements under 42 CFR § 489.2. Part B physician groups – the supplier type that most people normally associate with the term "clinics" – do not have certified provider or certified supplier agreements.

- Occupational therapy cannot be substituted for the physical therapy requirement. It may, however, be provided in addition to physical therapy or speech pathology services. (See Pub. 100-07, chapter 2, section 2292A.)

There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider if they are not operating in the same space at the same time. (See Pub. 100-07, chapter 2, section 2304.)

B. Processing Instructions for OPT/OSP Initial Form CMS-855A Applications

1. Receipt of Application

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

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

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

(C) Ensure that the OPT/OSP has submitted all documentation otherwise required per this chapter. For OPT/OSP initial enrollment, this also includes the following:

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

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

(The OPT/OSP must complete, sign, date, and include the Form CMS-1561, though the OPT/OSP need not complete those sections of the form reserved for CMS. For organizational OPT/OSPs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

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

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.11(B) prohibits the contractor from returning or rejecting the OPT/OSP application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.11(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The

contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification the contractor shall commence the actions described in section 10.2.1.11(B)(2)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

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

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

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

C. Extension Locations

1. Background

As discussed in Pub. 100-07, chapter 2, sections 2298 and 2298A, an OPT/OSP provider can, in certain instances, furnish services from locations other than its primary site. (The provider must designate one location as its primary location on the Form CMS-855A, however.) These sites are called extension locations. An extension location is defined at 42 CFR § 485.703 as "a location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency." Per Pub. 100-07, chapter 2, section 2298A, only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations. These two providers must provide outpatient therapy services at their Medicare approved location.

An OPT/OSP provider may also furnish therapy services in a patient's home or in a patient's room in a SNF. (See Pub. 100-07, chapter 2, section 2300. Note that when the OPT provides services away from the primary site or extension location(s), this is referred to as "off-premises activity" at other locations. Section 2300 (referenced) above discusses such activities.) Because these are not considered extension locations, neither the home nor the patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, chapter 2, section 2298B.)

OPT/OSP extension sites fall under the parent's Medicare provider agreement and CCN. They are assigned and identified by a unique 10-digit alphanumeric identification number (also sometimes referred to as a "Medicare Branch ID") linked to the parent CCN. PEOG is responsible for the assignment or termination of OPT/OSP extension site identifiers and for updating ASPEN accordingly.

2. Extension Site Changes

All extension site additions, deletions, changes, and relocations require a Form CMS-855A change of information application.

a. Additions

Addition of an extension site requires a referral to the state and thereafter to PEOG to review for final determination prior to approval. The approval letter sent to the OPT/OSP provider, with a copy to the state and/or AO, should include the assigned Medicare Branch ID and the effective date of the added extension site. The effective date of coverage for services provided from the extension site is the date CMS determines that the extension site meets all applicable federal requirements.

b. Deletions, Changes, and Revisions

Deletions, changes, and revisions do not require a referral to the state but do require post approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) per section 10.6.1.2(B) of this chapter.

D. CHOWs

For OPT/OSP CHOWs, the contractor shall follow the instructions in section 10.6.1.1 of this chapter.

E. Additional Information

For more information on OPT/OSP providers, refer to:

- Section 1861(p) of the Social Security Act
- 42 CFR Part 485, subpart H
- Pub. 100-07, chapter 2, sections 2290 – 2308
- Pub. 100-07, Appendix E

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

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

First, the tests they perform do not involve direct patient interaction, meaning that the test is conducted away from the patient's physical presence and is non-invasive. Second, the test involves off-site computer modeling and analytics.

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

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

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

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

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

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

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

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

iii. Synopsis

In sum:

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

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

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

- It must meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). **An IDTF must 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 above-mentioned 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).

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

B. IDTF Standards

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

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

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

- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in

the licensure requirements. No exemptions to applicable state licensing requirements are permitted, except when granted by the state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Ensure that the insurance policy 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 (excluding 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-855*I reassignment application* 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 these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while another supervising physician can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all supervising physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervising physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

M. IDTF - Information about Supervising Physicians

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

In addition:

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

space-sharing prohibition in 42 CFR § 410.33(g) does not apply in this particular scenario.

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

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

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

P. IDTF - Changes of Supervising Physicians

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

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

Q. Desk and Site Reviews

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

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

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

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

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

R. Mobile Units

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

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

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

- What their responsibilities are; and

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

S. Addition of Codes

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

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

If the enrolled IDTF (1) originally listed only general supervision codes, (2) was only reviewed for general supervision tests, and (3) now wants to perform tests that require direct or personal supervision, the contractor shall promptly suspend all payments for all codes other than those requiring general supervision. The contractor shall order an NSVC site visit through PECOS. All IDTF claims for the additional procedures shall be suspended until the

IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were 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.

10.2.2.5 – Intensive Cardiac Rehabilitation (ICR)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

A. Background

Under 42 CFR § 410.49(a), an intensive cardiac rehabilitation (ICR) program is defined as a physician *or non-physician practitioner*-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c). (*Nonphysician practitioners are eligible to supervise an ICR effective January 1, 2024.)*

ICR programs must be approved by CMS through the national coverage determination (NCD) process and must meet certain criteria for approval. Individual sites seeking to provide ICR services via an approved ICR program must enroll with their local Medicare contractor as an ICR program supplier.

B. ICR Enrollment

To enroll as an ICR site, a supplier must complete a Form CMS-855B with the supplier type of "Intensive Cardiac Rehabilitation" selected. The contractor shall verify that CMS has approved the ICR program through the NCD process. A list of approved ICR programs will be identified through the NCD listings, the CMS Web site, and the Federal Register. The contractor shall use one of these options to verify that the ICR program has met CMS approval.

An ICR supplier must separately and individually enroll each of its practice locations. The supplier can therefore only have one practice location (which shall receive its own Provider Transaction Access Number (PTAN)) on its Form CMS-855B enrollment application. The contractor shall use specialty code 31 for these enrollments.

The contractor may accept and process reassignments to ICRs from physicians and nonphysicians who are otherwise authorized to reassign benefits under existing law and policy.

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

- 42 CFR § 410.49
- Pub. 100-04, chapter 32, sections 140.2.2 - 140.2.2.6
- Pub. 100-02, chapter 15, section 232

10.2.3.9 – Occupational Therapists in Private Practice

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Regulatory Requirements - Occupational Therapist in Private Practice

Section 42 CFR § 410.59(c)(*1*)(i) through (iv) state that an occupational therapist in private practice must meet all the following:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the state in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: (A) solo practice; (B) a partnership; (C) group practice; or (D) as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. (A therapist's private practice office space refers to the location(s) where the practice is operated in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, such space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a critical access hospital, or a SNF.))

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

B. Qualified Occupational Therapist Requirements

Pub. 100-02, chapter 15, section 230.2(B) states that a qualified occupational therapist is an individual who meets the requirements in one of the four categories below:

Category #1 – The occupational therapist: (i) is licensed (if licensure applies) or otherwise regulated (if applicable) as an occupational therapist by the state in which practicing; (ii) graduated from an accredited education program for occupational therapists; and (iii) is eligible to take or has passed the examination for occupational therapists administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). The phrase “by the state in which practicing” includes any authorization to practice provided by the same state in which the service is furnished (including temporary licensure), regardless of the location of

the entity billing the services. The education program for U.S. trained occupational therapists is accredited by the Accreditation Council for Occupational Therapy Education (ACOTE).

The requirements above apply to all occupational therapists effective January 1, 2010 if the occupational therapist has not met any of the following requirements prior to January 1, 2010.

Category #2 - On or before December 31, 2009, the individual --

(a) Is licensed or otherwise regulated as an occupational therapist in the state in which practicing (regardless of the qualifications they met to obtain that licensure or regulation); or

(b) When licensure or other regulation does not apply--

(i) Graduated from an occupational therapist education program accredited by ACOTE; and

(ii) Is eligible to take, or has successfully completed, the NCBOT examination for occupational therapists.

Category #3 - On or before January 1, 2008 (and if the individual met the Medicare requirements for occupational therapists that were in 42 CFR § 484.4 prior to January 1, 2008), the individual--

(a) Graduated from an occupational therapy program approved jointly by the American Medical Association and the American Occupational Therapy Association (AOTA); or

(b) Is eligible for the National Registration Examination of AOTA or NBCOT.

Category #4 - On or before December 31, 1977, the individual--

(a) Had 2 years of appropriate experience as an occupational therapist; and

(b) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

C. Occupational Therapist Educated Outside the United States

Pub. 100-02, chapter 15, section 230.2(B) states that individuals educated outside the U.S. may meet the same qualifications as domestic trained occupational therapists. For example, the individual qualifies if he or she was licensed or otherwise regulated by the state in which practicing on or before December 31, 2009. The individual also qualifies if he or she:

- Graduated from an occupational therapy education program accredited as substantially equivalent to a U.S. occupational therapy education program by ACOTE, the World Federation of Occupational Therapists, or a credentialing body approved by AOTA;

- Passed the NBCOT examination for occupational therapists; and

- Effective January 1, 2010, are licensed or otherwise regulated, if applicable, as an occupational therapy by the state in which practicing.

D. Occupational Therapists - Additional References

In Pub. 100-02, chapter 15, see section 230.2(B) for more information regarding the required qualifications of occupational therapists and section 230.4 for information regarding the term "private practice."

E. Other Enrollment Information - Form CMS-855 Completion

All occupational therapists in private practice must respond to the questions in Section 2*J* of the Form CMS-855I. However, Section 2*J* does not apply if the occupational therapist: (1) plans to provide his/her services as a member of an established occupational therapist group, an employee of a physician-directed group, or an employee of a non-professional corporation; and (2) wishes to reassign his/her benefits to that group.

If the occupational therapist checks that he/she renders all his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be the person's home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, Section 4B of the Form CMS-855I should indicate where services are rendered (e.g., county, state, city of the patients' homes). Post office boxes are not acceptable.

If the individual answers "Yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for occupational therapy services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

10.2.3.10 – Physical Therapists in Private Practice

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Regulatory Requirements - Physical Therapist in Private Practice

Section 42 CFR § 410.60(c) states that to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

1. Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the state in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

2. Engage in the private practice of physical therapy on a regular basis as an individual in one of the following practice types: (i) a solo practice; (ii) a partnership; (iii) a group practice; or (iv) as an employee of any of (i), (ii), or (iii).

3. Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, such space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

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

B. Qualified Physical Therapist Definition

Pub. 100-02, chapter 15, section 230.1 states that a qualified physical therapist is a person who: (1) is licensed, if applicable, by the state in which he or she is practicing (unless licensure does not apply); (2) has graduated from an accredited physical therapist education program; and (3) passed an examination approved by the state in which physical therapy services are provided. The phrase "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The curriculum accreditation is provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or, for those who graduated before CAPTE, curriculum approval was provided by the American Physical Therapy Association (APTA). For internationally educated physical therapists, curricula are approved by a credentials evaluation organization either approved by the APTA or identified in 8 CFR 212.15(e) as it relates to physical therapists. For example, in 2007, 8 CFR 212.15(e) approved the credentials evaluation provided by the Federation of State Boards of Physical Therapy (FSBPT) and the Foreign Credentialing Commission on Physical Therapy (FCCPT).

The requirements above do not apply to a physical therapist effective January 1, 2010, if he or she has otherwise met the requirements outlined in Category #2, Category #3, Category #4, or Category #5 below. (Category #1 is outlined in the previous paragraph.)

Category #2 – A physical therapist whose current license was obtained on or prior to December 31, 2009, qualifies to provide physical therapy services to Medicare beneficiaries if he or she:

(a) Graduated from a CAPTE approved program in physical therapy on or before December 31, 2009 (examination is not required); or

(b) Meets both of the following:

(i) Graduated on or before December 31, 2009, from a physical therapy program outside the U.S. that is determined to be substantially equivalent to a U.S. program by a credentialed evaluation organization approved by the APTA or identified in 8 CFR § 212.15(e).

(ii) Passed an examination for physical therapists approved by the state in which he or she is practicing.

Category #3 – A physical therapist whose current license was obtained before January 1, 2008, may meet the requirements in place on that date (i.e., graduation from a curriculum approved by either the APTA, the American Medical Association, or both).

Category #4 – A physical therapist meets the requirements if he or she (a) is currently licensed as a physical therapist, (b) was licensed or qualified as a physical therapist on or before December 31, 1977, (c) had 2 years of appropriate experience as a physical therapist, and (d) passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Category #5 – A physical therapist meets the requirements if he or she is currently licensed and before January 1, 1966, he or she was:

- Admitted to membership by the APTA; or
- Admitted to registration by the American Registry of Physical Therapists; or
- Graduated from a 4-year physical therapist curriculum approved by a state Department of Education; or
- Licensed or registered and prior to January 1, 1970, he/she had 15 years of full-time experience in physical therapy under the order and direction of attending and referring doctors of medicine or osteopathy.

C. Physical Therapist Trained Outside the United States

Pub. 100-02, chapter 15, section 230.1(B) states that a physical therapist meets the requirements if he or she: (a) is currently licensed; (b) was trained outside the U.S. before January 1, 2008; (c) after 1928 graduated from a physical therapy curriculum approved in the country in which the curriculum was located and that country had an organization that was a member of the World Confederation for Physical Therapy; and (d) he/she qualified as a member of that organization.

D. Physical Therapists - Additional References

In Pub. 100-02, chapter 15, see section 230.2(B) for more information regarding the required qualifications of physical therapists and section 230.4 for detailed information regarding the term "private practice."

E. Site Visits of Physical Therapists in Private Practice

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

Unless otherwise stated in this chapter or another CMS directive, site visits will be performed in accordance with the following:

i. Initial application – If a physical therapist or physical therapist group submits an initial application for private practice, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier prior to the completion of the NSVC's site visit and the contractor's review of the results.

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

iii. New/changed location – Unless CMS has directed otherwise, if a private practice physical therapist or physical therapist group is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site

visit of the new/changed location through PECOS. This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the application prior to the completion of the NSVC's site visit and the contractor's review of the results.

Note that if the PT (being a moderate-risk provider under § 424.518) has multiple practice locations, the SVC will conduct a site visit of each location rather than simply one selected location.

F. Physical Therapists: Additional Site Visit Information

The contractor is also advised of the following:

- In Section 2*B* of the Form CMS-855B application, physical and occupational therapy groups are denoted as "Physical/Occupational Therapy Group in Private Practice." If a supplier that checks this box in Section 2*B* is exclusively an occupational therapy group in private practice – that is, there are no physical therapists in the group – the contractor shall process the application using the procedures in the "limited" screening category. No site visit is necessary. If there is at least one physical therapist in the group, however, the application shall be processed using the procedures in the "moderate" screening category. A site visit by the NSVC is required unless CMS has directed otherwise.

- If an entity is enrolled as a physician practice and employs a physical therapist within the practice, the practice itself falls within the "limited" screening category. This is because the entity is enrolled as a physician practice and not a physical therapy group in private practice. However, this does not exempt the physical therapist from the screening required at the "moderate" risk level.

- Unless CMS has directed otherwise, a site visit by the NSVC is required when a physical therapist submits an application for private practice initial enrollment and reassignment of benefits (Form CMS-*855I*). However, a site visit is not required for an enrolled private practice physical therapist who is reassigning his or her benefits only.

- If the private practice physical therapist's practice location is his or her home address and it exclusively performs services in patients' homes, nursing homes, etc., no site visit is necessary.

G. Other Enrollment Information

All physical therapists in private practice must respond to the questions in Section 2*J* of the Form CMS-855I. However, Section 2*J* does not apply if the physical therapist: (1) plans to provide his/her services as a member of an established PT group, an employee of a physician-directed group, or an employee of a non-professional corporation; and (2) the person wishes to reassign his/her benefits to that group. Such information will be captured on the group's Form CMS-855B application.

If the physical therapist checks that he/she renders all his/her services in patients' homes, the contractor shall verify that he/she has an established private practice where he/she can be contacted directly and where he/she maintains patient records. (This can be the person's home address, though all Medicare rules and instructions regarding the maintenance of patient records apply.) In addition, Section 4E of the Form CMS-855I

should indicate where services are rendered (e.g., county, state, city of the patients' homes). Post office boxes are not acceptable.

