CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10800	**Date: May 20, 2021**
	Change Request 12162

SUBJECT: Second General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make technical, editorial, and organizational changes to sections 10.2.2, 10.2.3, and 10.3.2 in Chapter 10 of Pub. 100-08.

EFFECTIVE DATE: June 22, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 22, 2021

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	10/10.2/10.2.2/Suppliers That Enroll Via the Form CMS-855B
N	10/10.2/10.2.2/10.2.2.1/Ambulatory Surgical Centers (ASCs)
N	10/10.2/10.2.2/10.2.2.2/Home Infusion Therapy Suppliers
N	10/10.2/10.2.2/10.2.2.3/Independent Clinical Laboratory Improvement Act (CLIA) Labs
N	10/10.2/10.2.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
N	10/10.2/10.2.2/10.2.2.5/Intensive Cardiac Rehabilitation (ICR)
N	10/10.2/10.2.2/10.2.2.6/Mammography Screening Centers (MSCs)
N	10/10.2/10.2.2/10.2.2.7/Pharmacies
N	10/10.2/10.2.2/10.2.2.8/Portable X-Ray Suppliers (PXRSs)
N	10/10.2/10.2.2/10.2.2.9/Radiation Therapy Centers (RTCs)
N	10/10.2/10.2.2/10.2.2.10/Suppliers of Ambulance Services
R	10/10.2/10.2.3/Individual Practitioners Who Enroll Via the Form CMS-855I
N	10/10.2/10.2.3/10.2.3.1/Anesthesiology Assistants
N	10/10.2/10.2.3/10.2.3.2/Audiologists
N	10/10.2/10.2.3/10.2.3.3/Certified Nurse-Midwives
N	10/10.2/10.2.3/10.2.3.4/Certified Registered Nurse Anesthetists (CRNAs)
N	10/10.2/10.2.3/10.2.3.5/Clinical Nurse Specialists
N	10/10.2/10.2.3/10.2.3.6/Clinical Psychologists
N	10/10.2/10.2.3/10.2.3.7/Clinical Social Workers
N	10/10.2/10.2.3/10.2.3.8/Nurse Practitioners
N	10/10.2/10.2.3/10.2.3.9/Occupational Therapists in Private Practice
N	10/10.2/10.2.3/10.2.3.10/Physical Therapists in Private Practice
N	10/10.2/10.2.3/10.2.3.11/Physicians
N	10/10.2/10.2.3/10.2.3.12/Physician Assistants
N	10/10.2/10.2.3/10.2.3.13/Psychologists Practicing Independently
N	10/10.2/10.2.3/10.2.3.14/Registered Dietitians/Nutrition Professionals
N	10/10.2/10.2.3/10.2.3.15/Speech Language Pathologists in Private Practice
N	10/10.2/10.2.3/10.2.3.16/Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an Ambulatory Surgical Center (ASC)

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.3/10.3.2/CMS-20134 – Enrollment Form: Information and Processing
N	10/10.3/10.3.2/10.3.2.1/CMS-20134 (Section 1 – Basic Information)
N	10/10.3/10.3.2/10.3.2.2/CMS-20134 (Section 2 – Identifying Information)
N	10/10.3/10.3.2/10.3.2.3/CMS-20134 (Section 3 – Final Adverse Legal Actions/Convictions)
N	10/10.3/10.3.2/10.3.2.4/CMS-20134 (Section 4 – MDPP Location Information)
N	10/10.3/10.3.2/10.3.2.5/CMS-20134 (Sections 5 & 6 – Owning and Managing Organizations and Individuals)
N	10/10.3/10.3.2/10.3.2.6/Reserved for Future Use
N	10/10.3/10.3.2/10.3.2.7/CMS-20134 (Section 7 – Coach Roster)
N	10/10.3/10.3.2/10.3.2.8/CMS-20134 (Section 8 – Billing Agency Information)
N	10/10.3/10.3.2/10.3.2.9/CMS-20134 (Section 13 - Contact Person)
N	10/10.3/10.3.2/10.3.2.10/CMS-20134 (Section 14 – Penalties for Falsifying Information)
N	10/10.3/10.3.2/10.3.2.11/CMS-20134 (Section 15 – Certification Statement and Authorized Officials)
N	10/10.3/10.3.2/10.3.2.12/CMS-20134 (Section 16 – Delegated Officials)
N	10/10.3/10.3.2/10.3.2.13/CMS-20134 (Section 17 – Supporting Documents)
N	10/10.3/10.3.2/10.3.2.14/Additional Form CMS-20134 Processing Information and Alternatives

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: 10800	Date: May 20, 2021	Change Request: 12162

SUBJECT: Second General Update to Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual

EFFECTIVE DATE: June 22, 2021
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I. GENERAL INFORMATION

A. Background: The CMS has recently completed transferring the entirety of Chapter 15 of Pub. 100-08 to Chapter 10 of Pub. 100-08. Chapter 10 outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR makes technical, editorial, and organizational changes to sections 10.2.2, 10.2.3, and 10.3.2 in Chapter 10 of Pub. 100-08. This CR is the second in a series of CRs that update various portions of Chapter 10 with technical revisions and any necessary policy changes.

B. Policy: This CR does not contain 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	
12162.1	The contractor shall observe the division of sections 10.2.2, 10.2.3, and 10.3.2 in chapter 10 of Pub. 100-08 into subsections based on supplier type and/or subject matter.		X							
12162.2	The contractor shall verify a Medicare Diabetes Prevention Program supplier's eligibility as described in section 10.3.2.1 in Chapter 10 of Pub. 100-08 and in Business Requirements		X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	(BRs) 12162.2.1 through 12162.2.6.									
12162.2.1	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.		X							
12162.2.2	The contractor shall verify that -- (1) Any letters provided have appropriate letterhead from the Centers for Disease Control and Prevention (CDC); and (2) Each reflects that the organization has met either preliminary or full recognition with an expiration date that has not passed.		X							
12162.2.3	The contractor shall verify that the organization code(s) 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 the CDC's online registry.		X							
12162.2.4	The contractor shall verify that -- (1) The CDC's online registry or any CMS-furnished list indicates that the		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	entity associated with that organization code is associated with an in-person delivery mode; and (2) A delivery mode of in-person is noted in the letter's letterhead.									
12162.2.5	The contractor shall verify that the CDC's online registry indicates that the entity associated with that organization code has met either preliminary or full recognition.		X							
12162.2.6	The contractor shall verify that the name associated with the organization code on the CDC's online registry is consistent with -- (1) What is listed on the letter; and (2) What is provided in Sections 2 and 4 of the Form CMS-20134.		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

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

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

VI. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents
(Rev. 10800; Issued: 05-20-2021)

10.2.2 – Suppliers That Enroll Via the Form CMS-855B

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

10.2.2.1 – Ambulatory Surgical Centers (ASCs)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

An ASC is defined in 42 CFR § 416.2 as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission; the entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in 42 CFR Part 416, subparts B and C (The ASC supplier agreement (Form CMS-370) is similar to the provider agreement signed by Part A providers.)

An ASC satisfies the criterion of being a "distinct" entity when it is separate and clearly distinguishable from any other healthcare facility or office-based physician practice. Thus, distinct entity means that surgical services may only be provided at the single location listed in the Medicare supplier agreement. Medicare-certified ASCs are not permitted to have multiple locations under the same supplier agreement. If an entity owns multiple surgical locations and wishes them to participate in Medicare as an ASC, each location must seek separate participation and enrollment and must demonstrate independent compliance with the ASC conditions of coverage, for the regulations do not permit configurations of multiple ASC locations under one Medicare agreement. (Each location would be considered a new, initial enrollment; thus, if an enrolled ASC wishes to add a second practice location, the transaction would constitute a new, initial enrollment rather than the addition of a practice location to an existing enrollment.) ASCs may only have one surgical location per CMS Certification Number (CCN). See also CMS Publication (Pub. 100-07), State Operations Manual, chapter 2, section 2210 for more information.

As stated in § 416.26(a), CMS may deem an ASC to be in compliance with any or all of the ASC conditions of coverage set forth in 42 CFR Part 416, subpart C if:

- *The ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met;*

- *In the case of deemed status through accreditation by a national accrediting body, where state law requires licensure, the ASC complies with state licensure requirements; and*

- *The ASC authorizes the release to CMS of the findings of the accreditation survey.*

Unless CMS deems the ASC to be in compliance with the ASC conditions of coverage in 42 CFR Part 416, subpart C, the state survey agency must survey the facility to ascertain compliance with those conditions. (See 42 CFR § 416.26(b).)

B. Enrollment Information

The contractor shall ensure that, as applicable, all licenses, certifications, and accreditations submitted by ASCs are included in the enrollment package that is forwarded

to the state and/or CMS Survey Operations Group (SOG) Location (previously known as the Regional Office and hereafter referenced as "SOG Location").