If the individual answers "Yes" to question 2, 3, 4, or 5, the contractor shall request a copy of the lease agreement giving him/her exclusive use of the facilities for physical therapist services only if it has reason to question the accuracy of his/her response. If the contractor makes this request and the supplier cannot furnish a copy of the lease, the contractor shall deny the application.

10.2.3.12 – Physician Assistants

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

(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 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) have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA);

  AND

- Be licensed by the state to practice as a PA. (The PA need not be currently NCCPA-certified.)

(In other words, either (1) or (2) in the first bullet must be met, and the licensure requirement in the second bullet must always be met.)

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 meant 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 above-mentioned 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. *Note that reassignments of benefits are now captured via the Form CMS-855I, for the Form CMS-855R has been discontinued.*

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 Sections *4(F)(1) and (2)* of the Form CMS-855I. *(The PA may, but is not required to, furnish the primary and secondary practice location information in Section 4(F)(3).)*

b. Initial Enrollment - If a PA is initially enrolling in Medicare and intends to reassign his/her benefits, *the PA shall complete Sections 4(F)(1) and (2) of the Form CMS-855I. (Section 4(F)(3) is optional.)*

See section 10.3.1.4 of this chapter for more information on reassignments.

10.2.3.18 – Mental Health Counselors (MHCs)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Definitions and Requirements

Effective January 1, 2024, Medicare covers services furnished by MHCs. An MHC is defined in 42 CFR § 410.54(a) as an individual who:

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as an MHC, clinical professional counselor, or professional counselor under the state law of the state in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as an MHC, clinical professional counselor, professional counselor, addiction counselor, or alcohol and drug counselor (ADC) by the state in which the services are performed.

Under 42 CFR § 410.54(b)(1), MHC services means services furnished by an MHC (as defined in § 410.54(a)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under state law (or the state regulatory 1417 mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service and must meet the requirements of § 410.54.

Per 42 CFR § 410.54(c)(2), MHC services furnished by an MHC to an inpatient of a Medicare-participating hospital are not MHC services for purposes of billing Medicare Part B:

B. Verification

As it does with Medicare supplier types, the contractor shall familiarize itself with the state licensure and associated education requirements for MHCs. This will assist the contractor in ascertaining whether the MHC meets all state requirements.

In verifying the supplier's compliance with:

1. § 410.54(a)(1) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit a copy of their master's or doctor's degree. Whether a master's or, instead, a doctor's degree is required will depend on the applicable state's requirements.

2. § 410.54(a)(2) – Except as stated in the discussion of § 410.54(a)(3) below, the contractor shall require the supplier to submit documentation verifying that they have performed, at a minimum, either 2 years or 3,000 hours of post-master's clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic. (The supplier need only meet the 2-year or the 3,000-hour standard, not both.) Such documentation shall be one of the following:

   (i) A statement from the provider/supplier at which the MHC performed the services in question (e.g., hospital, clinic) verifying that the MHC performed services at that setting for the required number of years or hours. The statement shall:

   (a) Be on the provider's/supplier's letterhead (e-mail is not acceptable); and

   (b) Be signed by: (1) the supervisor under whom the MHC performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO has already been approved as such in the

provider/supplier's enrollment record) if the provider/supplier is Medicare-enrolled.

The statement need not contain standard, boilerplate language. It need only confirm to the contractor's satisfaction that the year or hour requirement was met. Also, the contractor may accept statements from multiple providers/suppliers if the year or hour requirement was met by performing services at more than one setting. For instance, suppose Dr. Smith earned her MHC experience by performing 1,000 hours at Hospital X and 2,000 hours at Hospital Y. The contractor can accept one statement from Hospital X concerning the 1,000 hours and another from Hospital Y regarding the remaining 2,000 hours so long as each statement meets the requirements of subsections (B)(2)(i)(a) and (B)(2)(i)(b) above. Put otherwise, the MHC can combine years and hours from multiple providers/suppliers to meet the requirements in § 410.54(a)(2).

In addition:

- A statement from the MHC's current employer that the MHC met the year or time requirement at other settings besides the employer is not acceptable. All statements must be <u>from</u> the provider/supplier in which setting(s) the MHC performed the services. Using our example above, suppose Dr. Smith's supervisor at Hospital X was Dr. Jones. Dr. Jones is no longer with Hospital X, however. Dr. Smith submits a statement from Dr. Jones stating that Dr. Smith performed 1,000 hours of MHC service at Hospital X. This statement cannot be accepted because it is not from Hospital X.
- The setting can be any provider/supplier at which MHC services are furnished. It need not be one of the four provider/supplier types listed in § 410.54(a)(2). Moreover, the provider/supplier need not have been (or currently be) enrolled in Medicare at the time the MHC performed the services there; <u>or</u>

(ii) <u>A statement verifying that the MHC meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MHC is enrolling; or (2) national MHC credentialing organization</u>. The statement can be signed by any official of the state licensing/credentialing or national credentialing body. It must, however, be on the body's letterhead.

If the MHC fails to furnish the above documentation, the contractor shall develop for it consistent with the instructions in this chapter.

3. § 410.54(a)(3) – The contractor shall verify state licensure or certification consistent with existing policies for doing so in this chapter.

   If the contractor confirms to its satisfaction that the state already requires, as a condition of licensure or credentialing, the MHC to have:

   - Performed, at a minimum, either 2 years or 3,000 hours of clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic, the contractor can forgo verifying separate compliance with the § 410.54(a)(2) requirement described above; the MHC need not submit the documentation specified in subsection (B)(2). (This is because the licensure/credentialing already includes the year/hour requirement.)

   - A master's or doctor's degree (as applicable), the MHC need not submit a copy of his or her degree nor need the contractor verify that the MHC received said degree.

C. Further Information

1. *Other Titles - Individuals who meet all applicable statutory and regulatory qualifications to be an MHC --- even though they may be licensed or certified by their state under a different title to furnish mental health counseling --- may enroll as an MHC. This includes mental health professionals who otherwise meet the requirements of § 410.54(a). (While a clinical psychologist, for instance, must possess a doctoral degree in psychology to enroll as such in Medicare, only a master's degree is required for MHC enrollment.) In short, the individual's specific title under state law for purposes of mental health counseling is less important than whether the requirements of § 410.54(a) are met.*

   As an example, addiction counselors, ADCs, and licensed professional counselors (LPCs) may enroll as MHCs if they meet the MHC requirements. They cannot, however, enroll as addiction counselors, ADCs, or LPCs, for Medicare does not recognize such supplier types.

2. Pre/Post Degree – As indicated above, all 2 years/3,000 hours of clinical supervised experience must have been performed post-degree. Pre-degree experience does not count towards the required time total under § 410.53(a)(2), even if the state permits pre-degree experience to be counted towards meeting state requirements. For example, suppose State X requires 1,000 hours of supervised experience for licensure. The hours can be performed pre-degree or post-degree. Jones, who is licensed by X, performed her 1,000 hours before receiving her degree. Jones cannot apply these hours towards the § 410.53(a)(2) time requirement – even though she is licensed – and must furnish evidence of 2 years/3,000 hours post-degree experience. If, however, Jones had performed 500 hours pre-degree and 500 hours post-degree, she could apply the latter (but not the former) to the § 410.53(a)(2) time requirement.

3. Additional Policies - Like certain other individual practitioners, MHCs may opt-out of Medicare, form groups, reassign their benefits under § 424.80, receive reassigned benefits, and order/certify services to the extent otherwise permitted by law. They will complete the Form CMS-855I to bill for services and be subject to limited-risk screening (except as described in § 424.518(c)(3)).

   Until the Form CMS-855I is revised to include MHCs, the MHC shall check the "Undefined Non-Physician Practitioner Specialty" box and state "mental health counselor" in the line next thereto.

10.2.7 - Opioid Treatment Programs

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Legislative and Regulatory Background

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (hereafter referenced as the "SUPPORT Act") was designed to alleviate the nationwide opioid crisis by: (1) reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. Section 2005 of the SUPPORT Act attempted to fulfill these objectives, in part, by establishing a new Medicare benefit category for opioid treatment programs (OTPs).

An OTP is currently defined in 42 CFR § 8.2 as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. § 823(g)(1). There are three overarching (but not exclusive) requirements that an OTP must meet to bill for OTP services:

1. Accreditation

The OTP must have a current, valid accreditation by an accrediting body or other entity approved by the Substance Abuse and Mental Health Services Administration (SAMHSA), the federal agency that oversees OTPs. The accreditation process includes, but is not limited to, an accreditation survey, which involves an onsite review and evaluation of the OTP to determine compliance with applicable federal standards. There are currently six SAMHSA-approved accreditation bodies.

2. Certification

The OTP must have a current, full, valid certification by SAMHSA for such a program. The prerequisites for certification (as well as the certification process itself) are addressed in 42 CFR §8.11 and include, but are not restricted to, the following:

- Current and valid accreditation (described in subsection (A)(1) above)
- Adherence to the federal opioid treatment standards described in 42 CFR § 8.12
- Compliance with all pertinent state laws and regulations, as stated in § 8.11(f)(1)

Under 42 CFR §8.11(a)(3), certification is generally for a maximum 3-year period, though this may be extended by 1 year if an application for accreditation is pending. SAMHSA may revoke or suspend an OTP's certification if any of the applicable grounds identified in 42 CFR § 8.14(a) or (b), respectively, exist.

3. Enrollment

The SUPPORT Act also required that an OTP be enrolled in the Medicare program under section 1866(j) of the Act to bill and receive payment from Medicare for opioid use disorder treatment services.

In the Calendar Year (CY) 2020 Physician Fee Schedule final rule (published in the **Federal Register** on November 15, 2019 (84 FR 62567)), CMS established a new 42 CFR § 424.67 containing requirements that OTPs must meet and continually adhere to in order to enroll (and remain enrolled) in Medicare effective January 1, 2020. Since this latter date, OTPs have enrolled in Medicare consistent with 42 CFR § 424.67 and the general provider enrollment requirements of 42 CFR Part 424, subpart P (42 CFR § 424.500 et seq.). This section 10.2.7 outlines the specific enrollment policies associated with OTP enrollment.

A. OTP Enrollment Process

The instructions in this section 10.2.7(B) are in addition to, and not in lieu of, those in CMS Pub. 100-08, Program Integrity Manual (PIM), chapter 10. To the extent there are conflicting instructions, the policies in this section 10.2.7 shall take precedence.

1. Applicable Form CMS-855

a. General Requirements

As of November 16, 2020, OTPs may enroll (and remain enrolled) via the Form CMS-855B or the Form CMS-855A, but not both. Some OTPs currently enrolled via the Form CMS-855B may accordingly seek to change their enrollment to a Form CMS-855A. To ensure that the OTP is at no time enrolled under both Form CMS-855 application types, the contractor shall do the following:

- Upon receipt of an initial Form CMS-855A or Form CMS 855B from an OTP, the contractor shall confirm that the OTP is not currently enrolled as such via another Form CMS-855 application type. (For example, if the contractor receives an initial Form CMS-855A from an OTP, the contractor shall verify that the OTP is not already enrolled via the Form CMS-855B.)

- If the contractor determines that the OTP is not already enrolled as such, the contractor shall process the application normally.

- If, however, the contractor determines that the OTP is already enrolled as such via a different Form CMS-855 application type, the contractor shall verify with an authorized or delegated official of the OTP (by telephone or e-mail) that the OTP is changing its enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa). The OTP in this situation is not required to submit a Form CMS-855 application to voluntarily terminate its prior enrollment.

The Form CMS-855B has been updated to add "Opioid Treatment Program" as a listed provider type. (For the Form CMS-855A (at least until that form is updated), the OTP shall check the "Other" box in Section 2 and state "Opioid Treatment Program.")

An entity that is enrolling or is already enrolled in Medicare as another provider or supplier type may also seek enrollment as an OTP. It must, however, submit a separate Form CMS-855 application to do so; it cannot enroll or be enrolled as an OTP and another provider/supplier type via the same enrollment.

Note that the policies in this section 10.2.7 regarding an OTP's transition from a Form CMS-855B enrollment to a Form CMS-855A enrollment (or vice versa) only apply if the OTP is doing so in the same state in which it is currently enrolled as an OTP. If an OTP is enrolling under a different Form CMS-855 in a state different from that in which it is currently enrolled (e.g., a Form CMS-855B enrolled OTP in State X is enrolling via the Form CMS-855A in State Y), it is considered a brand new enrollment (and not merely a "switch" in OTP enrollment type); this would thus require, for instance, moderate or high-level screening as opposed to limited screening (as discussed further in section 10.2.7(B)(3) below).

2. Applicable Fee

An OTP is an "institutional provider" under 42 CFR § 424.502 and thus is required to pay an application fee pursuant to 42 CFR § 424.514. The contractor shall follow the application fee procedures outlined in chapter 10 of the PIM. A fee is required even when the OTP is changing its enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa.

3. Categorical Screening

Consistent with 42 CFR § 424.518, the contractor shall categorically screen OTP applications as follows:

a. Newly enrolling OTPs that **are not** changing their enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa -

- If the OTP has not been fully and continuously certified by SAMHSA since October 24, 2018, the contractor shall conduct high-risk level categorical screening.

- If the OTP has been fully and continuously certified by SAMHSA since October 24, 2018, the contractor shall conduct moderate-risk level categorical screening.

b. Newly enrolling OTPs that **are** changing their enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa - The contractor shall conduct limited-risk level categorical screening if the OTP had previously completed, as applicable, the moderate or high-risk level screening as part of its initial enrollment. Otherwise, moderate or high-risk level screening (as applicable under § 424.518) shall be conducted.

c. Revalidating OTPs – The contractor shall conduct moderate-risk level categorical screening.

d. Practice Location Addition – The contractor shall conduct moderate-risk level categorical screening (i.e., site visit of the new location consistent with the procedures outlined in this chapter 10).

4. Confirmation of Certification

When processing OTP initial applications (including those involving a change in Form CMS-855 application type) and revalidation applications, the contractor shall confirm and record in PECOS the OTP's SAMHSA certification status as follows:

a. Review the OTP directory at https://dpt2.samhsa.gov/treatment/directory.aspx. The OTP's certification must be full, current, and valid. ("Provisional" certification status is not acceptable.) The OTPs SAMHSA certificate (and the OTP's identification in the SAMHSA directory) need not have the exact same legal business name as that on the OTP's IRS document, though the contractor shall develop for clarification if it has questions as to whether the OTP on the application and in the directory are truly the same.

b. Verify that each location listed on the Form CMS-855 is separately and uniquely certified.

c. Enter into PECOS the OTP's relevant certification data obtained from the aforementioned OTP directory. This includes: (1) the OTP number; and (2) the certification effective date (which can be obtained from the OTP's renewal letter). The certification effective date is the date on which SAMHSA acknowledged notification from the accrediting organization and can be verified by reviewing the OTP's renewal letter information in the database. (The contractor need not obtain a copy of the letter from the OTP.)

The expiration date must be obtained via the SAMHSA operating certificate for the location in question; the OTP should submit said certificate with its application.

Irrespective of whether the OTP reported the data described in (4)(c) on the Form CMS-855, the contractor shall use the information in the OTP directory for purposes of data entry.

5. OTP Managing Employees

As with all enrolling providers and suppliers, the OTP must disclose all of its managing employees in Section 6 of the Form CMS-855. Such managing employees must include the OTP's medical director and program sponsor, which the OTP must have pursuant to 42 CFR §§ 8.12(b) and §§ 424.67(b)(5). The contractor shall verify that the medical director is a validly licensed physician or psychiatrist; he/she must be licensed by the state in which the OTP's primary practice location is situated. The contractor may develop with the OTP for any information it needs (and via any manner it chooses) to verify the person's licensure. If the contractor determines that the individual is not appropriately licensed, it shall contact its PEOG BFL for guidance.

The OTP must submit a copy of the organizational diagram required under Section 5 of the Form CMS-855 even if it merely changing its enrollment type from a Form CMS-855B to a Form CMS-855A (or vice versa).

6. OTP Personnel

i. Regulatory Background

Section 424.67 contains several important provisions concerning OTP personnel. These include:

- Completion of Attachment/Supplement (§ 424.67(b)(1)(i)) - Requires the OTP to maintain and submit to CMS (via the applicable Form CMS-855 supplement or attachment) a list of all physicians, other eligible professionals, and pharmacists (regardless of whether the individual is a W-2 employee of the OTP) who are legally authorized to prescribe, order, or dispense controlled substances on the OTP's behalf. The list must include the individual's (1) first and last name and middle initial, (2) social security number, (3) NPI, and (4) license number (if applicable).

- Felony Convictions (§ 424.67(b)(6)(i)(A)) - The OTP must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted of a federal or state felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. The applicable felonies are based on the same categories of detrimental felonies (as well as case-by-case detrimental determinations) found at § 424.535(a)(3). (It is immaterial whether the individual is (1) currently dispensing narcotics at or on behalf of the OTP or (2) a W-2 employee of the OTP.)

- Revoked/Preclusion List (§ 424.67(b)(6)(ii)) - The OTP must not employ or contract with any personnel (regardless of whether the individual is a W-2 employee of the OTP) who is (1) revoked from Medicare under § 424.535 or any other applicable section in Title 42 or (2) on the preclusion list.

- State Board Action (§ 424.67(b)(6)(iii)) - The OTP must not employ or contract with any personnel (W-2 or otherwise) who has a prior adverse action by a state oversight board (including, but not limited to, a reprimand, fine, or restriction) for a case involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

ii. Attachment and Verification

Attachment 3 of the Form CMS-855B *and Section 10 of the Form CMS-855A (hereafter collectively referenced as "attachment")* collect information on the individuals described in § 424.67(b)(1)(i) above. OTPs submitting the Form CMS-855B *or the Form CMS-855A* must complete this attachment as described in (and subject to) (ii)(A) below and --- once enrolled --- report any changes to the information thereon (e.g., new or deleted prescribers) consistent with 42 CFR § 424.516(e).

(A) When to Submit Attachment

(1) General Principles

The OTP need only submit the attachment for the first time as part of (i) an initial Form CMS-855B *or Form CMS-855A* enrollment, (ii) a Form CMS-855B *or Form CMS-855A*

revalidation (periodic or off-cycle), or (iii) a change from a Form CMS-855A enrollment to a Form CMS-855B enrollment *(or vice versa)*. The OTP is not required to complete it for the first time as part of a change of information request. Consider the following examples:

Example 1 - Smith OTP enrolled in Medicare via the Form CMS-855*A* in *February 2023*, prior to the Form CMS-855*A* being revised to include the attachment. Smith submits a change request in Ju*ly* 202*4* to add a new billing agency. Smith need not complete the attachment at this time because Smith's application does not fall within any of the three categories in (A)(i) through (iii) above.

Example 2 - Using Example 1, suppose Smith submitted a Form CMS-855*A* revalidation application (rather than a change of information) in Ju*ly* 202*4*. Smith would have to complete the attachment at that time *per (A)(1)(ii) above.*

Example 3 - Again using Example 1, suppose Smith is *currently enrolled via the Form CMS-855B, which it completed in July 2023. (The OTP attachment was completed, too.) Smith submits a Form CMS-855A in May 2024 to change its OTP enrollment to that form. Smith would have to complete the attachment on the CMS-855A form because (A)(1)(i) and (iii) above are met.*

Example 4 - Again using Example 1, assume Smith *enrolled via the Form CMS-855A in February 2023. Smith hires two pharmacists in March 2024.* Smith *need not* report these persons on the attachment nor complete the attachment in full, for no category in (A)(i) through (iii) above applies. *If, however, Smith enrolled via the Form CMS-855A in March 2024 (completing the attachment in the process) and hired the two pharmacists in June 2024, the latter would have to be reported on the attachment via a change of information.*

(2) Submission When Not Required

Instances could occur where the OTP submits the Form CMS-855 attachment for the first time when it was not required to do so (i.e., no category in (6)(A)(i) through (iii) applies). The two most likely scenarios would involve: (a) a Form CMS-855A OTP application submission (e.g., initial, change request); or (b) a Form CMS-855B-enrolled OTP submitting a change request.

In the case of (a), the contractor shall not process the attachment and may either keep it in the provider file or return it to the OTP via the general procedures in this chapter for returning applications. Regardless of which of the latter two approaches the contractor takes, the contractor shall: (i) notify the OTP that the attachment was not processed; (ii) explain why; and (iii) state that the attachment will need to be submitted at a later time as determined by CMS. If the contractor elects to retain the attachment, the notification in (i)/(ii)/(iii) above may be given in any matter the contractor chooses.

For (b), the contractor shall process the attachment consistent with the instructions in this section (6)(ii).

(B) Owning/Managing Individuals - Notwithstanding (6)(ii)(A) above, any person otherwise required to be reported on the attachment must also be disclosed in Section 6 of the Form CMS-855B if he or she qualifies as a 5 percent or greater owner, managing employee, partner, etc. To illustrate, assume Dr. Jones prescribes controlled substances on the OTP's behalf. He is also a managing employee of the OTP. The OTP is initially enrolling in Medicare via the Form CMS-855B. Jones would have to be listed in Section 6 and on the attachment. If Jones left the OTP altogether, the OTP would have to report this in both Section 6 and the attachment; if Jones no longer prescribes drugs for the OTP but remains a managing employee, this would have to be reported via the attachment but not in Section 6.

(C) Timeframe for Changes - Additions/deletions/changes to the information in the attachment must be reported within 90 days of the change per 42 CFR § 424.516(e)(2).

(D) Missing Data - In general, the contractor shall develop (using the procedures outlined in this chapter) for any data that is missing or unverifiable on the attachment. (This includes individuals who the contractor learns (via any means) should be listed on the attachment but were not.) However, and excluding names and social security numbers, the contractor may forgo such development if the missing/unverifiable information can be located and validated via other means. This could include, for example: (i) the NPI of the individual (who is also a managing employee) is listed in Section 6 of the Form CMS-855B; or (ii) the person's license number can be obtained through PECOS.

Note that the specific processing exception addressed in (D) applies only to OTPs. Other processing exceptions applicable to other provider and supplier types (as well as to OTPs) can be found elsewhere in this chapter.

(E) Validation of Individuals on Attachment - The contractor shall review all individuals listed on the attachment against the MED and the SAM. (The contractor may combine this step with its check of the same individual if the latter is also listed in Section 6 of the form; it need not perform two separate reviews.) The contractor shall contact its PEOG BFL for further guidance if the contractor determines or learns during its screening that the individual:

- Is OIG excluded;
- Is debarred (per the SAM);
- Is on the preclusion list;
- Has one of the actions described in §§ 424.67(b)(6)(i)(A), 424.67(b)(6)(ii); or §§ 424.67(b)(6)(iii) above; or
- Does not meet applicable requirements to prescribe, order, or dispense controlled substances on the OTP's behalf.

In reviewing all individuals listed on the attachment (and absent a CMS directive to the contrary), the contractor is not required to perform any validation activities beyond those which it would ordinarily perform for persons listed in Section 6. (For example, the contractor need not research each person to determine (i) whether he/she is licensed, (2) what his/her license number is, or (3) whether he/she has ever had a fine imposed against him/her related to patient harm.)

(F) Multiple Locations and Off-Site – All persons who meet the requirements of § 424.67(b)(1)(i) must be listed on the OTP's attachment regardless of where the individual is located (e.g., the primary practice location, one of the OTP's multiple locations, his/her home, etc.) The central issue is whether the individual is authorized to act on the OTP's behalf, not his/her location.

(G) Appropriate Attachment Sections

As there is no section on the Form CMS-855B attachment specific to prescribers, such persons should be listed in the "Ordering Personnel Identification" section rather than the "Dispensing Personnel Information" section. However, if the contractor determines that the prescriber was inadvertently listed in the "Dispensing" section, it need not require the OTP to move him/her to the "Ordering" section. In addition:

- If the person qualifies as both an ordering and dispensing individual but is only listed in one of the two sections of the attachment, the contractor need not require the OTP to list him/her in both.

- If the person qualifies as either an ordering or dispensing individual but is listed in the incorrect section (e.g., a dispenser is listed in the ordering section), the contractor need not require the OTP to move him/her to the other section.

iii. Person With Adverse Action but Need Not Be Listed on Attachment or in Section 6

There may be instances where the contractor learns (via any means) that an individual described in §§ 424.67(b)(6)(i)(A), 424.67(b)(6)(ii), or §§ 424.67(b)(6)(iii) has one of the actions described within those regulatory sections but was not required to be listed on the OTP's application (either on the attachment or elsewhere on the application). Examples could include the following:

- A W-2 nurse has restrictions on her license due to a patient harm case
- A non-prescribing/non-ordering physician under contract is currently on the preclusion list
- A physician assistant employee is currently revoked from Medicare.

These individuals may not have met the criteria under § 424.67(b)(1)(i) to be reported on the attachment or the OTP may not have yet been required to submit the attachment (e.g., the OTP is enrolled via the Form CMS-855A.) Regardless, if the contractor becomes aware of such an individual, it shall contact its PEOG BFL for guidance.

7. Provider Agreement

i. Basic Requirement

To enroll (and remain enrolled) in Medicare as an OTP, the OTP (including provider-based OTPs, as discussed in subsection (B)(9) below) must sign and adhere to the terms of the Form CMS-1561 Provider Agreement. (This is the same agreement signed by certified providers such as hospitals, hospices, and home health agencies. See 42 CFR Part 489, Subparts A through E (as well as CMS Pub. 100-07, State Operational Manual) for general information on provider agreements.) Given this, the contractor shall verify that the OTP submitted a signed and dated Form CMS-1561 with its initial enrollment package. The provider agreement must be signed by an authorized or delegated official (as those terms are defined in § 424.502) of the OTP; the signature can be handwritten or digital. This form may be accepted via mail, fax, email, or document upload. The legal business name on the Form CMS-1561 must match that on the Form CMS-855.

If the OTP failed to submit the Form CMS-1561 as described in the previous paragraph, the contractor shall develop for the document (or any missing or inconsistent data thereon) consistent with the procedures outlined in chapter 10 of the PIM.

ii. Criteria for Inapplicability

The requirement to submit, sign, and date a new Form CMS-1561 does not apply if the OTP meets all of the following requirements: (1) the OTP is already enrolled as such in Medicare; (2) the OTP already has a valid Form CMS-1561 agreement in effect; and (3) the OTP is newly enrolling solely to change its existing Form CMS-855B enrollment to a Form CMS-855A, or vice versa.

8. Locations

An OTP may have multiple practice locations under a single enrollment so long as they all have the same legal business name and employer identification number. However, it may not split its locations between a Form CMS-855A enrollment and a Form CMS-855B enrollment.

All locations must be under one enrollment. To illustrate, suppose an OTP is currently enrolled via the Form CMS-855B. It has four locations - W, X, Y, and Z. The OTP cannot keep W and X under its Form CMS-855B enrollment and switch Y and Z to a Form CMS-855A enrollment. It must retain all locations under the Form CMS-855B enrollment or move them all to a Form CMS-855A enrollment.

Instances might arise where an OTP lists multiple locations on its enrollment application, and one or more locations do not meet full status while one or more do. (For purposes of this situation, "full status" means that the location is separately and uniquely certified. See sections 10.2.7(a)(2) and (B)(4)(b) for more information.) Here, the contractor, in lieu of denying the entire application, may develop with the OTP to either: (1) update the location's status (if full status for it has since been obtained); or (2) remove the location from the enrollment application. Any such development---while encouraged, is not required---shall be performed consistent with the procedures and timeframes outlined in this chapter. The OTP's failure to fully and timely comply with the development request shall result in application's rejection. If the OTP does comply, the contractor can proceed as normal.

9. Provider-Based

As indicated in section 10.3.1.1.13(F)(1) of this chapter, an unenrolled OTP that wishes to become provider-based to a hospital cannot do so via the hospital's submission of a change of information application that adds the OTP as a practice location. The OTP must first enroll as an OTP via an initial enrollment, sign a provider agreement, undergo screening, etc. Once the OTP is enrolled, the hospital may add the OTP as a practice location on its enrollment. The situation is akin to that described in section 10.3.1.1.3(F)(1) regarding provider-based HHAs; section 10.3.1.1.3(F)(1) emphasizes that the HHA must separately enroll as such.

If a hospital submits an application to add--

(i) An unenrolled OTP as a practice location, the contractor shall return the change request on the basis of § 424.526(a)(7); the OTP must submit an initial enrollment application.

(ii) An enrolled OTP as a practice location, the contractor shall process the application consistent with the instructions in this chapter. A separate PECOS record for the OTP site (in its capacity as a hospital practice location) need not be created. Moreover:

- The enrolled OTP need not sign a new/additional provider agreement.
- The hospital need not complete the attachment regarding ordering, prescribing, and dispensing personnel, for the attachment is only completed by OTPs. However, if the OTP's addition as a provider-based location results in a change to any of the individually enrolled OTP's existing attachment information (e.g., new prescribers), the OTP must submit a change of information consistent with 42 CFR § 424.516(e)(2). Likewise, any other change to the OTP's individual enrollment stemming from its provider-based status (e.g., new ownership, change in managing employees) must be reported consistent with this chapter's instructions as well as 42 CFR Part 424, subpart P, § 424.67, and any other applicable regulations.
- The contractor need not confirm that the OTP location is still SAMHSA-certified.
- The hospital must pay an application fee since it is adding a new location.
- The application shall be screened at the limited screening level per 42 CFR § 424.518.
- Notwithstanding any other instruction to the contrary in this chapter, the contractor shall follow the basic process in subsection (C)(2)(a) below with respect to referring the practice location addition to PEOG so that a CCN can be assigned to the OTP practice location (e.g., include in the e-mail the hospital's and OTP's respective names, the hospital's CCN and NPI, and the individually enrolled OTP's CCN and NPI)

C. Approval

1. No State Agency or CMS Survey & Operations Group (SOG) Location Involvement

Unlike with many entities that complete the Form CMS-855A, there is no state agency or SOG Location involvement with OTP Form CMS-855A enrollments. Accordingly, no recommendations for approval or other type of referral need be made to the state or SOG Location nor will the SOG Location send any tie-in notice to the contractor. Except as otherwise stated in this section 10.2.7, the application will be reviewed and handled entirely at the contractor level.

2. Process of Approval

If the contractor determines that the OTP's application should be approved, it shall undertake the following:

a. For Form CMS-855A applications only, request via PEMACReports@cms.hhs.gov that CMS assign a Form CMS-855A CCN to the enrollment. (This task is required even if the OTP is merely changing its existing enrollment from a Form CMS-855B to a Form CMS-855A.)

b. As applicable (and except as stated in section (B)(7)(ii) above), send the Form CMS-1561 to PEMACReports@cms.hhs.gov for CMS to execute the signature on behalf of the Secretary. CMS will return the executed provider agreement within 3 business days. (The tasks in 2(a) and 2(b) can be completed via the same e-mail.)

c. As applicable, send a copy of the executed provider agreement to the OTP along with the enrollment approval letter. (The contractor shall retain the original provider agreement.)

3. Effective Date of Billing

For newly enrolling OTPs that are not changing their enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa), the contractor shall apply the effective date policies outlined in 42 CFR §§ 424.520(d) and 424.521(a) and explained in chapter 10 of the PIM.

For newly enrolling OTPs that are changing their enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa), the contractor shall apply to the new/changed enrollment the same effective date of billing that was applied to the OTP's initial/former enrollment. (See 42 CFR § 424.67(c)(2).) To illustrate, suppose an OTP initially enrolled via the Form CMS-855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020, the OTP elects to end its Form CMS-855B enrollment and enroll via the Form CMS-855A pursuant. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS-855A enrollment would be retroactive to April 1, 2020 (though the time limits for filing claims found in § 424.44 would continue to apply).

4. In cases where the OTP is changing its Form CMS-855 enrollment type, the contractor shall do the following:

a. End-date/deactivate the prior enrollment effective: (1) the date following that on which the OTP submitted its last claim under its prior enrollment; or (2) the prior enrollment's effective date of billing if no claims were submitted under the prior enrollment. The PECOS L & T basis shall be "Voluntary Termination." The deactivation reason shall be "Voluntary withdrawal: Applicant voluntarily withdrew from Medicare program.

b. Notify the OTP in the approval letter that the OTP's prior enrollment has been end-dated/deactivated and specify said end-date.