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

Unlike most other supplier types that enroll via the Form CMS-855B (and except as stated in this section 10.2.2.1), ASCs must receive a state or CMS-approved accrediting organization survey and SOG Location approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the state or deny the application. Except as stated otherwise in this chapter, the contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the SOG Location.

When enrolling the ASC, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. Once the contractor receives the approval letter or tie-in notice from the SOG Location for an ASC, the contractor is encouraged (but not required) to contact the SOG Location, state agency, or supplier for the applicable licensing and/or certification data and to enter it into the Provider Enrollment, Chain and Ownership System (PECOS).

(See the applicable sections of 10.6.1 et seq. of this chapter for more information on ASC tie-in notices/approval letters.)

An ASC must sign a supplier agreement with Medicare prior to enrollment.

C. ASCs and Reassignment

Physicians and non-physician practitioners who meet the reassignment exceptions in 42 CFR § 424.80, and CMS Pub. 100-04, Claims Processing Manual, chapter 1, sections 30.2.6 and 30.2.7 may reassign their benefits to an ASC. In such a reassignment, the individual and the ASC must sign the Form CMS-855R. However, the ASC need not separately and additionally enroll as a group practice in order to receive benefits. It can accept reassignment as an ASC.

D. ASCs Changes of Ownership (CHOWs)

Though ASCs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving ASCs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For more information on ASC CHOWs, see the applicable sections of 10.6.1 et seq. of this chapter.

E. Additional Information

For more information on ASCs, refer to:

- *42 CFR Part 416*

- *Pub. 100-07, chapter 2, section 2210 and Appendix L. (See Pub. 100-07, chapter 2, section 2210 for information regarding the sharing of space between ASCs and other providers and suppliers.)*

- *Pub. 100-02, Benefit Policy Manual, chapter 15, sections 260 – 260.5.3*

- *Pub. 100-04, chapter 14*

F. ASCs and Hospitals

See the following instructions for guidance regarding hospital-operated/affiliated ASCs:

- *Pub. 100-04, chapter 14, section 10.1*

- *Pub. 100-02, chapter 15, section 260.1*

10.2.2.2 – Home Infusion Therapy Suppliers
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Home infusion therapy suppliers are a supplier type that enroll via the Form CMS-855B.

A. General Background Information

Section 5012 of the 21st Century Cures Act ("the Cures Act") (Pub. L. 114-255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 1861(iii)(3)(D)(i) of the Act defines a "qualified home infusion therapy supplier" as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. A qualified home infusion therapy supplier must: (1)furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) be accredited by an organization designated by the Secretary; and (4) meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under Part C and in the private sector.

B. Home Infusion Therapy Supplier Eligibility and Enrollment Requirements

An entity that wishes to furnish home infusion therapy services to Medicare beneficiaries must enroll as a home infusion therapy supplier. The supplier must meet the following requirements:

- *Obtain and maintain a valid tax identification number and National Provider Identifier at the organizational level.*

- *Be currently and validly accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare. The CMS-recognized home infusion therapy supplier accreditation organizations include the Joint Commission (TJC), the Utilization Review Accreditation Commission (URAC), the Accreditation Commission for Health Care (ACHC), the Community Health Accreditation Partner (CHAP), the National Association Boards of Pharmacy (NABP), and the Compliance Team (TCT).*

- *Submit documentation containing an effective date of accreditation as well as the locations accredited for home infusion therapy with its application. (This may, but is not required to be, a copy of the accreditation certification and/or accreditation approval letter.)*

- *Be compliant with § 414.1515 and all provisions of 42 CFR Part 486, subpart I in order to enroll and maintain Medicare enrollment.*

- *Certify via the Form CMS-855B application that it meets and will continue to meet the specific requirements for enrollment described in 42 CFR § 424.68 and 42 CFR Part 424, subpart P.*

- *Successfully complete application screening at the limited categorical risk level per § 424.518(a).*

- *Pay an application fee at initial enrollment, revalidation, and when adding a practice location.*

- *Enroll in each state in which it has an accredited practice location. The supplier may provide services in patients' homes across state borders as long as it is appropriately licensed (if the state requires licensure); the supplier must be appropriately licensed (if the state requires licensure) in each state in which it furnishes home infusion therapy services in patients' homes.*

  The supplier completes Section 4D (Rendering Services in Patients Homes) of the Form CMS-855B application to report all locations where health care services are rendered in patients' homes. This includes locations across state borders. As an illustration, suppose
  the supplier has two accredited practice locations in Arkansas and furnishes home infusion therapy services in patients' homes in Arkansas and in Oklahoma; here, the supplier only needs to enroll in Arkansas. If, however, this same supplier wants to add another accredited practice location in Texas, it would have to enroll in in Texas.

10.2.2.3 – Independent Clinical Laboratory Improvement Act (CLIA) Labs
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Independent CLIA labs are a certified supplier type that enroll via the Form CMS-855B. In the context of provider enrollment, it is important to keep in mind when reviewing this section 10.2.2.3 the distinction between (1) a CLIA lab enrolling as an independent Medicare supplier and (2) a different provider/supplier type (e.g., physician group, rural health clinic) that has a CLIA certificate and whose laboratory services are under the same ownership and at the same location as the main provider/supplier.

A. General Background Information

As explained in CMS Publication (Pub.) 100-07, chapter 6, sections 6000 and 6002, the Clinical Laboratory Improvement Amendments of 1988 amended the Public Health Service Act (42 U.S.C. 263a) to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Except as provided at 42 CFR § 493.3, entities that meet the definition of a laboratory at 42 CFR § 493.2 must meet applicable federal requirements and have a CLIA certificate in order to operate.

Regulations implementing CLIA are codified under 42 CFR Part 493. These regulations require that all laboratories or entities performing laboratory testing:

- *Pay user fees as assessed by CMS to finance the entire cost of administering the CLIA program;*
- *Submit specific information to HHS or its designee;*
- *Comply with specific administrative and program requirements;*
- *Submit to surveys to assess compliance with CLIA requirements;*
- *Be subject to specified enforcement actions; and*
- *(1) Apply for CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization, or (2) be licensed or approved in accordance with state requirements if located in a state with a CMS-approved state laboratory licensure program.*

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 requires that laboratories participating in the Medicare program comply with CLIA requirements. Therefore, all laboratories, with the exception of laboratories located in and licensed or approved by a state with a CMS-approved state laboratory licensure program (CLIA-exempt laboratories) must obtain a CLIA certificate to operate and to be eligible for payment under Medicare and Medicaid. Although CLIA-exempt laboratories do not need a CLIA certificate to operate, they are assigned a CLIA identification number for Medicare and Medicaid payment purposes.

As stated in Pub. 100-07, chapter 6, section 6002, certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. These include:

- *Any facility or component of a facility that performs testing strictly for forensic purposes;*
- *Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients;*
- *Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. (However, all other testing conducted by a SAMHSA certified laboratory is subject to this rule.);*
- *Laboratories under the jurisdiction of the Department of Veterans Affairs;*

- *Department of Defense (DoD) laboratories are subject to requirements that CMS has determined to be comparable to those in CLIA. The DoD is responsible for assuring compliance with these requirements and for oversight of its laboratories under a Memorandum of Understanding (MOU) between the Secretary of HHS and the Secretary of DoD;*

- *Laboratory testing conducted in conjunction with the provision of home health or hospice care in an individual's home, where the home health agency or hospice employee merely* ***assists*** *the individual in performing a test, since tests performed by individuals in the home are not subject to CLIA (see Pub. 100-7, chapter 6, section 6010.1.2.1);*

- *Laboratories located in and licensed or approved by a state with a CMS-approved laboratory licensure program is approved by CMS (i.e., CLIA exempt as approved under 42 CFR part 493, Subpart E);*

- *Facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostic tests;*

- *Radiological facilities that perform only imaging procedures (e.g., x-rays, ultrasounds, magnetic resonance imaging, computerized tomography);*

- *Facilities performing only physiological testing (e.g., spirometry, slit-lamp test for eyes, breath analysis, pulse oximetry); and*

- *Any facility or component of a facility that performs substance use disorder testing (such as for alcohol and/or drugs) solely for employment purposes (such as disciplinary, administrative, or legal action).*

B. Certificates

See Pub. 100-07, chapter 6, sections 6006 through 6006.7, 6008, and 6014 for information regarding the various types of CLIA certificates.

C. Independent CLIA Lab Enrollment

1. Integrated Labs vs. Independent Labs

Labs that are "integrated" into an existing provider or supplier do not require a separate Form CMS-855B enrollment. "Integrated" labs typically are those that have exactly the same ownership and physical location as another enrolled supplier or provider. (Common examples include: (1) hospital labs and (2) a lab at a physician's office.) If a lab is considered "integrated," the parent provider/supplier shall identify the lab as a practice location in Section 4 of its Form CMS-855 and list the applicable CLIA number.

If the lab is not "integrated," the lab must enroll as an independent CLIA lab via the Form CMS-855B application. The contractor shall advise the lab that it must contact the applicable CLIA office; the lab cannot be enrolled until it receives a CLIA number. The contractor shall also ensure that the lab is CLIA-certified and, as applicable, state-licensed.

2. Additional Enrollment Policies

Unless stated otherwise in this chapter or in another CMS directive:

i. Practice Locations - Each practice location at which laboratory tests are performed must submit to the contractor a separate CLIA certificate for that location. The only exceptions to this requirement are: (1) laboratories within a hospital that are located at contiguous buildings, on the same campus, and under common direction; (2) non-profit or governmental laboratories that engage in limited public health testing; and (3) laboratories that are not at a fixed location (i.e., are mobile).

ii. States - The laboratory must submit to the contractor a separate certificate for each state in which testing is performed.

D. Procedure to Update CLIA Certificate for an Enrolled CLIA Lab

A Medicare-enrolled CLIA lab shall submit any updated CLIA certificate to its contractor with a Form CMS-855.

E. Site Visits of Independent CLIA Labs

1. *Initial and revalidation applications – If an independent CLIA lab submits an initial or revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the supplier is (or 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 National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier (or, in the case of revalidation, 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.*

2. *New/changed location - If an independent CLIA lab 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 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 switch the supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.*

F. Additional Information

For additional data on CLIA laboratories, refer to:

- *42 CFR Part 493*
- *Pub. 100-07, chapter 6*
- *Pub. 100-04, chapter 16*
- *Form CMS-116 (CLIA Application for Certification)*

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

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.

B. IDTF Standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Leasing and Staffing

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

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

D. Sharing of Space and Equipment

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

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

E. Multi-State IDTFs

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

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

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

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

F. One Enrollment per Practice Location

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

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

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

G. Interpreting Physicians

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

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who will provide interpretations subject to the anti-markup

payment limitation as detailed in CMS Pub. 100-04, chapter 1, § 30.2.9 - whether the service is provided to the IDTF on a contract basis or is reassigned.

The contractor shall ensure and document that:

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

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

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

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

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

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

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

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

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

J. IDTF Technician Licensure and Certification Requirements

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

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

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

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

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

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

different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

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

M. IDTF - Information about Supervising Physicians

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

In addition:

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

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

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

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

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

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

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

P. IDTF - Changes of Supervising Physicians

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

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

Q. Desk and Site Reviews

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

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

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

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

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

R. Mobile Units

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

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

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

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

S. Addition of Codes

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

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

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

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

T. IDTF That Performs Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration certification to perform the mammography. However, an entity that only

performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography screening center.

U. IDTF Ownership of CLIA Laboratory

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

10.2.2.5 – Intensive Cardiac Rehabilitation (ICR)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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-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). An ICR site under § 410.49(a) means a hospital outpatient setting or physician's office that is providing ICR utilizing an approved ICR program.

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

In order 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 shall only accept and process reassignments (Form CMS-855Rs) to ICR suppliers from physicians defined in section 1861(r)(1) of the Social Security Act. However, reassignments are not required.

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*

10.2.2.6 – Mammography Screening Centers (MSCs)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

As defined in 42 CFR § 410.34(a)(2), a screening mammography is a radiologic procedure "furnished to a woman without signs or symptoms of breast disease for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure." Section 410.34(a)(4) defines a "supplier of screening mammography" as a "facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in § 410.34(c) and (d)."

B. Enrollment of MSCs

Consistent with § 410.34(a)(7), in order to qualify for coverage of its services under the Medicare program (and to thus enroll in Medicare), an MSC supplier must meet the following requirements:

1. *Must have a valid provisional certificate, or a valid certificate, that has been issued by the Food and Drug Administration (FDA) indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.*

2. *Has not been issued a written notification by the FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.*

3. *Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by the FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).*

(The FDA is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic).)

Unless stated otherwise in this chapter or in another CMS directive, the MSC shall submit a copy of its FDA certificate with its application. If the supplier fails to submit the FDA certificate within 30 days of the MAC's request, the MAC shall reject the application consistent with section 10.4(H)(2) of this chapter.

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

- *42 CFR § 410.34*

- *Pub. 100-04, chapter 18, sections 20 through 20.1.2*

- *Pub. 100-02, chapter 15, section 280.3*

10.2.2.7 – Pharmacies
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Pharmacies are a supplier type that, depending upon the circumstances involved, enroll via the Form CMS-855B.

A. General Background Information

Pharmacies typically enroll with the National Supplier Clearinghouse via the Form CMS-855S. However, there are certain covered drugs that are billed through the physician fee schedule and not the schedule for durable medical equipment, prosthetics, orthotics and supplies. These drugs must be billed to the Part A/B Medicare Administrative Contractor (MAC), meaning that the pharmacy must enroll with the Part A/B MAC via the Form CMS-855B.

B. Additional Information

For more information on the billing and coverage policies for Part B drugs, see:

- *Pub. 100-04, chapter 17*
- *Pub. 100-02, chapter 15, sections 50 through 50.6*

10.2.2.8 – Portable X-Ray Suppliers (PXRSs)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

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

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

A PXRS does not have a supplier agreement.

B. Enrollment of PXRSs

1. Initial Application

Unlike most other supplier types that enroll via the Form CMS-855B, PXRSs must receive a state survey and SOG Location approval before they can enroll in Medicare. Accordingly, once it finishes reviewing the supplier's application, the contractor may only make a recommendation for approval to the state or deny the application. The contractor shall not enroll the supplier until it receives a tie-in notice or approval letter from the SOG Location and a follow-up site visit is performed per section 10.2.2.8(C) of this chapter.

When enrolling the PXRS, the contractor shall use the effective date that is indicated on the tie-in notice/approval letter. This is the date from which the supplier can bill for services. See section 10.6.1 et seq. of this chapter for more information on PXRS tie-in notices/approval letters.

2. Practice Location Information

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

- *Whether it furnishes services from a "mobile facility" or "portable unit." (A PXRS can be either, though it usually is a portable unit.) A "mobile facility" typically describes a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile homes and trailers. A portable unit involves a supplier transporting medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.*

- *Its base of operations. This is from where personnel are dispatched and where equipment is stored. It may or may not be the same address as the practice location.*

- *All geographic locations at which services will be rendered.*

- *Vehicle information if the services will be performed inside or from the vehicle. Unless stated otherwise in this chapter or in another CMS directive, copies of all licenses and registrations must be submitted as well.*

C Site Visits

1. Initial and Revalidation Applications

If a PXRS submits an initial or revalidation application, the contractor shall order a site visit through PECOS after the contractor receives the tie-in notice (or approval letter) from the SOG Location but before the contractor conveys Medicare billing privileges to the PXRS (or, in the case of revalidations, before the contractor makes a final decision regarding the application). This is to ensure that the supplier is (or 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 National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the supplier (or, for revalidations, approve the application) prior to the completion of the NSVC's site visit and the contractor's review of the results.

2. New/Changed Location

If a PXRS is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS after the contractor receives notice of approval from the SOG Location but before the contractor switches the supplier's enrollment record to "Approved." This is to ensure that the new/changed location 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 switch the supplier's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Reassignment

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

E. Additional Enrollment Information

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

Once the contractor receives the approval letter or tie-in notice from the SOG Location for the PXRS, the contractor is encouraged (but not required) to contact the SOG Location, state agency, or supplier for the applicable licensing and/or certification data.

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

F. PXRS and CHOWs

Though PXRSs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving PXRSs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For more information on PXRS CHOWs, see the applicable sections of 10.6.1 et seq. of this chapter.

G. Additional Information

For more information on PXRSs, refer to:

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

10.2.2.9 – Radiation Therapy Centers (RTCs)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

Under 42 CFR § 410.35, Medicare Part B pays for x-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

RTCs may receive reassigned benefits. An RTC need not separately enroll as a group practice in order to receive them.