10.3.1.1.2 – Section 2 (Identifying Information) - Form CMS-855A

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Licenses, Certification, and Accreditation Information

The extent to which the provider must furnish licensure, certification, or accreditation information in Section 2 depends upon the provider type involved. Requirements vary by provider type and by location; for instance, some states may require a particular provider to be "certified" but not "licensed," or vice versa.

The only licenses the provider must submit with the application are those required by Medicare or the state to function as the provider type in question. Licenses and permits that are not of a medical nature are not required. If the contractor knows that a particular state does not require licensure/certification and the "Not Applicable" boxes in the Identifying Information section of the Form CMS-855A are not checked, no further development is needed.

Regarding accreditation under the Identifying Information section of the Form CMS-855A, if the provider checks "Yes," the contractor shall ensure that the listed accrediting body is one that CMS recognizes in lieu of a state survey or other certification for the provider type in question. If CMS does not recognize the accrediting body, the contractor shall advise the provider accordingly. (Note, however, that the provider may not intend to use the listed accreditation in lieu of the state survey; it may have merely furnished the accrediting body in response to the question.)

Documents that are attainable only after state surveys or accreditation need not be included as part of the application, and the provider need not furnish the data requested in the Identifying Information section of the Form CMS-855A. However, the provider shall furnish those documents it can submit prior to the survey/accreditation. The contractor shall include all submitted licenses, certifications, and accreditations in the enrollment package it sends to the state.

(See section 10.3.1.1.14 of this chapter for information about processing alternatives involving licensure submissions.)

B. Correspondence Address and Telephone Number

The correspondence address must be one at which the contractor can directly contact the provider to resolve any issues once the provider is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, chain home office, or the provider's representative (e.g., attorney, financial advisor); however, it can be a P.O. Box. The contractor need not verify the correspondence address.

The provider may list any telephone number it wishes as the correspondence phone number. The number need not link to the listed correspondence address. If the provider fails to list a correspondence telephone number and it is required for the application submission, the contractor shall develop for this information via the procedures outlined in this chapter (e.g., the PCV for PECOS applications). The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the provider. The contractor is not required to verify the telephone number.

Unless CMS specifies otherwise, any change in the provider's phone number or address that the provider did not cause (i.e., area code change, municipality renames the provider's street) must still be updated via the Form CMS-855A.

C. E-mail Addresses

Regarding the correspondence e-mail address in the Correspondence Address and Telephone Number Section of the Form CMS-855A, this e-mail address can be a generic one. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the provider.

D. Medical Record Correspondence (MRC) Address

This is the address at which MRC (such as medical record review requests) is sent to the provider. In collecting and processing this data, the contractor shall follow the same basic instructions as those concerning the correspondence address outlined in sections 10.3.1.1.2(B) and (C) above (e.g., acceptance of generic e-mail address and telephone number; cannot be billing agency address; etc.). All processing alternatives that apply to correspondence address data also apply to MRC information.

***E*. Other Identifying Information**

Other than the tax identification number (TIN) and legal business name (LBN), the contractor may capture all information in the Correspondence Address and Telephone Number Section of the Form CMS-855A by telephone, the PCV (if applicable), e-mail, fax, or a review of the provider's web site.

10.3.1.1.4 – Section 4 (Practice Location Information) - Form CMS-855A

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. General Background

Unless CMS specifies otherwise, any change in the provider's phone number or address that the provider did not cause (i.e., area code change, municipality renames the provider's street) must still be updated via the Form CMS-855.

Any provider submitting a Form CMS-855A application must submit the 9-digit ZIP Code for each practice location listed.

(For paper applications only - If a practice location (e.g., hospital unit) has a CMS Certification Number (CCN) that is in any way different from that of the main provider, the contractor shall create a separate enrollment record in PECOS for that location. (This does not apply, however, to home health agency (HHA) branches, outpatient physical therapy/outpatient speech pathology (OPT/OSP) extension sites, and transplant centers.))

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

The contractor need not verify the provider's telephone number listed on the application, though the provider must report one. If it does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

If the contractor cannot verify the provider's address, the contractor shall request clarifying information from the provider. If the provider states that the facility is not yet operational, the contractor may continue processing the application. However, it shall indicate in its recommendation letter that the address of the facility could not be verified. For purposes of PECOS entry, the contractor can temporarily use the date the certification statement was signed as the effective date.

(For paper applications only: In Section 4A of the Form CMS-855A, if the "type of practice location" checkbox is blank, the contractor can confirm the information via the PCV, e-mail, or fax.)

B. Do Not Forward (DNF)

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

If the provider is closing its business and has a termination date, the contractor will likely need to make payments for prior services rendered. Since the practice location has been terminated, the contractor may encounter a DNF message. If so, the contractor should request the provider to complete the "special payment" address section of the Form CMS-855A and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so or unless an instruction in this chapter states otherwise. (See section 10.6.1.3(C)(5) of this chapter for additional information.)

C. Remittance Notices/Special Payments

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

If an enrolled provider that currently receives paper checks submits a Form CMS-855A change request (no matter what the change involves), the provider must also submit a Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT; once a provider changes its method of payment from paper checks to EFT, it must continue using EFT. A provider cannot switch from EFT to paper checks. The contractor shall verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

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

(i) One of the provider's practice locations

(ii) A P.O. Box

(iii) The provider's billing agent. (The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.)

(iv) The chain home office address. Per Pub.100-04, chapter 1, section 30.2, a chain organization may have payments to its providers sent to the chain home office. The provider must list the chain home office's LBN on the Form CMS-588. The TIN on the Form CMS-588 should be that of the provider.

(v) Correspondence address

(vi) A lockbox. (The contractor shall request additional information if it has any reason to suspect that the arrangement, at least with respect to any special payments that might be made, may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.)

D. Out-of-State Practice Locations

If a provider is adding a practice location in another state that is within the contractor's jurisdiction -- and, for PECOS applications, to the extent PECOS permits it --- a separate, initial Form CMS-855A enrollment application is not required if all of the following conditions are met:

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

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

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

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

(v) The provider type in question is not required to separately enroll each of its practice locations. (For example, a federally qualified health center (FQHC) would not meet this criterion because FQHCs must separately enroll each location.)

Consider the following examples:

EXAMPLE 1 - The contractor's jurisdiction consists of States X, Y and Z. Jones Health Care Facility (JHCF), Inc. is enrolled in State X with 3 sites. It wants to add a fourth site in State Y. The new site will be under JHCF, Inc. JHCF will not be establishing a separate corporation, LBN, or TIN for the site, and - per the state and CMS policy - a separate survey and provider agreement are not necessary; moreover, CMS policy does not require this provider type to separately enroll each of its practice locations. Since all 5 conditions above are met, JHCF, Inc. can add the fourth location via a change of information request, rather than an initial application. The change request must include all information relevant to the new location (e.g., licensure, new managing employees). (For paper applications only---and to the extent required---the contractor shall create a separate PECOS enrollment record for the State Y location.)

EXAMPLE 2 - The contractor's jurisdiction consists of States X, Y and Z. JHCF, Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y but under a

newly created, separate legal entity - JHCF, LP. The fourth location must be enrolled via a separate, initial Form CMS-855A.

EXAMPLE 3 - The contractor's jurisdiction consists of States X, Y and Z. Jones Health Services (JHS), Inc., is enrolled in State X with 1 location. It wants to add a second location in State Z under JHS, Inc. However, it has been determined that a separate survey and certification of the new location are required. A separate, initial Form CMS-855A for the new location is required.

E. Additional Practice Location Information

1. Special Payments

In the "Practice Location Information/Where Do You Want Remittance Notices or Special Payments Sent" section, if neither box is checked and no address is furnished, the contractor can contact the provider by telephone, e-mail, the PCV, or fax to confirm the provider's intentions. If the provider replies that the "special payments" address is the same as the practice location, no further development is needed. If, however, the provider wants payments sent to a different address, the provider must furnish this address in the "Where Do You Want Remittance Notices or Special Payments Sent" section of the Form CMS-855A.

Note that the provider/supplier can only have one special payment address per enrollment for both PECOS and paper applications. See section 10.3(C)(2)(b) for more information.

2. Base of Operations

In the Practice Location Information/Base of Operations section, if the "Check here" box is not checked and no address is furnished, the contractor can contact the provider by telephone, e-mail, the PCV, or fax to confirm the provider's intentions. If the provider replies that the base of operations address is the same as the practice location, no further development is needed. If the provider indicates that the base of operations is at a different location, the provider must furnish this address in the Base of Operations section of the Form CMS-855A.

3. Vehicle Information

In the Practice Location Information/Vehicle Information section, if the vehicle certificates are furnished but the applicable Form CMS-855A sections are blank, the contractor can verify via telephone, the PCV, e-mail, or fax that said vehicles are the only ones the provider has.

4. Primary Practice Location (PPL) Checkboxes

The provider must identify one – but no more than one – of the practice locations it lists in Section 4(A) as its PPL. If the provider identifies multiple PPLs or no PPLs, the contractor shall develop for additional information/clarification consistent with the instructions in Chapter 10. If the provider lists multiple practice locations, identifies one of them (e.g., Location A) as its PPL, and fails to check the PPL boxes for the other listed locations (Locations B, C, and D), the contractor can assume --- absent evidence to the contrary -- that Location A is the PPL and need not require the provider to check "No" for the PPL checkboxes for Locations B, C, and D.

5. Date First Patient Seen

For each practice location listed in Section 4(A), the provider must identify the date (month, day, and year) on which the first patient was or will be seen. If the provider fails to submit this data, the contractor shall develop for it consistent with the procedures in this chapter.

6. Medical Record Storage

In Section 4(C)(2), the provider must check whether it stores its patient medical records electronically and, if it checks "Yes," identify the service used to store these records. In the latter case, an actual website need not be disclosed. Only a general reference to the type of electronic storage is required (e.g., in-house software program, online service, vendor, etc.). It lies within the contractor's discretion to determine whether the description – which, again, need only be general in nature – adequately identifies the type of electronic service; if an inadequate description is furnished, the contractor shall develop for it consistent with the procedures in this chapter. Moreover, if a website is listed, the contractor need not access it to verify that the link is indeed where the records are stored.

7. Provider-Based

If the provider checks the "Outpatient Provider-Based Department" (PBD) box in Section 4(A), it must check one of the seven succeeding checkboxes that outlines the type of PBD involved. Except if CMS directs otherwise, the contractor need not verify any of the furnished PBD data in Section 4(A), including whether the department is indeed a PBD or the type of PBD involved. In addition, even if the contractor knows the department is provider-based, the provider need not check that it is a PBD. Only if the provider checks the PBD checkbox must it also identify the type.

10.3.1.3 – Form CMS-855I – Medicare Enrollment Application for Physicians and Non-Physician Practitioners

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

This application should be completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries *and, as applicable, wish to reassign their benefits under § 424.80.* (This includes a physician or practitioner who (1) is the sole owner of a professional corporation, professional association, or limited liability company and (2) will bill Medicare through this business entity.)

10.3.1.3.1 - Section 1 (Basic Information) – Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Purpose and Verification

In this section, the supplier indicates the reason for submittal of the application. *(This includes establishing, terminating, or changing reassignments.)* Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. For example, suppose a supplier is voluntarily terminating an enrollment as one supplier type and enrolling as a different supplier type; both transactions cannot be reported on the same application.

Excluding (1) the voluntary termination checkbox and (2) the effective date of termination---and except as stated in section 10.6.1.3 of this chapter---any blank data/checkboxes in the Basic Information section can be verified through any means (e.g., the PCV, e-mail, telephone, fax).

B. Voluntary Termination Reminder

When a practitioner submits a Form CMS-855I application to either (1) add a practice location in a new state or (2) relocate to a new state entirely, the contractor that received the application shall determine whether the practitioner still has an active PECOS enrollment record in the "other" state(s). If PECOS indeed indicates that the individual has an active practice location in the other state(s), the contractor should remind the practitioner that if he/she no longer intends to practice in that state, he/she must submit a Form CMS-855I voluntary termination application to the contractor for that jurisdiction. The reminder should be furnished in the approval letter that the receiving contractor sends to the practitioner or, if more appropriate, via the PCV, e-mail, or other form of written correspondence.

C. Break in Medical Practice

If the contractor receives a Form CMS-855I from a practitioner who was once enrolled in Medicare but has not been enrolled with any Medicare contractor for the previous 2 years, the contractor shall verify with the state (a) where the practitioner last worked and (b) whether the practitioner was convicted of a felony or had his/her license suspended or revoked. If such an adverse action was imposed, the contractor shall take action consistent with the instructions in this chapter.

10.3.1.3.2 - Section 2 (Personal Identifying Information) – Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Licensure Information

1. General Instructions

(The extent to which the applicant must complete the licensure information depends upon the supplier type involved. Requirements will vary by supplier type and by location; for instance, some states may require a particular supplier type to be "certified" but not "licensed," or vice versa. (The license *and certification* "Not Applicable" checkbox*es* are for instances where a state does not require licensure).)

The only licenses that must be submitted with the application are those required by Medicare or the state to function as the supplier type in question. Licenses and permits that are not of a medical nature are not required. In addition, and as mentioned above, instances can occur where the supplier need not be licensed at all in a particular state; the contractor shall still ensure, however, that the supplier meets all applicable state and Medicare requirements.

The contractor shall verify that the supplier is licensed and/or certified to furnish services in:

- The state in which the supplier is enrolling.

- Any other state within the contractor's jurisdiction in which the supplier (per the "Practice Location Information" section of the Form CMS-855I) will maintain a practice location.

The contractor shall also ensure that the individual answers "Yes" or "No" to the Section 2(B)(1) question regarding compact licenses if individual indicates that he/she is licensed. (See subsection (A)(6) below for more information on compact licenses.)

2. Notarization

If the applicant submits a license that is not notarized or "certified true," the contractor shall verify the license with the appropriate state agency. (A notarized copy of an original document has a stamp that states "official seal," along with the name of the notary public, the

state, the county, and the expiration date of the notary's commission. A certified "true copy" of an original document has a raised seal that identifies the state and county in which it originated or is stored.)

3. Temporary Licenses

If the supplier submits a temporary license, the contractor shall note the expiration date in PECOS. Should the supplier fail to submit the permanent license after the temporary license expiration date, the contractor shall initiate revocation procedures. (A temporary permit – one in which the applicant is not yet fully licensed and must complete a specified number of hours of practice to obtain the license – is not acceptable.)

4. Revoked/Suspended Licenses

If the applicant had a previously revoked or suspended license reinstated, the applicant must submit a copy of the reinstatement notice with the application.

5. License Expiration/Revocation Dates for Non-Certified Suppliers

For expired licenses, the contractor shall enter in PECOS the day after the expiration as the expiration date. For revoked and suspended licenses, the contractor shall enter in PECOS the revocation date (not the day after) as the expiration date. (See section 10.6.19(T) of this chapter for special instructions related to periodic license reviews.)

6. Interstate License Compacts

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

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

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

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

B. Correspondence Address, Medical Record Correspondence Address, and Telephone Number

1. Correspondence Address

The correspondence address must be one where the contractor can directly contact the applicant to resolve any issues once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

The contractor need not verify the correspondence address.

2. Medical Records Correspondence Address

The medical records correspondence address must be one where the contractor can directly contact the applicant regarding medical records once the supplier is enrolled in Medicare. It cannot be the address of a billing agency, management services organization, or the supplier's representative (e.g., attorney, financial advisor). It can, however, be a P.O. Box or, in the case of an individual practitioner, the person's home address.

Note that: (1) the contractor need not verify the medical records correspondence address; and (2) the medical records correspondence address does not apply to individuals reassigning all benefits.

3. Telephone Number

The supplier may list any telephone number he/she wishes as the correspondence or medical record correspondence phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence or medical record telephone number and it is required for the application submission, the contractor shall develop for this information – preferably via the PCV, e-mail, or fax. The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier. The contractor need not verify the telephone number.

C. E-mail Addresses

An e-mail address listed on the application can be a generic e-mail address. It need not be that of a specific individual. The contractor may accept a particular e-mail address if it has no reason to suspect that it does not belong to or is not somehow associated with the supplier.

D. Specialties

A physician must indicate his/her supplier specialty via a checkmark, an "X," or other symbol; if the physician has more than one specialty, he/she must indicate these specialties, showing "P" for primary and "S" for secondary. (Non-physician practitioners must indicate their supplier type.)