B. Additional Information

For additional background on radiation therapy services, see:

- *42 CFR § 410.35*

- *Pub. 100-04, chapter 13*
- *Pub. 100-02, chapter 15, section 90*

10.2.2.10 – Suppliers of Ambulance Services
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

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

A. General Background Information

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

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

B. Types of Ambulance Services

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

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

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

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

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

5. Paramedic ALS Intercept Services (PI) - Per § 414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the

services meet the requirements in § 410.40(d). In general, PI involves an arrangement between a BLS ambulance supplier and an ALS ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. Under § 410.40(d)(1) through (3), respectively, PI must meet the following requirements:

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

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

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

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

C. Ambulance Qualifications

1. Vehicle Design and Equipment

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

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

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

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

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

2. Vehicle Personnel

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

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

D. Completion of the Form CMS-855B

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

E. Geographic Area: Single Contractor Jurisdiction

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

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

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

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

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

F. Geographic Area: Multiple States

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

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

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

G. Practice Locations

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

- *A site at which the supplier's vehicles are garaged*
- *A site from which the supplier's personnel are dispatched*
- *The supplier's base of operations (i.e., the supplier's primary headquarters). The supplier can only have one base of operations.*

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

Consider the following scenarios:

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

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

H. Licensure Information

With respect to licensure:

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

I. Paramedic Intercept Information

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

J. Air Ambulances

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

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

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

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

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

In addition:

- *The contractor shall access the following FAA Web site on a quarterly basis to validate all licenses/certifications of air ambulance operators that are enrolled with the contractor: https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/enforcement/reports/. This helps ensure that the supplier's licenses/certifications are active and in good-standing.*

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

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

K. Hospital-Based Ambulances

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

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

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

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

10.2.3 - Individual Practitioners *Who* Enroll Via the Form CMS-855I

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

This section provides background information on physicians and non-physician practitioners (NPPs). While Medicare has established *f*ederal standards governing these supplier types, these practitioners must also comply with all applicable state and local laws as a precondition of enrollment.

It is important that contractors review *Publication (*Pub*)*. 100-02, Medicare Benefit Policy Manual, *c*hapter 15 *and Pub. 100-04, Claims Processing Manual,* for specific information regarding the required qualifications of the suppliers listed in this section 10.2.3 et seq.

10.2.3.1 – Anesthesiology Assistants

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.69(b) define an anesthesiology assistant as a person who:

1. *Works under the direction of an anesthesiologist;*

2. *Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on non-physician anesthetists; and*

3. *Is a graduate of a medical school-based anesthesiologist's assistant educational program that: (i) is accredited by the Committee on Allied Health Education and Accreditation; and (ii) includes approximately 2 years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.*

10.2.3.2 – Audiologists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Section 1861(ll)(3)(B) of the Social Security Act and Pub. 100-02, chapter 15, section 80.3.1 state that a qualified audiologist means an individual with a master's or doctoral degree in audiology who:

1. *Is licensed as an audiologist by the state in which the individual furnishes such services; or*

2. *In the case of an individual who furnishes services in a state that does not license audiologists, has:*

    - *Successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), and*

    - *Performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and*

    - *Successfully completed a national examination in audiology approved by the Secretary.*

Given these requirements (and as stated in the aforementioned section 80.3.1), a Doctor of Audiology (AuD) 4th year student with a provisional license from a state does not qualify unless he or she also holds a master's or doctoral degree in audiology.

See Pub. 100-04, chapter 12, section 30.3 for further information regarding audiologist billing.

10.2.3.3 – Certified Nurse-Midwives
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.77 list the Medicare qualifications for certified nurse-midwives (CNMs). These qualifications require that a CNM:

- *Be a registered nurse who is legally authorized to practice as a nurse-midwife in the state where services are performed;*
- *Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and*
- *Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American Midwifery Certification Board.*

For more information on CNMs, refer to:

- *Section 1861(gg) of the Social Security Act*
- *Pub. 100-02, chapter 15, section 180*
- *Pub. 100-04, chapter 12, section 130.1*

10.2.3.4 – Certified Registered Nurse Anesthetists
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.69(b)(1) through (4) state that a Certified Registered Nurse Anesthetists (CRNA) is a registered nurse who:

(1) Is licensed as a registered professional nurse by the state in which the nurse practices;

(2) Meets any licensure requirements the state imposes with respect to non-physician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in § 410.69(b)(3) and within 24 months after that graduation meets the requirements of § 410.69(b)(4)(i).

For more information on CRNAs, refer to:

- *Section 1861(bb) of the Social Security Act*
- *Pub. 100-04, chapter 12, section 140.1*

10.2.3.5 – Clinical Nurse Specialists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.76 state that a clinical nurse specialist must meet all of the following requirements:

1. *Be a registered nurse who is currently licensed to practice in the state where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with state law.*

2. *Have a master's degree in a defined clinical area of nursing from an accredited educational institution or a Doctor of Nursing Practice (DNP) doctoral degree; and*

3. *Be certified as a clinical nurse specialist by a recognized national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary.*

Pub. 100-02, chapter 15, section 210 states that CMS recognizes the following organizations as national certifying bodies for clinical nurse specialists at the advanced practice level:

a. *American Academy of Nurse Practitioners;*

b. *American Nurses Credentialing Center;*

c. *National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;*

d. *Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);*

e. *Oncology Nurses Certification Corporation;*

f. *AACN Certification Corporation; and*

g. *National Board on Certification of Hospice and Palliative Nurses.*

10.2.3.6 – Clinical Psychologists

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.71(d) state that to qualify as a clinical psychologist, a practitioner must meet the following requirements:

1. *Hold a doctoral degree in psychology (that is, a Ph.D., Ed.D., Psy.D.), and*

2. *Is licensed or certified, on the basis of the doctoral degree in psychology, by the state in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.*

A clinical psychologist must agree to meet the consultation requirements of 42 CFR § 410.71(e)(1) through (e)(3). Under 42 CFR § 410.71(e), the practitioner's signing of the Form CMS-855I indicates his or her agreement to adhere to the requirements of § 410.71(e)(1) through (e)(3).

For more information on clinical psychologists, refer to Pub. 100-02, chapter 15, section 160.

10.2.3.7 – Clinical Social Workers
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.73(a) define a clinical social worker as an individual who:

1. *Possesses a master's or doctor's degree in social work;*

2. *After obtaining the degree, has performed at least 2 years of supervised clinical social work; and*

3. *Either is licensed or certified as a clinical social worker by the state in which the services are performed or, in the case of an individual in a state that does not provide for licensure or certification as a clinical social worker—*

    a. *Is licensed or certified at the highest level of practice provided by the laws of the state in which the services are performed; and*

    b. *Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting, such as a hospital, skilled nursing facility (SNF), or clinic.*

For more information on clinical social workers, refer to Pub. 100-02, chapter 15, section 170.

10.2.3.8 – Nurse Practitioners
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.75(b) state that a nurse practitioner must be a registered professional nurse who is authorized by the state in which the services are furnished to practice as a nurse practitioner in accordance with state law. The individual must also meet one of the following criteria:

1. *Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:*

    a. *Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.*

    b. *Possesses a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.*

(If the aforementioned master's or doctoral degree is required to obtain a license as a nurse practitioner in the state, the contractor need not separately verify the degree or require the practitioner to submit applicable documentation.)

2. *Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in (1)(a) above.*

3. *Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.*

Pub. 100-02, chapter 15, section 200 lists the following organizations as CMS-recognized national certifying bodies for nurse practitioners at the advanced practice level:

- *American Academy of Nurse Practitioners*
- *American Nurses Credentialing Center*
- *National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties*
- *Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses)*
- *Oncology Nurses Certification Corporation*
- *AACN Certification Corporation*
- *National Board on Certification of Hospice and Palliative Nurses*

10.2.3.9 – Occupational Therapists in Private Practice

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Regulatory Requirements - Occupational Therapist in Private Practice

Section 42 CFR § 410.59(c)(i) through (iv) state that an occupational therapist in private practice must meet all of 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 2K of the Form CMS-855I. However, Section 2K 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 of 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. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Regulatory Requirements - Physical Therapist in Private Practice

Section 42 CFR § 410.60(c) states that in order 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 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 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.

F. Physical Therapists: Additional Site Visit Information

The contractor is also advised of the following:

- *In Section 2A of the Form CMS-855B application, physical and occupational therapy groups are denoted as "Physical/Occupational Therapy Group(s) in Private Practice." If a supplier that checks this box in Section 2A 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.*

- *If a newly-enrolling private practice physical therapist lists several practice locations, the enrollment contractor has the discretion to determine the location at which the NSVC will perform the required site visit.*

- *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 and Form CMS-855R). However, a site visit is not required for an enrolled private practice physical therapist who is reassigning his or her benefits only (Form CMS-855R).*

- *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 2K of the Form CMS-855I. However, Section 2K 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 of 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.

10.2.3.11 – Physicians

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

As described in § 1861(r)(1) of the Social Security Act and in 42 CFR § 410.20(b), a physician must be legally authorized to practice medicine by the state in which he/she performs such services in order to enroll in the Medicare program and to retain Medicare billing privileges. Such individuals include: (1) doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, or optometry; and (2) a chiropractor who meets the qualifications specified in 42 CFR § 410.22.

See Pub. 100-04, chapter 19, section 40.1.2 for special licensure rules regarding practitioners who work in or reassign benefits to hospitals or freestanding ambulatory care clinics operated by the Indian Health Service or by an Indian tribe or tribal organization.

10.2.3.12 – Physician Assistants

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Physician Assistant Requirements Under § 410.74

Current federal regulations at 42 CFR §§ 410.74 discuss the requirements that a physician assistant (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.

(v) Furnishes services that are billed by the employer of a PA; and

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

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

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

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

B. PA Employer

Pub. 100-02, chapter 15, section 190(D) currently states:

- *Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself. In other words, the PA cannot individually enroll in Medicare and receive direct payment for his or her services. This also means that the PA does not reassign his or her benefits to the employer, for the employer must receive direct payment anyway.*

- *The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., limited liability company, limited liability partnership) in a state that permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for its services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as providers or suppliers of services.*

- *PAs also have the option under their benefit to furnish services as an independent contractor (1099 employment arrangement) in which case the contractor serves as the PA's employer and Medicare payment is made directly to the contractor.*

C. Other PA Enrollment Information

As stated in the instructions on the Form CMS-855I, PAs who are enrolling in Medicare need only complete Sections 1, 2, 3, 13, and 15 of the Form CMS- 855I. The PA must furnish his/her NPI in Section 2A of the application and must list his/her employer information (including the employer's NPI) in Section 2I.

The contractor must verify that the employers listed are: (1) enrolled in Medicare; and (2) not excluded or debarred from the Medicare program. (An employer can only receive payment for a PA's services if both are enrolled in Medicare.) If an employer is excluded or debarred, the contractor shall deny the application.

Since PAs currently cannot reassign their benefits – even though they are reimbursed through their employer – they should not complete a Form CMS-855R.

10.2.3.13 – Psychologists Practicing Independently

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Pub. 100-02, chapter 15, section 80.2 states that a psychologist practices independently when:

- *He/she render services on his/her own responsibility, free of the administrative and professional control of an employer, such as a physician, institution, or agency;*
- *The persons he/she treats are his/her own patients;*
- *He/she has the right to bill directly, collect and retain the fee for his/her services; and*
- *The psychologist is state-licensed or certified in the state where furnishing services.*

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions are met: (1) the office is confined to a separately-identified part of the facility that is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and (2) the psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).

Independently practicing psychologists have a more limited benefit under the Medicare program than clinical psychologists. With a degree starting at the master's level of psychology, independently practicing psychologists are authorized to bill the program directly solely for diagnostic psychological and neuropsychological tests that have been ordered by a physician, clinical psychologist, or non-physician practitioner who is authorized to order diagnostic tests. Independently practicing psychologists are not authorized to supervise diagnostic psychological and neuropsychological tests. Any tests performed by an independently practicing psychologist must fall under the psychologist's state scope of practice.

The contractor shall ensure that all persons who check "Psychologist Billing Independently" in Section 2H of the Form CMS-855I answer all questions in Section 2J2. If the supplier answers "no" to question 1, 2, 3, 4a, or 4b, the contractor shall deny the application.

See Pub. 100-04, chapter 12, sections 160 and 160.1 for more information on psychologists billing independently.

10.2.3.14 – Registered Dietitians/Nutrition Professionals
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Federal regulations at 42 CFR § 410.134(a) through (c) state that a registered dietitian (or nutrition professional) is an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose;

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(c) Is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian"' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) above.

There are two exceptions to these requirements (as stated in 42 CFR § 410.134(d)(i) and (ii)):

(i) A dietitian or nutritionist licensed or certified in a state as of December 21, 2000, is not required to meet the requirements of (a) and (b) above.

(ii) A registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) above.

10.2.3.15 – Speech Language Pathologists in Private Practice
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Consistent with 42 CFR § 410.62(c), in order to qualify as an outpatient speech-language pathologist in private practice, an individual must meet the following requirements:

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

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

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

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

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

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

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

10.2.3.16 – Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an Ambulatory Surgical Center (ASC)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Since Part A/B MACs make payments for implantable prosthetics and DME to hospitals, physicians, or ASC, A/B MACs shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. A manufacturer of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may enroll in the Medicare program as a supplier with the National Supplier Clearinghouse if it meets the definition of a supplier as well as the requirements in 42 CFR § 424.57.

10.3.2 - CMS-20134 - Enrollment Form: Information and Processing

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

The *Form CMS-20134 application (Medicare Enrollment Application for Medicare Diabetes Prevention Program (MDPP) Suppliers)* should be completed by organizations furnishing MDPP services to Medicare beneficiaries. In-Person MDPP suppliers participating in the Center for Medicare and Medicaid Innovation's expanded model, which exclusively furnishes MDPP to beneficiaries in in-person settings with limited exceptions for virtual makeup sessions, may begin enrolling in Medicare on January 1, 2018.

This section 10.3.2 et seq. contains instructions for processing the various sections of the Form CMS-20134 and addresses important related MDPP policies.

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

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Reason for Submittal

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter or another CMS directive, 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.

With the exception of (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, 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://nccd.cdc.gov/DDT_DPRP/CMS/DPRP_Recognized_Organizations_Full_List.aspx*
- *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 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.

10.3.2.2 – CMS-20134 (Section 2 - Identifying Information)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Correspondence Address and Telephone Number

Regarding the Correspondence Address section of the Form CMS-20134, 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. Although the contractor need not verify the correspondence address, the latter cannot be the address of a billing agency, management services organization, chain home office, 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.

Concerning the telephone number in the Correspondence Address section of the Form CMS-20134, the supplier may list any telephone number it wishes as the correspondence phone number. The number need not link to the listed correspondence address. If the supplier fails to list a correspondence telephone number and the latter is required for the application submission, the contractor shall develop for this information – preferably via email 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 is not required to verify the telephone number.

B. 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.

Regarding unavoidable phone number or address changes (and unless CMS specifies otherwise), any change in the supplier's phone number or address that the supplier did not cause (e.g., area code change, municipality renames the supplier's street) must still be updated via the Form CMS-20134.

C. Supplier Identification Information

Regarding Supplier Identification Information – Business Information, the contractor may capture all information in the Identifying Information (Business Information) section (with the exception of the TIN and legal business name (LBN) by telephone, fax, e-mail, or a review of the supplier's Web site.

10.3.2.3 – CMS-20134 (Section 3 - Final Adverse Legal Actions/Convictions)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Refer to section 10.6.6 of this chapter for information regarding final adverse actions.

10.3.2.4 – CMS-20134 (Section 4 - MDPP Location Information)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Background

The MDPP location address must be a valid address with the United States Postal Service (USPS). Addresses entered into the Provider Enrollment, Chain and Ownership System (PECOS) are verified via computer software to determine if they are valid and deliverable. The contractor shall verify that each practice location listed on the application actually exists and is a valid address with the 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.

As for telephone numbers, the contractor shall verify that the reported telephone number is operational and connects to the practice location/business listed on the application. However, the contractor need not contact every location for applicants that are enrolling multiple locations; the contractor can verify each location's telephone number with the contact person listed on the application and note the verification accordingly in the contractor's verification documentation per section 10.6.19(H) of this chapter. (The telephone number must be one where patients and/or customers can reach the applicant to ask questions or register complaints.) The contractor may also match the applicant's telephone number with known, in-service telephone numbers - via, for instance, the Yellow Pages or the Internet - to correlate telephone numbers with addresses. If the applicant uses his/her/its cell phone for their business, the contractor shall verify that this is a telephone connected directly to the business. If the contractor cannot verify the telephone number, it shall request clarifying information from the applicant; the inability to confirm a telephone number may indicate that an onsite visit is necessary. In some instances, a 1-800 number or out-of-state number may be acceptable if the applicant's MDPP location is in another state but his/her/its practice locations are within the contractor's jurisdiction.

In addition:

- *Any supplier submitting a Form CMS-20134 application must submit the 9-digit ZIP Code for each practice location listed.*

- *For suppliers paid via the Multi-Carrier System (MCS), the practice location name entered into PECOS shall be the LBN.*

- *In the MDPP Location Information section of the Form CMS-20134, the checkboxes identifying the type of MDPP location must be completed to indicate if the location is the MDPP supplier's administrative location or the community setting. If the type of location is apparent to the contractor, the MDPP supplier need not complete the administrative location type. The contractor can confirm the information via telephone, e-mail, or fax.*

- *Each administrative location shall be verified. However, the contractor need not separately contact each location on the application. Such verification can be done via the contact person listed on the application; the contact person's verification shall be documented in the supplier file pursuant to section 10.6.19(H) of this chapter.*

B. Do Not Forward (DNF)

Unless instructed otherwise in another CMS directive, the contractor shall follow the DNF initiative instructions in CMS Publication (Pub.) 100-04, chapter 1, section 80.5. Returned paper checks, remittance notices, or electronic funds transfer (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 (Practice Location section of the Form CMS-20134) or EFT information has changed. The supplier should submit a Form CMS-20134 or Form CMS-588 request to change this address; if the supplier does not have an established enrollment record in PECOS, it must complete an entire Form CMS-20134 and Form CMS-588. The Durable Medical Equipment MAC is responsible for obtaining, updating, and processing Form CMS-588 changes.