The contractor shall verify that any supplier identifying a secondary specialty on the Form CMS-855I application has the appropriate medical license. The contractor shall validate the license using the state's medical license website. If an active license is not found, the contractor shall develop via telephone, fax, email, or mail to confirm the supplier's intent and to obtain a copy of the license, if applicable.

The contractor shall deny the application if the individual fails to meet the requirements of his/her physician specialty (primary and/or secondary) or supplier type.

Notwithstanding the foregoing instructions in this subsection (D), if a Form CMS-855I enrollment application is submitted to report a primary or secondary specialty change, the

contractor shall not contact the physician, practitioner, or contact person directly to confirm either the change itself or the individual's intent to change his/her specialty.

E. Education

1. Non-Physician Practitioners - The contractor shall verify all required educational information for non-physician practitioners. While the non-physician practitioner must meet all federal and state requirements, he/she need not provide documentation of courses or degrees taken to satisfy these requirements unless the contractor requests it. To the maximum extent possible, the contractor shall use means other than the practitioner's submission of documentation---such as a state or school web site---to validate the person's educational qualifications.

2. Physicians - A physician need not submit a copy of his/her degree unless the contractor requests it. To the maximum extent possible, the contractor shall use means other than the physician's submission of documentation---such as a state or school web site--to validate the person's educational status.

F. Relocation to a New State: License Reviews

When a practitioner submits a Form CMS-855I application to either (1) add a practice location in a new state or (2) relocate to a new state entirely, the contractor that received the application shall review state licensing board information for the "prior" state to determine:

- Whether the practitioner had his/her medical license revoked, suspended, or inactive (due to retirement, death, or voluntary surrender of license), or otherwise lost his/her license, and

- If the practitioner has indeed lost his or her medical license, whether he/she reported this information via the Form CMS-855I within the timeframe specified in 42 CFR § 424.520.

If the practitioner is currently enrolled and did not report the adverse action to Medicare in a timely manner, the contractor shall---unless another directive in this chapter instructs otherwise, such as section 10.6.6----revoke the practitioner's Medicare enrollment and establish the appropriate reenrollment bar length. If the practitioner is submitting an initial enrollment application (e.g., is moving to a new state and contractor jurisdiction) and did not report the adverse action in Section 3 of the CMS-855I, the contractor shall--- unless another directive in this chapter instructs otherwise---- deny the enrollment application.

10.3.1.3.4 – Section 4 (Business Information) - Form CMS-855I

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Practice Location Verification

The contractor shall verify that the practice locations listed on the application exist and are valid addresses with the United States Postal Service (USPS). PECOS includes a USPS Address Matching System Application Program Interface (API), which validates address information entered and flags the address if it is determined to be invalid, unknown, undeliverable, vacant, unlikely to deliver mail (No-Stat), a CMRA (i.e., UPS Store, mailboxes, etc.), or a known invalid address false positive. These address types are not permitted in PECOS and are flagged upon entry. To reiterate: the practice location address in the Practice Location Information section must be a valid address with USPS; addresses entered in PECOS are verified via computer software to determine if they are valid and deliverable.

Each practice location is to be verified. However, the contractor shall not call the practice locations (or the contact person listed on the application) to validate them. The verification means described in the previous paragraph (and, if applicable to the provider/supplier type, a site visit) shall instead be used. Only if development is needed to confirm the location (e.g., USPS cannot validate the location) may the contractor telephone the location or contact person.

Any supplier submitting a Form CMS-855I application must submit the 9-digit ZIP Code for each practice location listed.

If the "*Business Structure Information*" checkbox*es* in Section 4A *are* blank, the contractor can confirm the information via the PCV, e-mail, or fax.

A practitioner who only renders services in patients' homes (i.e., house calls) must supply his/her home address in the Practice Location Information section. In addition, if a practitioner renders services in a retirement or assisted living community, the Practice Location Information section must include the name and address of that community. In either case, the contractor shall verify that the address is a physical address. Post office boxes and drop boxes are not acceptable.

If the physician or non-physician practitioner uses his/her home address as his/her practice location and exclusively performs services in patients' homes, nursing homes, etc., no site visit is necessary.

If an individual practitioner (1) is adding a practice location and (2) is normally required to complete a questionnaire in the Personal Identifying Information section of the Form CMS-855I specific to its supplier type (i.e., physical therapists), the person must submit an updated questionnaire to incorporate services rendered at the new location.

For suppliers paid via the Multi-Carrier System (MCS)--and except as otherwise stated in section 10.3--the practice location name entered in PECOS shall be the legal business name.

B. Telephone Number Verification

The contractor need not verify the supplier's telephone number listed on the application, though the supplier must report one. If the supplier does not, the contractor shall develop for a phone number using the procedures outlined in this chapter.

C. Unintended Changes

Unless CMS specifies otherwise, any change in the supplier's phone number or address that the supplier did not cause (i.e., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-855I.

D. Remittance Notices/Special Payments Mailing Address section

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

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

- The supplier's billing agent. The contractor shall request additional information if it has any reason to suspect that the arrangement – at least with respect to any special payments that might be made – may violate the Payment to Agent rules in Pub. 100-04, chapter 1, section 30.2.

- Correspondence address

If neither box in this section is checked and no address is provided, the contractor can contact the supplier by telephone, the PCV, e-mail, or fax to confirm the supplier's intentions. If the "special payments" address is the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in the Remittance Notices/Special Payments Mailing Address section must be completed via the Form CMS-855I.

E. Do Not Forward (DNF)

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

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

F. EFT

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

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

- A Form CMS-588 that switches its payment mechanism to EFT. (The change request cannot be processed until the Form CMS-588 is submitted.) All future payments (excluding special payments) must be made via EFT.

- The contractor shall also verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.

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

G. Solely-Owned Organizations

1. Paper Applications

All pertinent data for solely-owned organizations can be furnished via the Form CMS-855I alone. The contractor, however, shall require the supplier to submit a Form CMS-855B *and* CMS-855I if, during the verification process, it discovers that the supplier is not a solely-owned organization. (**NOTE**: A solely-owned supplier type that normally completes the Form CMS-855B to enroll in Medicare must still do so. For example, a solely-owned LLC that is an ambulance company must complete the Form CMS-855B even though the Practice Location Information/Sole Proprietor/Sole Proprietorship section makes mention of solely-owned LLCs. Use of the Practice Location Information section of the Form CMS-855I is limited to suppliers that perform physician or practitioner services.)

(Sole proprietorships need not complete the Business Information portions of Section 4 of the Form CMS-855I. Per definition, a sole proprietorship is not a corporation, professional association, etc. Do not confuse a sole proprietor with a physician whose business is that of a corporation, LLC, etc., of which he/she is the sole owner.)

In the Business Information section, the supplier may list a type of business organization other than a professional corporation, a professional association, or a limited liability company (e.g., closely-held corporation). This is acceptable so long as that business type is recognized by the state in which the supplier is located.

The contractor shall verify all data furnished in the Business Information section (e.g., legal business name, TIN, adverse legal actions). If the Business Information section is left blank, the contractor may assume it does not pertain to the applicant.

A solely-owned physician or practitioner organization that utilizes the Business Information section to enroll in Medicare can generally submit change of information requests to Medicare via the Form CMS-855I. However, if the change involves data not captured on the Form CMS-855I, the change must be made on the applicable CMS form (e.g., Form CMS-855B).

H. Individual Reassignment/Affiliation Information

If the applicant indicates that he/she intends to render all or part of his/her services in a private practice, clinic/group, or any organization to which he/she would reassign benefits, the contractor shall ensure that the applicant (or the group or organization*, as applicable) has completed Section 4(F)(1)/(2) of the Form CMS-855I for each party to which the applicant is reassigning benefits.* The contractor shall also verify that *each* individual, clinic/group practice, or organization *to which benefits are being reassigned* is enrolled in Medicare. If it is not, the contractor shall enroll the individual, clinic/group practice, or organization prior to approving the reassignment.

See section 10.3.1.4 of this chapter for detailed instructions regarding the processing of reassignments.

I. Sole Proprietor Use of EIN

The practitioner may obtain a separate EIN if he/she wants to receive reassigned benefits as a sole proprietor.

J. NPI Information for Groups

If a *reassignee* is already established in PECOS (i.e., status of "approved" unless the Form CMS-855I is submitted for the purpose of revalidation), the *reassignor* need not submit the *reassignee's* NPI in *Section 4(F)* of the Form CMS-855I.

K. Out-of-State Practice Locations

Except as stated otherwise in section 10.3 or in another CMS directive, if a supplier is adding a practice location in another state, a separate, initial Form CMS-855I enrollment application is required for that location even if:

- The location is part of the same organization (e.g., a solely-owned corporation),
- The location has the same tax identification number (TIN) and legal business name (LBN), and
- The location is in the same contractor jurisdiction.

To illustrate, suppose the contractor's jurisdiction consists of States X, Y, and Z. Dr. Jones, a sole proprietor, is enrolled in State X with 2 locations. He wants to add a third location in State Y under his social security number and his sole proprietorship's employer identification number. A separate, initial Form CMS-855I application is required for the State Y location.

10.3.1.4 - Reassignment of Medicare Benefits *Via the Form CMS-855I*

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Background

Consistent with 42 CFR § 424.80(b)(1) and (b)(2) and Pub. 100-04, Chapter 1, sections 30.2.1(D) and (E) and 30.2.6 and 30.2.7, Medicare may pay: (1) a physician or other provider's or supplier's employer if the provider or supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services; or (2) an entity (i.e., a person, group, or facility) that is enrolled in the Medicare program for services furnished by a physician or other provider or supplier under a contractual arrangement with that entity. This means that Part A and Part B entities other than physician/practitioner group practices can receive reassigned benefits, assuming the requirements for a reassignment exception are otherwise met.

Reassignments of benefits are now facilitated via the Form CMS-855I. The Form CMS-855R has been discontinued.

B. General Reassignor Policies

An individual who renders Medicare Part B services and seeks to reassign his/her benefits to an eligible entity should complete Sections 4(F)(1) and (2) of the Form CMS-855I for each party eligible to receive reassigned benefits; the individual must be enrolled in Medicare as a physician/practitioner prior to reassigning his/her benefits. The applicable sections of the Form CMS-855I (e.g., Section 1(A) (Reason for Submittal); Section 1(B) (Reassignment of Benefits checkbox); Sections 4(F)(1) and (2); Section 15; etc.) must also be completed for any individual who is adding, terminating, changing an existing reassignment. (Note that Section 4(F)(3) is optional.)

The individual can report multiple new, changed, or terminated reassignments to parties with the same or different employer identification numbers (EINs) on a single Form CMS-855I by submitting separate Section 4(F)s and Section 15(C)s with the appropriate reassignee signatures. (For instance, if a physician is reassigning to Groups A, B, and C, an

authorized/delegated official of A, B, and C, respectively, must sign a separate Section 15(C).) The contractor shall issue one approval letter using the applicable model letter in sections 10.7.6(D) and 10.7.6(M) of chapter 10.

For reassignment terminations, the effective date of termination as indicated on the Form CMS-855I is the day after the effective date of termination. Payment will no longer be made to the reassignee the day after the termination effective date. To illustrate, suppose a physician submits a Form CMS-855I to terminate a reassignment to a group. She lists June 30, 2025, as the termination date. The termination effective date listed in PECOS and any correspondence to the supplier should be July 1, 2025.

There could be rare situations where an unenrolled individual seeks to reassign his/her benefits and submits only Section 4(F) of the Form CMS-855I. The contractor in this situation shall develop for an initial enrollment application from the individual.

The contractor need not verify whether the reassigning individual is a W-2 employee or a 1099 contractor.

Regarding reassignment and revoked or deceased physicians, see section 10.6.17(G)(1) of this chapter.

C. Policies Concerning Reassignees

1. Site of Service

Per Pub. 100-04, chapter 1, section 30.2.7, a reassignment of benefits to any eligible party is permitted regardless of where the service was rendered or whether the party owns or leases that location. As such, the contractor need not verify the reassignee's ownership or leasing arrangement with respect to the reassignment.

2. Organization/Group Receiving the Reassigned Benefits

The most common reassignment situation is a physician/practitioner who reassigns his/her benefits to a physician/practitioner group. Here, the reassignee's authorized or delegated official must sign Section 15(C) of the reassignor's Form CMS-855I.

3. Individual Receiving Reassigned Benefits

An individual can receive reassigned benefits. This can occur, for instance, when a physician/practitioner reassigns his/her benefits to a physician/practitioner who is either (1) a sole proprietor or (2) the sole owner of an entity listed in the Business Information section of the Form CMS-855I. Here, the only required forms are separate Form CMS-855Is from the reassignor and the reassignee. (No Form CMS-855B or Form CMS-855A is involved.) The reassignee must sign Section 15(C) of the reassignor's Form CMS-855I. (Note that Section 15(C) applies to all reassignees, regardless of whether they are organizations or individuals. In the former case, the organization's authorized/delegated official must sign Section 15(C); with the latter, the individual reassignee must sign.)

The contractor shall follow the instructions in Pub. 100-04, Chapter 1, sections 30.2 – 30.2.16 to ensure that the reassignee is indeed eligible to receive reassigned benefits.

4. Additional Information

If the reassignee is not enrolled in Medicare, said party must complete, as applicable, an initial Form CMS-855B, Form CMS-855A, or Form CMS-855I.

Benefits are reassigned to a provider or supplier, not to the provider/supplier's practice location(s). As such, the reassignor need not update his/her reassignment data on the Form CMS-855I each time the reassignee adds a practice location.

When a group practice adds a new practice location, each physician/practitioner who reassigns to the group and wants to bill from this new location must have a new PTAN issued to him/her if the group is issued a new PTAN. (The group will only be issued a new PTAN if the new location is in a separate fee locality.)

D. Additional Signature Policies

1. Who Must Sign

For initial/new reassignments, both the reassignor and reassignee (or an authorized/delegated official of the latter) must sign, respectively, Section 15(B) and (C) of the reassignor's Form CMS-855I. If either required signature is missing, the contractor shall develop for it.

For changes in reassignment data or for reassignment terminations (and as similar situations were handled with the Form CMS-855R), only the reassignor or reassignee must submit the termination or applicable changed information in Section 4(F) and sign Section 15(B) or (C) (as applicable).

2. Official On/Not on File

An authorized/delegated official who signs Section 15(C) of the Form CMS-855I must be currently on file with the contractor as such. If this is a new enrollment --- with a joint submission of the Form(s) CMS-855A or CMS 855B and Form CMS-855I --- the person must be listed on the Form CMS-855A or Form CMS-855B as an authorized/delegated official.

There may be situations where a Form CMS-855I is submitted and the reassignee is already enrolled in Medicare via the Form CMS-855B. However, the authorized/delegated official is not on file. In this case, the contractor shall develop for a Form(s) CMS-855A or CMS-855B change request that adds the new authorized/delegated official.

3. Development Needed

If the contractor must develop for information in Section 4(F)(1) or (2), the following apply:

(i) Initial reassignments (as part of an initial Form CMS-855I or a Form CMS-855I change of information that adds a new reassignment): Both the reassignor and reassignee (or, for entities, an authorized/delegated official thereof) must sign any certification statement that must accompany the reassignor's response.

(ii) All other transactions – Only the reassignor or reassignee need sign any required certification statement.

4. Other Signature Policies

The contractor shall follow all other applicable signature policies (e.g., form of signature) outlined in section 10.3.1.3.6 of this chapter.

5. Processing Alternatives

As applicable, the contractor may apply the processing alternatives identified in section 10.3.1.3.7 to the Section 4(F) data.

E. Inter-Jurisdictional Reassignments

If a reassignor is reassigning their benefits to a reassignee located in another contractor jurisdiction (a permissible practice), the principles in this section 10.3.1.4(E) apply unless another CMS directive states otherwise.

1. The reassignor must be properly licensed or otherwise authorized to perform services in the state in which he/she has his/her practice location. The practice location can be an office or even the individual's home (for example, a physician interprets test results in his home for an independent diagnostic testing facility).

2. The reassignor need not – pursuant to the reassignment - enroll in the reassignee's contractor jurisdiction nor be licensed/authorized to practice in the reassignee's state. If the reassignor will be performing services within the reassignee's state, the reassignor must enroll with the contractor for (and be licensed/authorized to practice in) that state.

3. The reassignee must enroll in the contractor jurisdictions in which (1) it has its own practice location(s), and (2) the reassignor has his or her practice location(s). In Case (2), the reassignee:

(i) Shall identify the reassignor's practice location as a practice location on its Form CMS-855B or Form CMS-855I.

(ii) Shall select the practice location type as "Other health care facility" and specify "Telemedicine location" in the Practice Location Information of its Form CMS-855.

(iii) Need not be licensed/authorized to perform services in the reassignor's state.

To illustrate, suppose Dr. Smith is in Contractor Jurisdiction X and is reassigning his benefits to Jones Medical Group in Contractor Jurisdiction Y. Jones must enroll with X and with Y. Jones need not be licensed/authorized to perform services in Dr. Smith's state. However, in the Practice Location Information section of the Form CMS- 855B it submits to X, Jones must list Dr. Smith's location as its practice location.

F. Reassignment to CAHs

Reassignment to a Part A provider or supplier might occur when: (1) a physician or practitioner reassigns benefits to a hospital, skilled nursing facility, or critical access hospital billing under Method II (CAH II); or (2) a nurse practitioner reassigns to a CAH II.

If the entity receiving the reassigned benefits is not a CAH II, it must enroll with the contractor via a Form CMS-855B, and the physician/practitioner reassigning benefits must complete and submit a Form CMS-855I.

If the entity receiving the reassigned benefits is a CAH II, the entity need not complete a separate Form CMS-855B to receive reassigned benefits. The physician/practitioner can reassign benefits directly to the CAH II's Part A enrollment. The distinction between CAHs billing Method I vs. Method II only applies to outpatient services. It does not apply to inpatient services.

Under Method I:

- *The CAH bills for facility services*

- *The physicians/practitioners bill separately for their professional services*

Under Method II:

- *The CAH bills for facility services*

- *If a physician/practitioner has reassigned his/her benefits to the CAH, the CAH bills for that particular physician's/practitioner's professional service*

- *If a CAH has elected Method II, the physician/practitioner need not reassign his/her benefits to the CAH. For those physicians/practitioners who do not reassign their benefits to the CAH, the CAH only bills for facility services and the physicians/practitioners separately bill for their professional services (akin to Method I).*

Although physicians and non-physician practitioners are not required to reassign their benefits to a CAH that bills Method II, doing so allows them to participate in the Electronic Health Records (EHR) Incentive Program for Eligible Professionals (EPs).

In this scenario, the Form CMS-855I shall be submitted to the Part B MAC and the Form CMS-855A submitted to the Part A MAC. The Part B MAC is responsible for reassigning the individual to the Part A entity.

The reassignment to the Part A entity shall only occur if the Form CMS-855A for the CAH II has been finalized. This can be determined by viewing PECOS to identify if an approved enrollment exists for the CAH II. If one does not, the Part B MAC shall return the Form CMS-855I to the provider on the ground that it is inapplicable to the transaction in question (i.e., the Form CMS-855A has not been finalized). If an enrollment record exists but is pending state/SOG review, the Part B MAC shall contact the Part A MAC to determine if state/SOG Location (as applicable) approval has been received but not yet updated in PECOS prior to returning the applications.

G. Reassignments Related to Revoked or Deactivated Reassignee

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

When sending a deactivation, revocation, or voluntary withdrawal letter to the deactivated or revoked non-certified Part B supplier, said letter shall include the following language: "Please notify all physician assistants and/or group members who reassign benefits to your organization that, in accordance with 42 CFR §424.540(a)(2), their Medicare enrollment status may be deactivated if they fail to update their enrollment record within 90 calendar days."

H. Group and Reassignment Reactivation

If a group practice submits a reactivation application after being deactivated for non-response to a revalidation request, the contractor shall reactivate the group's reassignments when the group's reactivation application has been approved; Form CMS-855I applications for the reassignments are not required. The effective dates assigned to the reassigned providers shall align with the group's effective date per existing reactivation instructions. (This section 10.3.1.4(H) only applies to deactivations based on a non-response to a revalidation request.)

I. Additional Information

The contractor:

- Shall follow this chapter's existing instructions *(and all other applicable CMS guidance) for validating information furnished by a physician/practitioner on the Form CMS-855I, including any reassignment data in Sections 4(F)(1) and (2).*

- Shall *follow the instructions in section 10.6.2 of this chapter regarding the application of effective dates.*

10.3.2.1 – CMS-20134 (Section 1 - Basic Information)

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Reason for Submittal

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter, in another CMS directive, or as permitted by PECOS, the supplier may only check one reason for submittal. For example, suppose a supplier is changing its tax identification number (TIN). The supplier must submit two applications: (1) an initial Form CMS-20134 as a new supplier; and (2) a Form CMS-20134 voluntary termination. Both transactions cannot be reported on the same application.

Excluding (1) the voluntary termination checkbox and (2) the effective date of termination data in the Basic Information section of the Form CMS-20134, any blank data/checkboxes in the Basic Information section can be verified through any means the contractor chooses (e.g., e-mail, telephone, the PCV, fax).

B. Centers for Disease Control (CDC) Diabetes Prevention Recognition Program (DPRP)

To be eligible to enroll as an MDPP supplier, an entity must have either:

- MDPP preliminary recognition or
- DPRP full recognition

Note that MDPP preliminary recognition includes both interim preliminary recognition as designated by CMS as well as preliminary DPRP recognition as designated by the CDC.

Organizations with preliminary or full CDC DPRP recognition must submit to CMS a copy of its recognition letter provided by CDC. To verify the applicant's eligibility, the contractor shall:

- Verify that a letter has been submitted for each organizational code provided in Sections 2 and 4 of the Form CMS-20134

- Verify that (1) any letters provided have appropriate letterhead from CDC and (2) each reflects that the organization has met either preliminary or full recognition with an expiration date that has not passed.
- Verify that the organization code or codes provided in Sections 2 and 4 of the Form CMS-20134 matches both the organization code on the letter(s) and the organization code on CDC's online registry, which is updated just-in-time and can be found at *https://dprp.cdc.gov/cms/download*.
- Verify that the CDC's online registry or any list provided by CMS indicates that the entity associated with that organization code is associated with an in-person delivery mode and that a delivery mode of in-person is noted in the letter's letterhead.
- Verify that CDC's online registry indicates that the entity associated with that organization code has met either preliminary or full recognition.
- Verify that the name associated with the organization code on CDC's online registry is consistent with what is listed on the letter, as well as what is provided in Sections 2 or 4 of the Form CMS-20134

Certificates or letters of the above recognitions are the only eligibility documents required by Medicare to function as the supplier type in question. Any other licenses, certificates, and permits that (1) are not of a medical nature or (2) are of a medical nature but unrelated to MDPP are not required.

C. Recognition Status

In situations where an MDPP supplier is required to submit a copy of its CDC recognition but fails to do so, the contractor need not obtain such documentation from the supplier if the contractor can verify the information independently. This may be done by: (1) reviewing and printing (or electronically saving in PECOS) confirming pages from the Centers for Disease Control and Prevention Web site; (2) requesting and receiving from the CDC written confirmation of the supplier's status therewith; or (3) utilizing another third-party verification source. Similarly, if the supplier submits a copy of the applicable recognition but fails to complete the applicable section of the form, the section need not be completed if the data in question can be verified on the recognition itself or via any of the three mechanisms described above in this paragraph. The contractor shall not develop for a correction to the form if the recognition information can be verified as described above.

The above-referenced written confirmation of the supplier's status can be in the form of a letter, fax, or email, but it must be in writing. Documentation of a verbal conversation between the contractor and the body in question does not qualify as appropriate confirmation.

10.4.1.2 – Receipt of Application

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

A. Acknowledgment of Receipt of Application

The contractor may, but is not required to, send out acknowledgment letters or e-mails in cases where PECOS did not automatically do so.

B. Pre-Screening of Application

The contractor is no longer required to pre-screen provider enrollment applications.

C. Reassignment Packages

(For PECOS applications, note that some of the following instructions regarding development may not apply and the contractor can thus disregard them. This is because PECOS will require the applicable missing forms at the time the provider is completing the application.)

In situations where an entity wants to simultaneously (i) enroll a group practice, (ii) enroll the individual practitioners therein, and (iii) reassign benefits accordingly, the instructions below apply. *(With the elimination of the Form CMS-855R, the prior instructions in this section 4.1.2(C) may differ from those below.)* As early in the process as possible, the contractor shall examine the incoming forms to see if a reassignment may be involved; also, the contractor is encouraged (though not required) to have the same analyst handle all applications in the package.
For instance, suppose a brand-new group wants to enroll but submits only the Form CMS-855B without including the Form CMS-855Is *(and the reassignment information thereon)* for its group members (i.e., the Form CMS-855B arrives alone without the other forms). *The* contractor shall develop for the other forms if they are not submitted upon receipt and processing of the Form CMS-855B.

10.5- Timeliness and Accuracy Standards

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Sections 10.5(A) through 10.5(B)(4) of this chapter address the timeliness and accuracy standards applicable to the processing of Form CMS-855, Form CMS-20134 applications (initial and change of information and revalidation) and opt-out affidavits. Even though the provisions of 42 CFR § 405.818 contain processing timeframes that differ than those in sections 10.5(A) through 10.5(B)(4), the contractor shall adhere to the standards specified in sections 10.5(A) through 10.5(B)(4).

The term "PECOS applications" means web-based applications. For special instructions regarding the processing of applications submitted via PECOS 2.0, see section 10.3 of this chapter. The PECOS instructions in section 10.3 take precedence over those in this section 10.5.

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

The processing of an application or opt-out affidavit generally includes, but is not limited to, the following activities:

- For paper applications - Receipt of the application or opt-out affidavit in the contractor's mailroom and forwarding it to the appropriate office for review. (This is the intake process.)
- For PECOS applications - Electronic receipt of the application.
- For paper applications – Completing the intake process.
- Ensuring that the information on the application or opt-out affidavit is verified.
- Requesting and receiving clarifying information.
- Site visit (if necessary).
- Requesting fingerprints (if necessary).

- For certified providers/suppliers (and as applicable to the transaction and/or provider/supplier type), formal notification to the state and/or CMS Survey & Operations Group (SOG) Location of the contractor's approval, denial, or recommendation for approval of the application.

(Note: The timeliness metrics discussed in this section are a combination of Part A applications and Part B applications and opt-out affidavits.)

For purposes of sections 10.5(A) and 10.5(B) below:

- The term "site visit" means that the provider or supplier requires an on-site review to determine whether the provider or supplier is operational based on the provider/supplier type.

- The term "development" means that the contractor needs to contact the provider or supplier for additional information. (A development request (via letter, fax, email, the PCV, or telephone contact for development) to the provider or supplier is considered to be the first development request.)

- The term "fingerprinting" means that 5 percent or greater owners (including partners who own at least 5 percent) of a provider or supplier is required to submit fingerprints for an additional level of screening.

A. Standards for Initial and Change of Information Applications and Opt-Out Affidavits

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term "initial applications" also includes:

- Form CMS-855 or Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the new owner.

- "Complete" Form CMS-855 or Form CMS-20134 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, or (c) as a Form CMS-855 or Form CMS-20134 reactivation.

- Opt-out affidavits submitted for an eligible practitioner's first opt-out period.

For purposes of sections 10.5(A)(1) through 10.5(A)(4) of this chapter, the term "changes of information" also includes:

- Form CMS-855 and Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the old owner.

- Form CMS-588 changes submitted without a need for an accompanying complete Form CMS-855 or Form CMS-20134 application.

- *Reassignment applications* that are not part *of an initial, revalidation, or reactivation* application *(e.g., adding a new reassignment, changing an existing reassignment).*

- Form CMS-855 and Form CMS-20134 voluntary terminations.

- Opt-out early termination requests (of initial opt-out affidavits), changes of information and cancellation requests.

Initial and change of information application and opt-out timeliness standards shall be reported together. Likewise, initial, change of information, and opt-out affidavit accuracy shall be reported together.

1. Paper Initial and Change of Information Applications and Opt-Out Affidavits - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 65 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initial, changes of information, termination requests and cancellation requests) that require a site visit, development and/or fingerprinting within 100 calendar days of receipt.

b. Form CMS-855 and Form CMS-20134 Initial and Change of Information Applications and Opt-Out Affidavits That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS- 20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 30 calendar days of receipt.

The contractor shall process 100 percent of all Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits (initials, changes of information, and termination and cancellation requests) that do not require a site visit, development and/or fingerprinting within 65 calendar days of receipt.

2. Paper Initial and Change of Information Applications and Opt-Out Affidavits – Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 initial and change of information applications and opt-out affidavits in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in sections 10.5(A)(1) through 10.5(A)(2) of this chapter) and all other applicable CMS directives.

3. PECOS Initial and Change of Information Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with existing instructions; site visit (if required) and/or requesting fingerprints (if necessary).

a. PECOS Initial and Change of Information Applications That Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Initial and Change of Information Applications That Do Not Require a Site Visit, Development and/or Fingerprinting

The contractor shall process 95 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Initial and Change of Information Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS initial and change of information applications in full accordance with all the instructions in this chapter (excluding the timeliness standards identified in section 10.5(A)(3) above) and all other applicable CMS directives.

B. Standards for Revalidation Applications

For purposes of sections 10.5(B)(1) through 10.5(B)(3)(b) of this chapter, the term "revalidation applications" includes complete Form CMS-855 or Form CMS-20134 revalidation applications submitted by enrolled providers.

1. Paper Revalidation Applications that Require Site Visits, Development and/or Fingerprinting - Timeliness

Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. Form CMS-855 and Form CMS-20134 Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting – Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that require site visits, development and/or fingerprinting within 65 calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 100 calendar days of receipt.

b. Paper Revalidation Applications that do not Require Site Visits, Development, and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications that do not require site visits, development and/or fingerprinting within 30 calendar days of receipt and process 100 percent of paper Form CMS-855 and Form CMS-20134 revalidation applications within 65 calendar days of receipt.

2. Paper Revalidation Applications - Accuracy

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 revalidations in full accordance with all the instructions in this chapter (with the exception of the timeliness standards identified in section 10.5(B)(1) above) and all other applicable CMS directives.

3. PECOS Revalidation Applications - Timeliness

This process generally includes, but is not limited to, verification of the application in accordance with existing instructions; requesting and receiving clarifying information in accordance with existing instructions; site visit (ifrequired) and/or requesting fingerprints (if necessary). Please refer to section 10.5 above for definitions of site visits, development, and fingerprinting.

a. PECOS Revalidation Applications That Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of all Form CMS-855 and Form CMS- 20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 50 calendar days of receipt and process 100 percent of all Form CMS-855 and Form CMS-20134 PECOS revalidation applications that require a site visit, development and/or fingerprinting within 85 calendar days of receipt.

b. PECOS Revalidation Applications That Do Not Require a Site Visit, Development and/or Fingerprinting - Timeliness

The contractor shall process 80 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 15 calendar days of receipt and process 100 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications that do not require a site visit, development and/or fingerprinting within 50 calendar days of receipt.

4. PECOS Revalidation Applications - Accuracy

The contractor shall process 98 percent of Form CMS-855 and Form CMS-20134 PECOS revalidation applications in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in sections 10.5(B)(1) and 10.5(B)(3)(b) above) and all other applicable CMS directives.

C. General Timeliness Principles

Unless stated otherwise in this chapter or in another CMS directive, the principles discussed below apply to all applications discussed in sections 10.5(A)(1) through 10.5(B)(3) of this chapter (e.g., change of ownership (CHOW) applications submitted by old and new owners, CMS-588 forms).

1. Clock Stoppages

The processing timeliness clock temporarily stops when the situations identified in section 10.5(C)(1) occur:

- Referring an application to the Office of Inspector General (OIG) or the Unified Program Integrity Contractor (UPIC).

- Waiting for a final sales agreement (e.g., CHOW, acquisition/merger).

- Contacting: (i) the SOG Location, and/or state agency regarding a provider-based or CHOW determination; (ii) the SOG Location or state agency with a question regarding the application of a CMS policy; (iii) contacting the SOG Location or state agency.

- Referring a provider or supplier to update their information in the National Plan & Provider Enumeration System.