In situations where the 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-20134 and to sign the certification statement. The contractor, however, shall not collect any other information unless there is a need to do so.

C. Remittance Notices/Special Payments

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

In the MDPP Location Information/Remittance Notice and Special Payments Address section of the Form CMS-20134, if neither box is checked and no address is provided, the contractor can contact the supplier by telephone, e-mail, or fax to confirm the supplier's intentions. If the "special payments" address is indeed the same as the practice location, no further development is needed. If, however, the supplier wants payments to be sent to a different address, the address in Section 4B of the Form CMS-20134 must be completed.

If an enrolled supplier that currently receives paper checks submits a Form CMS-20134 change request – no matter what the change involves – the following apply:

- *The supplier must 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 verify that the bank account complies with Pub. 100-04, chapter 1, section 30.2.*

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

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

- *One of the supplier's practice locations*

- *A P.O. box*

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

- *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*

LBN of the chain home office must be listed on the Form CMS-588. The TIN on the Form CMS-588 should be that of the supplier.

- *Correspondence address*
- *A lock box*

D. Additional MDPP Supplier Location Information

The MDPP set of services is unique in that it is delivered in group settings and can be delivered by non-traditional health care providers who meet certain eligibility criteria. Given this aspect of MDPP suppliers, MDPP services are often delivered within community locations to increase access. Thus, the locations associated with MDPP suppliers differ slightly than traditional practice locations of other health care providers and suppliers.

1. Administrative Locations

MDPP suppliers must have at least one administrative location and report all administrative locations on their Form CMS-20134 or PECOS equivalent. As noted in section 10.1.1 of this chapter, an administrative location is the physical location: (1) associated with the supplier's operations; (2) from where coaches are dispatched or based; and (3) where MDPP services may or may not be furnished. If an entity enrolls as an MDPP supplier but does not furnish MDPP services at its administrative location, it should deliver and disclose any and all community settings where it furnishes MDPP services.

An administrative location:

- *Cannot be a private residence*
- *Must have signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building. Such signage may include, for example, the MDPP supplier's LBN or doing business as (DBA) name, as well as hours of operation.*
- *Must be open for business and have employees, staff, or volunteers present during operational hours*

All administrative locations related to the MDPP supplier must be disclosed. However, given that MDPP suppliers may be non-traditional health care providers engaged in non-health care related activities, not all organizations run by the entity may constitute an administrative location. For example, if an advocacy organization operates two sites and only one of them offers MDPP services, only the site offering MDPP would be considered an administrative location. Should a coach be based or dispatched from their non-administrative location site to offer MDPP services in community settings, this location would become an administrative location. (See section 10.2.6 of this chapter for information regarding the frequency with which MDPP suppliers must report this change.)

As MDPP suppliers fall within the high-risk level of categorical screening under 42 CFR § 424.518, their administrative locations are subject to site visits. See sections 10.6.20(A) and (B) of this chapter for additional information concerning site visits.

2. Community Settings

When determining whether a location is considered an administrative location or a community setting, MDPP suppliers must consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually provides other services benefiting the community. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services; that is, a community setting is a location where the supplier furnishes MDPP services outside of its administrative locations in a meeting location that is open to the public but not primarily associated with the supplier.

An MDPP supplier must update its enrollment application with locations where services are furnished in community settings. While these settings are not subject to site visits, they serve as a form of recordkeeping and accountability for the MDPP supplier.

3. Out-of-State Practice Locations

If a supplier is adding a practice location in another state that is within the contractor's jurisdiction, a separate, initial Form CMS-20134 enrollment application is not required if both of the following conditions are met:

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

- *The location does not have a separate TIN and LBN*

Consider the following examples:

Example 1 - The contractor's jurisdiction consists of States X, Y and Z. Jones MDPP Center (JMC), Inc., is enrolled in State X with 3 locations. It wants to add a fourth location in State Y. The new location will be under JMC, Inc. JMC will not be establishing a separate corporation, LBN, or TIN for the fourth location. Both of the above conditions are therefore met. JMC 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).

Example 2 - The contractor's jurisdiction consists of States X, Y and Z. Jones MDPP Practice (JMP), Inc., is enrolled in State X with three locations. It wants to add a fourth location in State Y but under a newly created, separate entity - Jones MDPP Practice, LP. The fourth location must be enrolled via a separate, initial Form CMS-20134.

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

10.3.2.5 – CMS-20134 (Sections 5 & 6 - Owning and Managing Organizations and Individuals)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Sections 5 and 6 of the Form CMS-20134 collect data regarding the MDPP supplier's organizational and individual owners and managing parties. For detailed information regarding the completion of these sections and the validation of the data thereon, see section 10.6.7 of this chapter.

10.3.2.6 – Reserved for Future Use

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

10.3.2.7 – CMS-20134 (Section 7 – Coach Roster)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Background Information

Only organizations, and not individuals, are eligible to enroll as an MDPP supplier. However, MDPP services are furnished to Medicare beneficiaries by MDPP coaches in group settings. Though these individuals furnish MDPP services on behalf of MDPP suppliers, only the MDPP supplier itself enrolls in Medicare. To enable CMS to better ensure the integrity of the program and the safety of the beneficiaries it serves, MDPP suppliers must report identifying information on coaches in the Coach Roster section of the Form CMS-20134. If a coach is being added or changed, the updated information must be reported via a Form CMS-20134 change request

B. Coach Eligibility and Screening

As indicated in section 10.2.6 of this chapter and as outlined in the MDPP supplier standards, MDPP suppliers cannot include on their roster (or allow MDPP services to be furnished by) an ineligible coach. Accordingly, an MDPP coach must not:

- *Currently have Medicare billing privileges revoked and be currently subject to a reenrollment bar*
- *Currently have its Medicaid billing privileges terminated for-cause or be excluded by a state Medicaid agency*
- *Currently be excluded from any other federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.*
- *Currently be debarred, suspended, or otherwise excluded from participating in any other federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.*
- *Have, in the previous 10 years, one of the following state or federal felony convictions:*
    - *Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.*
    - *Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.*
    - *Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.*

- *Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.*

Upon enrollment or any changes to the Coach Roster section of the Form CMS-20134 that results in a new coach being added, the contractor shall verify that the coach is not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG) or through the System for Award Management (SAM) (formerly, the General Services Administration Excluded Parties List System) and, to the extent possible, whether or not an individual coach meets the above eligibility criteria. Should the contractor determine that an ineligibility criterion has been met pursuant to that screening but is either unsure of the matter or unclear as to what action should next be taken, the contractor may contact its Provider Enrollment & Oversight Group (PEOG) Business Function Lead (BFL) for guidance.

C. Coach Eligibility Start and End-Dates

MDPP coaches may have a high turnover rate. To document which coaches are active with a supplier at a given time, each coach will have an eligibility start and, if applicable, an eligibility end-date.

For each change to the Coach Roster section of the Form CMS-20134, the MDPP supplier must indicate the date of such change. (If the date of change for an individual coach is completely blank, the contractor must develop for this information.) Per 42 CFR § 424.205(d), an MDPP supplier must report all changes to its coach roster within 30 days of the change.

If the contractor determines the coach to be ineligible, the coach's eligibility start and end-date shall be documented as the same date; this effectively means that the coach was never eligible. Two other means by which a coach may get an eligibility end-date are as follows:

- *When the MDPP supplier removes that coach from its roster. Here, the eligibility end-date would be the date the MDPP supplier indicated when it updated the Coach Roster section to remove the coach.*
- *When the MDPP supplier with which he or she is associated is revoked or does not revalidate its enrollment. Here, the coach's eligibility end-date is the same as the date the MDPP supplier's billing privileges were no longer effective.*

An MDPP supplier may only be paid for services furnished by eligible coaches within their eligibility start and end-dates.

D. Consequences for Coach Ineligibility

If the contractor or CMS determines that an MDPP supplier has an ineligible coach on its roster, the MDPP coach would be non-compliant with the MDPP supplier standards. The supplier would thus have its enrollment denied or revoked, as appropriate under §§ 424.530(a)(1) or 424.535(a)(1). Consistent with existing procedures, MDPP suppliers may submit a corrective action plan (CAP) removing this coach from its roster within 30 days of receiving notice of its enrollment denial or revocation, and, if compliant and as applicable, could obtain or maintain Medicare enrollment. (See section 10.6.18 of this chapter for more information on CAPs.) In this CAP situation, the supplier need not submit any documentation beyond updating the Coach Roster section of the Form CMS-20134 to remove the ineligible coach.