- Contacting CMS' Provider Enrollment & Oversight Group (PEOG) for the following reasons: questions regarding the application or CMS policy; an adverse legal action review; affiliations/overpayments found on the monthly report or PECOS; Advanced Provider Screening criminal alerts; delayed site visits; referrals to PEOG (if required under this chapter) for final review of certain certified provider/supplier applications.

- Referring a provider to the Social Security Administration to resolve a discrepancy involving a social security number or to the Internal Revenue Service to resolve a tax identification number or individual tax identification number issue.

- Contacting another contractor for any type of PECOS update (i.e.: locked associates).

- Contacting the PECOS Maintainer for resolutions to system issues (i.e.: RightNow tickets).

- Practice location and special payment address changes as well as specialty changes with future dates.

- If fingerprints are required, the timeliness clock stops when the fingerprint request is issued and resumes when the contractor receives the results. (If additional information is developed at the same time as the fingerprint request is issued, no action shall be taken on the developed information until after the fingerprint results are received.)

- Any other clock stoppage expressly permitted in this chapter or by CMS

Should a dependent application be needed to continue processing, the processing clock stops when the development is issued and resumes once the development is received.

Consistent with section 10.6.19(I), the contractor shall document in PECOS any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. The contractor will thus be able to furnish explanatory documentation to CMS should the applicable time limits be exceeded. To illustrate, assume that a contractor received an initial Form CMS-855I application on March 1. On March 30, the contractor sent a question to CMS and received a response on April 7. The processing time clock stops from March 31 to April 7. The contractor should document PECOS to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

2. Calendar Days

Unless otherwise stated in this chapter, all days in the processing time clock are "calendar" days, not "business days." If the final day of a metric falls on a weekend or holiday, this remains the day by which the application must be processed. If the contractor cannot finish processing the application until the next business day, it should document in PECOS that the final day of the metric fell on a Saturday/Sunday/holiday and furnish any additional explanation as needed.

3. Date-Stamping – Paper Applications Only

All incoming correspondence must be date-stamped on the day it was received in the contractor's mailroom. This includes, but is not limited to:

- Any Form CMS-855 or Form CMS-20134 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- Letters from providers. (The first page of the letter must be date-stamped.)

- Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)

- Data that the provider furnishes (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because some contractors interleaf the new/changed pages within the original application. Thus, it is necessary to determine the sequence in which the application and the additional pages were received.)

(Note: PECOS applications are considered "date stamped" on the date the application was received.)

The timeliness clock begins on the date on which the application/envelope is date-stamped in the contractor's mailroom, not the date on which the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the above bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

In addition, and unless stated otherwise in this chapter or in another CMS directive, all incoming enrollment applications (including change requests) must be submitted via mail (unless circumstances require submission via fax or email).

4. When the Processing Cycle Ends

For (1) Form CMS-855A applications, and (2) Form CMS-855B applications submitted by ambulatory surgical centers (ASCs) or portable x-ray suppliers, the processing cycle ends on the date that the contractor enters a final status in PECOS (e.g., denied, returned, rejected, approval recommended) rather than the date on which the contractor sends formal notification of approval recommended, etc., to the state or SOG Location. (Note that accompanying applications (e.g., Form CMS-855*I reassignment* application submitted with a Form CMS-855B for an ASC) would also end their processing cycle).

In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the state), the cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

For (1) Form CMS-855I applications, (*2*) Form CMS-855B applications from suppliers other than ASCs and portable x-ray suppliers, (*3*) Form CMS-20134 and (*4*) Form CMS-855S applications the processing cycle ends on the date that the contractor enters a final status (approved, denied, rejected, returned, etc.) in PECOS.

5. PECOS Applications

See section 10.3 of this chapter for additional information on the processing of PECOS applications.

10.6.1.2 – Changes of Information – Transitioned Certified Providers and Suppliers

((Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

(Until further notice from CMS, the instructions in this section 10.6.1.2 apply only to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, FQHCs, Part A OPT/OSP providers, ASCs, PXRSs, hospitals, hospices, and ESRD facilities. The contractor shall continue to use the existing change of information instructions--now in section 10.6.22.1 of this chapter--for all non-transitioned certified provider/supplier types.

When executing the instructions in this section 10.6.1.2, the contractor can disregard directives that obviously do not apply to the transitioned provider/supplier type in question (e.g., references to hospitals).

All references to the SOG Location (formerly the "RO") in this section 10.6.1.2 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

The instructions in this section 10.6.1.2 address the handling of changes of information involving certified providers and certified suppliers. With the transition of certain functions from the SOG Locations to the contractors and the Provider Enrollment & Oversight Group (PEOG), the processing instructions for these changes of information are slightly different from previous guidance. In particular: (1) the SOG Locations will be much less involved in the process; (2) tie-in and tie-out notices will no longer be issued; (3) the contractor will be responsible for finalizing changes previously requiring SOG Location approval; and (4) recommendations of approval will be made to (and reviewed by) the state agency (hereafter occasionally referenced simply as "state") only and not the SOG Location.

Except as stated otherwise:

(1) Any provider-specific instructions in section 10.2.1 et seq. of this chapter pertaining to changes of information (e.g., relocation of a federally qualified health clinic site; *addition or deletion of an OPT/OSP extension site*) take precedence over those in this section 10.6.1.2.

(2) Any instructions pertaining to ownership changes in section 10.6.1.1 et seq. of this chapter take precedence over those in this section 10.6.1.2.

(3) Any instructions pertaining to voluntary terminations of entire enrollments and/or provider agreements in section 10.6.1.3 of this chapter take precedence over those in this section 10.6.1.2.

(4) Any instructions in this section 10.6.1.2 concerning the voluntary termination of a branch, sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.1.2 when processing this transaction.

Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Changes of Information Requiring Recommendation to the State

1. Types

The following Form CMS-855 transactions require an approval recommendation to (and review by) the state prior to approval:

- Addition of outpatient physical therapy/outpatient speech pathology extension site
- Addition of HHA branch
- Addition or deletion of a prospective payment system (PPS)-excluded psychiatric unit, rehabilitation unit, or transplant program.
- Addition or deletion of swing-bed approval (see Section 2A2 of the Form CMS-855A)
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- Addition, deletion, or relocation of a hospice practice location
- Addition, change, and/or relocation of a hospital practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)
- Addition of PXRS practice location

2. Initial Contractor Review and Recommendation

The contractor shall process the change request consistent with the instructions in this chapter (e.g., verification of data, developing for missing or conflicting data). If the contractor determines that the change/addition should be approved, it shall send the appropriate recommendation letter (see section 10.7 et seq.) to the state with all applicable documentation that the contractor currently sends in such situations. The SOG Location need not be copied on the letter.

Nothing in this section 10.6.1.2(A)(2):

- Prohibits the contractor from returning or rejecting the application if grounds for doing so exist.
- Supersedes any applicable requirement for performing a site visit (including the timing of such visits).

3. State Review and Contractor Receipt of Recommendation

The state will review the recommendation of approval, the application, and any other pertinent information. If the state decides to perform a survey, it will do so and notify the contractor thereof.

a. State Recommends Approval

If the state concludes that the change/addition should be approved, it will make a recommendation to this effect to the contractor, typically via a Form CMS-1539 and/or similar confirming documentation. No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov containing general identifying data about the provider (including LBN, NPI, CCN, specialty, facility name and address), a copy of the Form CMS-1539 (or other similar documentation evidencing the state's approval recommendation, if available), the draft provider approval letter, and a description of the change to be made. If, to the contractor's knowledge, a new CCN is required, the name and address of the new entity requiring the CCN should be furnished along with the effective date. If a termination is involved (e.g., HHA branch), the contractor shall include the old CCN and the termination date in the e-mail.

Once PEOG responds to the contractor, the latter may finalize its processing of the application (e.g., sending copies of the provider notification of approval to the state and, if applicable, accrediting organization; switching the PECOS record from "approval recommended" to "approved").

b. State Does Not Recommend Approval

If the state does not recommend approval, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov for guidance. The e-mail to him/her shall contain (1) the identifying data described in (3)(a) above; (2) a copy of the notification from the state declining to recommend approval; and (3) any other information the contractor deems pertinent. PEOG will review the matter and furnish the contractor additional instructions, which the contractor shall follow.

4. Additional Policies

a. Post-Recommendation Inquiries - Once the contractor has made its recommendation for approval to the state, any inquiry the contractor receives from the provider regarding the status of its change request shall be referred to the state.

b. Pending State Recommendation - So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive the state's recommendation after 120 days, it may contact the state to see if its recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to ascertain the recommendation's status.

c. State Practice - The PECOS record should not be switched to "Approved" until the contractor receives the state's approval recommendation. However, if the contractor knows that the state in question generally does not review this type of transaction, the contractor need not send the transaction to the state and shall instead follow the instructions in section 10.6.1.2(B) below.

B. Post-Approval State Notification Required

Form CMS-855 changes that do not mandate a recommendation to the state but do require post-approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) include:

- Except as described in section 10.6.1.2(A), deletions/voluntary terminations of practice locations or hospital subunits. (Note that this scenario is different from cases where the provider is voluntary terminating its enrollment as a whole (per section 10.6.1.3 of this chapter) rather than simply terminating a single location or subunit within its enrollment.)

- LBN, TIN, or "doing business as name" changes that do not involve a CHOW.

- Except as described in section 10.6.1.2(A), address changes that generally do not require a survey of the new location.

- Addition, change, and/or relocation of a hospital practice location (including physician/practitioner group practice locations) for which a survey is not required.

- *Deletion, change, and/or relocation of an OPT/OSP extension site or practice location.*

- Ownership changes that involve neither a 42 CFR § 489.18 CHOW nor a § 424.550(b) exempt or non-exempt change in HHA majority ownership (e.g., a 15 percent owner of a hospice sells her ownership stake).

The contractor shall:

(1) Inform PEOG, the state, and the AO (if appropriate) of the changed information (via any mechanism it chooses, including copying PEOG/state/AO on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction. Such notice to the PEOG/state/AO shall specify the type of information that is changing. (Prior PEOG approval of the change is not required, though PEOG will update applicable national database as needed.)

(2) Switch the PECOS record to "Approved."

C. All Other Changes of Information

1. General Principle

For all Form CMS-855 change requests not identified in section 10.6.1.2(A)(1) and (B) above (and except as stated in subsection (C)(2) below), the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made; and (2) switch the PECOS record to "Approved." The contractor need not notify the state, SOG Location, or PEOG of the change.

2. FQHCs

If an FQHC is adding, deleting, or changing a Section 13 contact person , the contractor shall send an approval letter via e-mail and copy the MedicareProviderEnrollment@cms.hhs.gov mailbox (with "FQHC COI" in the subject line) thereon. (Aside from this exception, all other instructions in subsection (C)(1) apply to this scenario.) See section 10.2.1.4(D) of this chapter for more information on FQHC changes of information.

D. Revalidations, Reactivations, and Complete Form CMS-855 Applications

1. When Referral Required - In situations where the provider submits a (1) Form CMS-855 reactivation, (2) Form CMS-855 revalidation, or (3) full Form CMS-855 as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in section 10.6.1.2(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855, the contractor shall make a recommendation to the state and await the state's approval recommendation before switching the record to "Approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state needs to consider is the new hospital unit.

2. No Referral Required - If the application contains new/changed data falling within one of the categories in section 10.6.1.2(B), the contractor can switch the PECOS record to "Approved." It shall also inform the state of the changed information (via any mechanism it chooses, including copying the state on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction.

E. Unsolicited Notifications from State

If the contractor receives notice of a provider's change of information from the state but the provider never submitted the required Form CMS-855 change request to the contractor, the contractor shall: (1) alert the state of the situation; and (2) contact the provider and have it complete and submit the change request. However, if the data in question is not collected on the Form CMS-855, the contractor need not make this request.

F. Special ESRD Instructions

Notwithstanding any other contrary instruction in this chapter, if an ESRD change of information application results in the issuance of a new or additional CCN, the contractor shall copy the ESRD Network on the approval letter it sends to the provider. The contact information for the ESRD Network can be found at https://esrdnetworks.org/membership/esrd-networks-contact-information/.

G. Clock Stoppages and Processing Alternatives

While awaiting PEOG's reply on any matter in this section 10.6.1.2 in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.2 negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.2.

10.6.2 – Establishing Effective Dates

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

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

A. Date of Enrollment/Approval

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

For suppliers other than ambulatory surgical centers and portable x-ray suppliers, 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. Physicians; physician assistants; nurse practitioners; audiologists; clinical nurse specialists; certified registered nurse anesthetists; anesthesiology assistants; certified nurse- midwives; clinical social workers; clinical psychologists; independently billing psychologists, registered dietitians or nutrition professionals; physical therapists; occupational therapists; speech-language pathologists; mental health counselors; marriage and family therapists; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified above.

b. Ambulance suppliers

c. Part B hospital departments

d. CLIA labs

e. Opioid treatment programs.

f. Mammography centers

g. Mass immunizers/pharmacies

h. Radiation therapy centers

i. Home infusion therapy suppliers

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

2. Background

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

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

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

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

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

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

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

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

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

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

The contractor shall interpret the above-mentioned phase "circumstances precluded enrollment" to mean that the supplier meets all program requirements (including state licensure) during the 30-day period before an application was submitted 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 the requirements of 42 CFR § 424.521(a) are met. The effective date entered in PECOS and the Multi-Carrier System will be April 1; claims submitted for services provided before April 1 will not be paid.

C. Effective Date of Reassignment

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

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

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

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

D. Effective Date for Certified Providers and Certified Suppliers

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

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

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

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

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

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

F. Form CMS-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 Medicare Diabetes Prevention Program (MDPP) Suppliers

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

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

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

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

H. Future Effective Dates

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

10.6.7.1 – Organizational Owning and Managing Information

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

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

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

1. <u>5 percent or greater direct or indirect ownership interest in the provider</u>

(i) Direct Ownership

Examples of direct ownership are as follows:

- The provider is a skilled nursing facility that is wholly (100%) owned by Company A.
- A hospice wants to enroll in Medicare. Company X owns 50% of the hospice.

In the first example, Company A is considered a direct owner of the skilled nursing facility, in that it actually owns the assets of the business. Likewise, Company X is a direct owner of the hospice mentioned in the second example. It has 50% actual ownership of the hospice.

(ii) Indirect Ownership

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

(iii) Examples of Direct vs. Indirect Ownership

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

> **EXAMPLE 1:** The supplier listed in the Identifying Information of the Form CMS-855B is an ambulance company that is wholly (100 percent) owned by Company A. Company A is considered a direct owner of the supplier (the ambulance company) in that it actually owns the assets of the business. Now assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of the supplier.

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

EXAMPLE 2

LEVEL 3	**Individual X**	**Individual Y**
	5%	30%
LEVEL 2	**Company C**	**Company B**
	60%	40%
LEVEL 1	**Company A**	
	100%	

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

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

LEVEL 1

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

LEVEL 2

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

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

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

LEVEL 3

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

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

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

2. 5 percent or greater mortgage or security interest

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

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

(b) The interest is equal to or exceeds 5 percent of the total property and assets of the provider.

All entities with at least a 5 percent mortgage, deed of trust, or other security interest in the provider must be reported in the Organizational Ownership and/or Managing Control section. This frequently will include banks, other financial institutions, and investment firms. To calculate whether this interest meets the 5% threshold, divide the dollar amount of the mortgage/deed of trust/other obligation secured by the provider or any of the property or assets of the provider by the dollar amount of the total property and assets of the provider.

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

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

3. Partnerships

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

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

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

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

4. Managing control of the provider

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

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

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

- Consulting firms
- Management services companies
- Medical staffing companies
- Non-profit entities
- *Private equity companies*
- *Real estate investment trusts*

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

B. Special Requirements for Governmental and Tribal Entities

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

In addition, governmental and tribal entities:

- Must be identified in the Organizational Ownership and/or Managing Control section even if they are already listed in the Identifying Information section.

- Governmental and tribal entities need not submit a copy of an IRS 501(c)(3) form if it is otherwise obvious to the contractor that the entity is a governmental or tribal entity. The contractor can assume that the governmental or tribal entity is non-profit. (See section 10.6.7(D)(3) below and section 10.6.4(G) of this chapter for more information on non-profit entities.)