E. Special Revocation for Knowingly Using an Ineligible Coach

While MDPP supplier standards indicate that an MDPP supplier may not include an ineligible coach on its roster or allow him/her to furnish MDPP services on its behalf to Medicare beneficiaries, the MDPP supplier is not prohibited from continuing to employ or otherwise permit the coach to volunteer for other services unrelated to MDPP. Should CMS identify that an MDPP supplier is knowingly allowing an ineligible coach to continue furnishing MDPP services, the MDPP supplier would be revoked under § 424.205(h)(5) and any other revocation authority. In this context, "knowingly" means that the MDPP supplier meets all of the following five conditions; specifically, the supplier:

- *Received an enrollment denial or revocation notice for failing to meet the MDPP standard in § 424.205(d)(3);*
- *Was provided notice by CMS or the contractor of the coach's ineligibility, and the applicable reason(s);*
- *Submitted a CAP to remove the coach;*
- *Became compliant once again and obtained or maintained its enrollment; but*
- *Continued to allow the ineligible coach who was removed from the Coach Roster section of the Form CMS-20134 to provide MDPP services in violation of the CAP.*

See section 10.4(M)(4)(d) of this chapter for more information.

10.3.2.8 – CMS-20134 (Section 8 – Billing Agency Information)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Regarding the Billing Agency Information section of the Form CMS-20134, refer to section 10.6.8 of this chapter.

Note that if the telephone number in Section 8 is blank, the number can be verified with the supplier by telephone, e-mail, or fax. If the section is blank (including the check box), no additional development is necessary.

10.3.2.9 – CMS-20134 (Section 13 – Contact Person)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

If Section 13 is completely blank, the contractor need not develop for this information and can simply contact an authorized or delegated official. If neither box in Section 13 is checked but the contact person information is incomplete (e.g., no telephone number listed), the contractor can either: (1) develop for this information by telephone, e-mail, or fax; or (2) contact an authorized or delegated official.

There is no current option on the Form CMS-20134 to delete a contact person. Therefore, the contractor shall accept the end-date of a contact person via phone, email, fax, or mail from the individual supplier, 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 Form CMS-20134.

(See section 10.6.9 of this chapter for more information regarding the Contact Person section of the Form CMS-20134.)

10.3.2.10 – CMS-20134 (Section 14 – Penalties for Falsifying Information)
(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

See the Penalties for Falsifying Information section of the Form CMS-20134 for an explanation of penalties that apply to MDPP suppliers for deliberately furnishing false information on the Form CMS-20134 to obtain or maintain Medicare enrollment.

10.3.2.11 – CMS-20134 (Section 15 – Certification Statement and Authorized Officials)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

Unless indicated otherwise below or in another CMS directive, the instructions in this section apply to (1) signatures on the paper Form CMS-20134, (2) signatures on the certification statement for Internet-based PECOS applications, and (3) electronic signatures

Valid, acceptable signatures include handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options, created in software, such as Adobe). The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

All signatures (handwritten or digital) are valid and appropriate in regards to (1) signatures on the paper Form CMS-855R and (2) uploaded signatures on the certification statement for Internet-based PECOS applications.

The MDPP supplier may submit its certification statement via e-signature or paper to its Medicare contractor.

A. Certification Statement - Paper Submissions

A signed certification statement shall accompany the paper Form CMS-20134. If the supplier submits an invalid certification statement or no certification statement at all, the contractor shall still continue processing the application. An appropriate certification statement shall be solicited as part of the development process – preferably via email or fax. This includes certification statements that are: (a) unsigned; (b) undated; (c) was signed (as reflected by the date of signature) more than 120 days prior to the date on which the contractor received the application); (d) missing altogether; or (e) stamped. The contractor shall send one development request that lists all of the missing/deficient required data/documentation, including the certification statement. The contractor may reject the supplier's application if the supplier fails to furnish the missing information and/or correct the deficient data on the enrollment application - including all necessary documentation - within 30 calendar days from the date the contractor requested the information or documentation.

Unless stated otherwise in this chapter or in another CMS directive:

- *The contractor shall, as stated above, begin processing the application upon receipt and shall develop for missing/deficient certification statements and all other missing/deficient information, including the application fee, upon review.*
- *As applicable, the certification statement may be returned via scanned email or fax.*
- *As mentioned previously, signature dates cannot be prior to 120 days of the receipt date of the application.*
- *For paper applications that require development, it is only necessary that the dated signature of at least one of the supplier's authorized or delegated officials be on the*

certification statement that must be sent in within 30 days; the signatures of the other authorized and delegated officials need not be obtained.

- *For paper change of information applications (as the term "changes of information" is defined in section 10.4(J) of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as being an authorized or delegated official of the supplier, the contractor may accept the certification statement but shall develop for information on this person.*

- *The contractor need not compare the signature on the Form CMS-20134 with the same authorized or delegated official's signature on file to ensure that it is the same person.*

- *The contractor shall not request the submission of a driver's license or passport to verify a signature.*

B. Certification Statement - Internet-based PECOS Submissions

If the supplier submits its application online but chooses to submit its certification statement via paper rather than through e-signature, it shall do so via PECOS upload functionality. The supplier shall not mail in its paper certification statement, for it will not be accepted.

Unless stated otherwise in this chapter or in another CMS directive:

- *The contractor shall, as stated above, begin processing the application upon receipt and shall develop for missing/deficient certification statements and all other missing/deficient information (including the application fee) upon review.*

- *As mentioned previously, signature dates cannot be prior to 120 days of the receipt date of the application.*

- *For Internet-based PECOS applications that require development, it is only necessary that the dated signature of at least one of the supplier's authorized or delegated officials be on the certification statement that must be sent in within 30 days; the signatures of the other authorized and delegated officials need not be obtained.*

- *For Internet-based PECOS change of information applications (as the term "changes of information" is defined in section 10.4(J) of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as being an authorized or delegated official of the supplier, the contractor may accept the certification statement but shall develop for information on this person.*

- *The contractor need not compare the signature on the Form CMS-20134 with the same authorized or delegated official's signature on file to ensure that it is the same person.*

- *The contractor shall not request the submission of a driver's license or passport to verify a signature.*

C. Certification Statement Development

If the supplier submits an invalid certification statement (e.g., unsigned; undated; stamped signature; signed more than 120 days of the receipt date; incorrect individual signed it; not all authorized officials signed it) or neglects to send a certification statement altogether, the contractor shall treat this as missing information and develop for a correct certification statement using the procedures outlined in this chapter. The contractor shall send a development letter to the supplier – preferably via email or fax.

Any development request that requires the submission of a newly signed certification statement may be submitted: (1) via scanned email, fax, or mail for paper applications; and (2) by upload, fax, email or e-signature for web applications. Only the actual signature page is required; the additional page containing the certification terms need not be submitted. This also applies to the supplier's initial submission of a certification statement; such instances require the submission of only the signature page and not the certification terms.

D. Authorized Officials

Except as stated otherwise, the instructions in this section 10.3.2.11(D) apply to: (1) signatures on the paper Form CMS-20134; (2) signatures on the certification statement for Internet-based PECOS applications; and (3) electronic signatures.)

1. Requirements

As defined in 42 CFR § 424.502, an authorized official is 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. The person must have the authority to legally and financially bind the supplier to) the requirements set forth in 42 CFR § 424.510 (and other applicable Medicare regulations) and to act on behalf of the organization.

An authorized official is not restricted to the examples of the titles outlined above; however, the person must hold a position of similar status and authority within the provider or supplier organization. Additional titles could include, but are not limited to, executive director, administrator, president, and vice-president. The contractor shall consider the individual's title and the authority granted by the organization when determining whether an individual qualifies as an authorized organization. If the contractor is unsure of the person's qualifications or authority, it shall contact its PEOG BFL for further clarification. The contractor shall obtain PEOG BFL approval if the only role of the listed authorized official is "Contracted Managing Employee."

If an authorized official is listed as a "Contracted Managing Employee" in the Individual Ownership and/or Managing Control section of the Form CMS-20134 and does not qualify as an authorized official under some other category in this section, he/she cannot be an authorized official. The contractor shall notify the supplier accordingly. If the person is not listed as a "Contracted Managing Employee" in the Individual Ownership and/or Managing Control section and the contractor has no reason to suspect that the person does not qualify as an authorized official, no further investigation is required. Should the contractor have doubts that the individual qualifies as an authorized official, it shall contact the official or the applicant's contact person to obtain more information about the official's job title and/or authority to bind. If the contractor remains unconvinced that the individual qualifies as an authorized official, it shall notify the supplier that the person cannot be an authorized official. If that person is the only authorized official listed and the

supplier refuses to use a different authorized official, the contractor shall deny the application.

For purposes of determining an authorized official's qualifications, identifying the supplier is not determined solely by the supplier's TIN. Rather, the organizational structure is the central factor. For instance, suppose a chain drug store, Company X, wants to enroll 100 of its pharmacies with the contractor. Each pharmacy has a separate TIN and must therefore enroll separately. Yet all of the pharmacies are part of a single corporate entity – Company X. In other words, there are not 100 separate corporations in our scenario but merely one corporation whose individual locations have different TINs. Here, an authorized official for Pharmacy #76 can be someone at X's headquarters (assuming the definition of authorized official is otherwise met), even though this main office might be operating under a TIN that is different from that of #76. This is because headquarters and Pharmacy #76 are part of the same organization/corporation.