C. Submission of Diagram

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

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

855/20134. If the data is inconsistent, the contractor shall develop for revised Form CMS-855/20134 data and/or a revised chart, as applicable. If the data remains inconsistent after development, the contractor may reject the application.

D. Supporting Data/Contractor Request and Additional Information

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

2. **Proof of Owning/Managing Control and Percentages -** Proof of ownership interest, partnership interest, managerial control, security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

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

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

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

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

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

   If an enrolling provider claims that it is a disregarded entity, the contractor need not obtain written confirmation of this from the provider notwithstanding the instruction in the Supporting Documents section of the Form CMS-855 or CMS-20134 that such confirmation is required. As a disregarded entity does not receive a CP-575 form from the IRS confirming its legal business name (LBN) and tax identification number (TIN), the contractor may accept from the enrolling provider any government form (such as a W-9) that lists its LBN and TIN. The disregarded entity's LBN and TIN shall be listed in the Identifying Information/Business Information section of the Form CMS-855.

6. **Ownership Disclosures**

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

(i) The provider/supplier must disclose ALL persons and entities that meet the definition of "owner" in section 10.1.1 of this chapter
(ii) The applicable ownership percentage must be disclosed for each owner listed
(iii) There cannot be indirect owners without direct owners (i.e., the provider/supplier cannot list only indirect owners and no direct owners)
(iv) The combined disclosed ownership percentages for the provider/supplier's organizational and individual direct owners cannot be greater than 100 percent

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

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

7. ***PECOS Entry***

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

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

The provider ***must*** *respond to all three of these data requests on its application. The contractor shall develop for this information if the provider fails to do so.*

(PECs and REITs are defined in 42 CFR § 424.502.)

8. Indirect Owner Checkbox

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

9. Type of Entity

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

10.6.7.2 – Individual Owning and Managing Information

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

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

(i) Ownership - A 5 percent or greater direct or indirect ownership interest in the provider.

(ii) Mortgage/Security Interest - A 5 percent or greater mortgage or security interest in the provider.

(iii) Partnership Interests

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

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

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

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

(v) Corporate Officers and Directors/Board Members

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

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

With respect to corporations, the term "director" refers to members of the board of directors. If a corporation has, for instance, a Director of Finance who nonetheless is not a member of the board of directors, he/she would not need to be listed as a director/board member in this section. However, he/she may need to be listed as a managing employee in this section.

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

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

B. Specific Reporting Policies

1. Proof of Owning/Managing Control and Percentages –- Proof of ownership interest, partnership interest, managerial control (including W-2s and other proof of employment), security interest, percentage of ownership or control, etc., need not be submitted unless the contractor requests it. This also means that articles of incorporation, partnership agreements, etc., need not be submitted absent a contractor's request.

2. Government Entities – Government entities need only report their managing employees, for they do not have owners, partners, corporate officers, or corporate directors.

3. Minimum Number of Managing Employees - The provider must report all managing employees but must have at least one if it is completing the Form CMS-855A, CMS-855B, CMS-855S, or CMS-20134. An individual completing the Form CMS-855I need not list a managing employee if he/she does not have one.

4. Practice Locations on the Form CMS-855I - All managing employees at all practice locations listed in the Business Information/Practice Location Information section of the Form CMS-855I must be reported in the Managing Employee Information section. The only exceptions to this are individuals who are (a) employed by hospitals, health care facilities, or other organizations shown in the Business Information/Practice Location Information section (e.g., the chief executive officer of a hospital listed in this section) or (ii) managing employees of any group/organization to which the practitioner will be reassigning his/her benefits; these persons need not be reported.

5. Partnership Interests Involving Indirect Owners - Only partnership interests in the enrolling provider need be disclosed. Partnership interests in the provider's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the enrolling provider, this indirect ownership interest would have to be reported.

6. Ownership Disclosures – Concerning ownership disclosures, the contractor shall adhere to the instructions in section 10.6.7.1(D)(6).

10.6.9 – Contact Persons

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

Unless stated otherwise in this chapter *(such as section 10.3)* or in another CMS directive -- or unless the provider requests that the contractor communicate with only a specific individual (e.g., an authorized official) or via specific means (e.g., only via the correspondence address e-mail) -- the contractor has the discretion to use the contact persons collected via the Forms CMS-855A, CMS-855B, CMS-855I, CMS-855O, CMS-855S and CMS-20134 for all written and oral communications (e.g., mail, e-mail, telephone) related to the provider's Medicare enrollment. Such communication need not be restricted to a particular enrollment application of the provider's that the contractor is currently processing. Nor is the contractor required (again, unless either CMS or the provider directs otherwise) to send certain materials to the correspondence mailing or e-mail address rather than the contact person's mailing or e-mail address.

The provider may have as many contact persons as it wishes.

If the contractor discovers that a particular contact person qualifies as an owning or managing individual, the provider shall list the person in the Individual Ownership and/or Managing Control section of the application.

If multiple contact persons are listed, the contractor has the discretion to select the individual to contact unless the provider indicates otherwise via any means. In addition:

(i) The contractor may use multiple contact persons throughout the enrollment process; it need not use the same individual for the entire duration unless, again, the provider indicates otherwise.

(ii) All contact persons shall be stored in PECOS and shall not be removed unless the provider requests the removal via letter, e-mail, fax, or---if the applicable Form CMS-855 contains an option for deleting a contact person---the Form CMS-855. Irrespective of whether the applicable Form CMS-855 contains such a deletion option, the contractor may accept end-dates of a contact person via telephone, email, fax, or mail from the provider, the authorized or delegated official, or a current contact person on file. The contractor shall document in the comment section in PECOS who requested the termination, how it was requested (email, phone, or fax) and when it was requested. The addition of contact persons must still be reported via the appropriate Form CMS-855.

10.6.12 – Opting-Out of Medicare

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

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

A. Who May Opt-Out of Medicare

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

Physicians who are:

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

Non-physician practitioners who are:

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

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

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

- Full name (first, middle and last),
- Birthdate,
- Address, telephone number, *and e-mail address*
- License information,
- NPI (if one has been obtained),
- SSN (if no NPI has been issued, though note that this cannot be an individual tax identification number (ITIN)), and
- *Contact person name, telephone number, and e-mail address (if different from the opting-out physician or practitioner)*

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

2. Opting-Out and Ordering/Certifying/Referring

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

If this information is requested but not received, the eligible practitioner's affidavit can still be processed; however, 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): Medicare Identification Number (if issued); date of birth; specialty; e-mail address; any request to order/certify/refer.

C. Effective Date of an Opt-Out Period

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

1. Eligible Practitioners Who Have Never Enrolled In Medicare

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

2. Non-Participating Practitioners

If an eligible practitioner who is a non-participating provider decides to terminate 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.

4. Opt-Out After Enrollment

(This section 10.6.12(C)(4) applies notwithstanding any instruction to the contrary in this chapter.)

If an enrolled physician or eligible practitioner is now opting-out, the existing PECOS enrollment record shall be end-dated the same day as the affidavit effective date.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, 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 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.

G. Failure to Properly Cancel or Terminate Opt-Out

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

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

10.6.21 – Miscellaneous Enrollment Topics

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

A. Special Form CMS-855S Instructions

1. Addresses

If an address (e.g., correspondence address, practice location) on the Form CMS-855S lacks a city, state, or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

2. Insurance

With respect to the comprehensive liability insurance supplier standard in 42 CFR § 424.57(a)(10), the contractor shall: (1) verify with the insurance agent that the insurance policy is active and current; and (2) ensure that the contractor (i.e., the NPE contractor) is listed as the policy holder on the certificate. The contractor may contact the insurance agent via any manner it chooses; however, verification shall be documented consistent with section 10.6.19 of this chapter (e.g., documenting telephonic communications).

B. Transitioned Certified Providers and Suppliers – E-Mails to PEOG for Final Application Review and/or Approval

As described in this chapter, the contractor must refer various matters involving transitioned certified provider/supplier enrollment applications to PEOG for final application review and approval (e.g., system updates, assignment of CCN, etc.) When making such referrals---and notwithstanding any other instruction to the contrary in this chapter---the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.) This instruction, to reiterate, only applies to e-mails to PEOG involving: (1) transitioned certified providers/suppliers; and (2) instances where the contractor is explicitly required per this chapter to send the matter PEOG for final review, approval, and/or denial of an application (e.g., initial application, CHOW, certain COIs) and to wait for PEOG's determination. (See, for example, section 10.6.1.2(A)(3)(a) of this chapter.)

C. Contacting State or SOG Location for Updates

1. "Transitioned" Certified Providers/Suppliers - In situations where the contractor recommends approval to the state (initial applications, CHOWs, certain changes of information, etc.), the contractor---if it has not received the state's recommendation within 120 days after the contractor sent its recommendation---may contact the state to ascertain whether said recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to determine the recommendation's status.

2. "Non-Transitioned" Certified Providers/Suppliers – If, as described in subsection (H)(1) above, the contractor recommends approval to the state, the contractor may contact the state

for an update on the recommendation's status beginning 120 days after the recommendation was sent and every 30 days thereafter. If the state informs the contractor (via any means) that the application has been forwarded to the SOG Location, the contractor may contact the SOG Location for a status update every 30 days beginning on the date the contractor received this notice from the state.

D. Survey and Certification Documents – All Certified Providers and Certified Suppliers

1. Documents from the State/AO

As applicable to the provider/supplier type in question, the state or accrediting organization (AO) must provide the signed CMS-1561 (or other/similar contract) and copy of the HHS-690 to the contractor with its approval recommendation. (Note that the contractor can accept a CMS-1561 or HHS-690 from either the state or AO.)

If the state/AO neither furnished said documents **nor** otherwise indicated that they were uploaded into the Automated Survey Process Environment (ASPEN)/Internet Quality Improvement and Evaluation System (IQIES), the contractor shall contact the state/AO via any means for the applicable document(s). If the state/AO responds within 10 days of the contractor's request by either (a) sending the document(s) to the contractor or (b) stating that it has uploaded the document(s) into ASPEN/IQIES, the contractor can continue processing the application consistent with applicable instructions. (If the state/AO indicated (b) above, the contractor shall note this in its referral to PEOG.) If the state/AO does neither (a) nor (b) within this 10-day period, the contractor shall: (1) proceed with sending the referral to PEOG consistent with existing instructions; and (2) include evidence of the state/AO's lack of responsiveness (e.g., e-mail evidence of the contractor's request).

2. AO Documents to PEOG

As applicable to the situation and provider/supplier type, the contractor shall include the AO deeming letter in referrals to PEOG that are required under this chapter (e.g., initial approvals).

10.6.21.1 – Additional Miscellaneous Enrollment Topics

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

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

A. Type of Practice Location

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

B. Voluntary Terminations for Non-Certified Suppliers

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

C. Initial Enrollments with Multiple Locations

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

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

1. Certified Providers/Suppliers – If, per this chapter, the site visits are to be performed after the contractor receives a recommendation of approval from the state, the contractor shall wait until all site visits are completed before taking the next required step (e.g., referring the application to PEOG to final review).

2. Site Visit Failure – If one of the locations fails its site visit, the contractor shall follow existing guidance for handling such situations (e.g., approving the application but without the failed location).

D. Verification of Telephone Numbers

Except when the provider or supplier has a regulatory supplier standard regarding maintenance of a telephone number (e.g., § 410.33(g)(5) for IDTFs), the contractor need not verify the provider's or supplier's phone number listed on the application.

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

E. Sales Agreement

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

10.7.19 – ESRD Approval Letters

(Rev. 12639; Issued: 05-16-24; Effective: 06-17-24; Implementation: 06-17-24)

In the ESRD situations described in this section 10.7.19, the letters below shall be used as directed in section 10.2.1.3 notwithstanding any other instruction to the contrary in this chapter.

A. ESRD Service Station/Modality Changes

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

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your State Agency has notified [insert contractor name] [insert contractor number] that your end-stage renal disease (ESRD) facility changed [your approved service modalities and/or number of stations.] Therefore, your facility is now approved for a total of [number of in-center hemodialysis stations] maintenance stations and the services outlined below:

Medicare Enrollment Information

Legal Business Name (LBN)
Doing Business As (DBA)
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Effective Date

CMS Certification Information

CCN
Effective Date
Changed Information
Effective Date of Change(s) (Include detailed changes or section. Select from list below.)

__In-Center Hemodialysis *(HD)*
__In-Center Peritoneal Dialysis *(PD)*
__In-Center Nocturnal HD
__*Home HD Training and Support*
__*HD in LTC*
__*Home PD Training and Support*
__*PD in LTC*
__*Dialyzer Reuse*

You should report to the [State Agency ([SA])] any changes in location, services, or organization which might affect your certification status or the status of your ESRD facility. In addition, providers must notify CMS when there is a change of ownership. Therefore, you must notify your Medicare Administrative Contractor (MAC) and the [SA] promptly if there is a change in the legal status of the ownership of this facility.

We look forward to continuing to work with you in the administration of the Medicare program. If you have any questions regarding this, please contact [STATE AGENCY NAME], [STATE AGENCY EMAIL ADDRESS].

[Include appropriate MAC signature]

Cc: State Agency
Accrediting Organization (if appropriate)

B. State Agency Approved Initial

[Month, Day, Year]
[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency [and Accrediting Organization}]. Your initial enrollment application is approved.

Your unit has been approved as a renal dialysis [facility/center]. This approval is for a total of [number] maintenance stations. Your [facility/center] is approved to provide the following services:

[List all that apply--]

__In-Center Hemodialysis *(HD)*
__In-Center Peritoneal Dialysis *(PD)*
__In-Center Nocturnal *HD*
__*Home HD Training and Support*
__*HD in LTC*
__*Home PD Training and Support*
__*PD in LTC*
__*Dialyzer Reuse*

Medicare Enrollment and Provider/Supplier Information

Medicare Enrollment Information
Legal Business Name (LBN)
Doing Business As Name
Primary Practice Location Address
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Enrollment Effective Date

Please inform the [State Survey Agency/AO] if you wish to relocate your [facility/center], change the services that you are currently providing, change the number of approved stations, or undergo a change in ownership.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.
Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

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

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

• Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
• State the issues or findings of fact with which you disagree and the reasons for disagreement.
• Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services
Provider Enrollment & Oversight Group
ATTN: Division of Provider Enrollment Appeals
7500 Security Blvd.
Mailstop: AR-19-51
Baltimore, MD 21244-1850

Or emailed to: ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]
CC: State Agency [and AO, if applicable]

C. Change of Ownership

[Month, Day, Year]

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

Subject: ESRD Medicare Change of Ownership

Dear Administrator:

[Insert Contractor name [and Contractor number]] has received a response from the State Agency. Your change of ownership application is now approved.

[INSERT or CHECK THE APPLICABLE PARAGRAPH]:

__ [Facility status is not changing]
When an ESRD facility undergoes a change of ownership, the new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from free-standing to hospital-based]
When an ESRD facility undergoes a change of ownership and changes its status from a free-standing ESRD facility to a hospital-based ESRD center, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD center is issued a new CCN number that links it to the provider with which it is associated. The new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from hospital-based to free-standing]
When an ESRD center undergoes a change of ownership and changes its status from a hospital-based ESRD center to a free-standing ESRD facility, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD facility is issued a new CCN to indicate the free-standing designation. The new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner. Therefore, the CCN of [old CCN] is hereby terminated effective [Date of CHOW]. Your facility's approved CCN is provided below.

Your facility has been approved for a total of [number of in-center hemodialysis stations] maintenance stations. Also, your facility is approved to provide the following services:

[CHECK OR INSERT ALL APPLICABLE]

__In-Center Hemodialysis *(HD)*
__In-Center Peritoneal Dialysis *(PD)*
__In-Center Nocturnal *HD*
__*Home HD Training and Support*

__HD in LTC
__Home PD Training and Support
__PD in LTC
__Dialyzer Reuse

Medicare Enrollment Information

Legal Business Name (LBN)
Doing Business As Name
Primary Practice Location Address
Provider/Supplier Type
National Provider Identifier (NPI)
Provider Transaction Access Number (PTAN)
Effective Date of Change of Ownership

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system. Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

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

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

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Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a reconsideration

request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

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For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]

[Company]
CC: State Agency [and AO, if applicable]