2. Required Signature

For Form CMS-20134 initial applications, the certification statement must be signed and dated by an authorized official of the supplier. (See sections 10.1.1 and 10.3.2.11(D) of this chapter for a definition of "authorized official.") The supplier can have an unlimited number of authorized officials so long as each meets the definition of an authorized official. The Individual Ownership and/or Managing Control section of the Form CMS-20134 must be completed for each authorized official.

(For revalidation and changes of information, either the authorized or delegated official must sign the application. (See sections 10.1.1 and 10.3.2.12 of this chapter for a definition of "delegated official.").

3. Changes and Deletions in Authorized Officials

A change in authorized officials does not impact the authority of existing delegated officials to report changes and/or updates to the supplier's enrollment data or to sign revalidation applications.

If an authorized official is being deleted, the contractor need not obtain (1) that official's signature or (2) documentation verifying that the person is no longer an authorized official.

4. Authorized Official Not on File

If the supplier submits a change of information (e.g., change of address) and the authorized official signing the form is not on file, the contractor shall ensure that: (1) the person meets the definition of an authorized official; and (2) the Individual Ownership and/or Managing Control section of the Form CMS-20134 is completed for that person. The signature of an existing authorized official is not needed to add a new authorized official. Note that the original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting.

5. Effective Date

The effective date in PECOS for the Certification Statement section of the Form CMS-20134 should be the date of signature.

6. Social Security Number

To be an authorized official, the person must have and must submit his/her social security number (SSN). An Individual Taxpayer Identification Number (ITIN) cannot be used in lieu of an SSN in this regard.

7. Telephone Number

The authorized official's telephone number can be left blank. No further development is needed.

10.3.2.12 – CMS-20134 (Section 16 – Delegated Officials)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Background

A delegated official is an individual to whom an authorized official listed in the Certification Statement section of the Form CMS-20134 delegates the authority to report changes and updates to the supplier's enrollment record or to sign revalidation applications. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to enrollment information is that of the authorized official currently on file with Medicare. A delegated official has no authority to sign an initial application. However, the delegated official may (i) sign a revalidation application and (ii) sign off on changes/updates submitted in response to a contractor's request to clarify or submit information needed to continue processing the supplier's initial application.

The delegated official must be an individual with an "ownership or control interest" in (as that term is defined in § 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the supplier.

Section 1124(a)(3) defines an individual with an ownership or control interest as:

- *A five percent direct or indirect owner of the provider,*
- *An officer or director of the provider (if the provider is a corporation), or*
- *Someone with a partnership interest in the provider (if the provider is a partnership)*

For purposes of information captured in the Delegated Official section only, the term "managing employee" means any individual (including a general manager, business manager, or administrator) who exercises operational or managerial control over the supplier, or who conducts the day-to-day operations of the supplier. However, this does not include persons who, either under contract or through some other arrangement, manage the day-to-day operations of the supplier but who are not actual W-2 employees. For instance, suppose the supplier hires Joe Smith as an independent contractor to run its day-to-day-operations. Under the definition of "managing employee" in the Individual Ownership and/or Managing Control section of the Form CMS-20134, Smith would have to be listed in that section. Yet under the Delegated Official section definition (as described above), Smith cannot be a delegated official because he is not an actual W-2 employee of the supplier. Independent contractors are not considered "managing employees" under the Delegated Official section of the Form CMS-20134.

The Ownership Interest and Managing Control Information in the Individual Ownership and/or Managing Control section of Form CMS-20134 must be completed for all delegated officials.

B. Specific Delegated Official Policies

1. *Further Delegation – A delegated official may not delegate his/her authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the supplier's Medicare data or to sign revalidation applications.*

2. *W-2 Form - Unless the contractor requests it to do so, the supplier need not submit a copy of the owning/managing individual's W-2 to verify an employment relationship.*

3. *Number of Delegated Officials - The supplier can have as many delegated officials as it chooses. Conversely, the supplier need not have any delegated officials. Should no delegated officials be listed, however, the authorized official(s) remains the only individual(s) who can report changes and/or updates to the supplier's enrollment data.*

4. *Effective Date - The effective date in PECOS for the Delegated Official section of the Form CMS-20134 should be the date of signature.*

5. *Social Security Number - To be a delegated official, the person must have and must submit his/her SSN. An ITIN cannot be used in lieu of an SSN in this regard.*

6. *Deletion of Delegated Official - If a delegated official is being deleted, documentation verifying that the person no longer is or qualifies as a delegated official is not required. Also, the signature of the deleted official is not needed.*

7. *Delegated Official Not on File - If the supplier submits a change of information (e.g., change of address) and the delegated official signing the form is not on file, the contractor shall ensure that (1) the person meets the definition of a delegated official, (2) the Individual Ownership and/or Managing Control section of the Form CMS-20134 is completed for that person, and (3) an authorized official signs off on the addition of the delegated official. (NOTE: The original change request and the addition of the new official shall be treated as a single change request (i.e., one change request encompassing two different actions) for purpose of enrollment processing and reporting.)*

8. *Signature on Paper Application - If the supplier submits a paper Form CMS-20134 change request, the contractor may accept the signature of a delegated official in the Certification Statement or Delegated Official sections of the Form CMS-20134.*

9. *Telephone Number - In addition, the delegated official's telephone number can be left blank. No further development is needed.*

10.3.2.13 – CMS-20134 (Section 17 – Supporting Documents)

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

(In addition to the instructions in this section 10.3.2.13, refer to the Supporting Documents section of the Form CMS-20134 for information concerning supporting documents.)

As already stated in this section 10.3.2.1, MDPP suppliers must have MDPP preliminary recognition or full recognition, as determined by CMS. See section 10.3.2.1 for more information on required documentation.

10.3.2.14 – Additional Form CMS-20134 Processing Information and Alternatives

(Rev. 10800; Issued: 05-20-21; Effective: 06-22-21; Implementation: 06-22-21)

A. Unsolicited Additional Information

If the supplier submits missing/clarifying data or documentation on its own volition (i.e., without being contacted by the contractor), the contractor shall include this additional data/documentation in its overall application review. Any new or changed information a supplier submits prior to the date the contractor finishes processing a previously submitted change request is no longer considered to be an update to that change request. Rather, it is considered to be and shall be processed as a separate change request. The contractor may process both changes simultaneously, but the change that was submitted first shall be processed to completion prior to the second one being processed to completion.

B. Information Disclosed Elsewhere

If a data element on the supplier's Form CMS-20134 application is missing but the information is disclosed (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, the contractor need not obtain the missing data via an updated Form CMS-20134 page and a newly-signed certification statement; no further development – not even by telephone – is required. The following information, however, must be furnished in the appropriate section(s) of the Form CMS-20134, even if the data is identified elsewhere on the form or in the supporting documentation:

- *Any final adverse action data requested in the Final Adverse Legal Actions/Convictions section (Section 3) and Organizational and Individual Ownership and/or Managing Control Final Adverse Legal Action History sections (Sections 5B and 6B) of the Form CMS-20134*

- *The applicant's legal business name (LBN) or legal name (Note: If an application is submitted with a valid National Provider Identifier (NPI) and Provider Transaction Access Number (PTAN) combination but (1) the LBN field is blank, (2) an incomplete or inaccurate LBN is submitted, or (3) the applicant includes a DBA name in the MDPP Location Information section of the Form CMS-20134, the contractor need not develop if it can confirm the correct LBN based on the NPI and PTAN combination provided.*

- *Tax Identification Number*

(The contractor may use the shared systems, PECOS, or its supplier files as a resource to determine the PTAN or NPI before developing with the supplier.)

If required supporting documentation currently exists in the supplier's file, the supplier need not submit that documentation again during the enrollment process. The contractor shall utilize the existing documentation for verification. Documentation submitted with a previously submitted enrollment application, or documentation currently uploaded in PECOS, qualifies as a processing alternative unless stated otherwise in this chapter or any CMS directive. Per section 10.6.19(H) of this chapter, the contractor shall document in the supplier file that the missing information was found elsewhere in the enrollment package. However:

- *This excludes information that must be verified at the current point in time (e.g., a license without a primary source verification method)*

- *The contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa*

C. City, State, and ZIP Code

If an address (e.g., correspondence address, practice location) lacks a city, state or zip + four, the contractor can verify the missing data in any manner it chooses. (Note that the contractor can obtain the zip + four from either the USPS or the Delivery Point Validation in PECOS.)

D. Inapplicable Questions

The supplier need not check "no" for questions that obviously do not apply to its supplier type.