CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11891	**Date: March 9, 2023**
	Change Request 13036

SUBJECT: Second Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0

I. SUMMARY OF CHANGES: The purpose of this CR is to update various sections in Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual, with policies concerning the implementation of PECOS 2.0.

EFFECTIVE DATE: April 21, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 19, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.2/10.2.1.8/Hospitals and Hospital Units
R	10/10.2/10.2.2.2/Home Infusion Therapy Suppliers
R	10/10.2/10.2.2.3/Independent Clinical Laboratory Improvement Act (CLIA) Labs
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.2.10/Suppliers of Ambulance Services
R	10/10.2/10.2.4/Other Medicare Part B Services
R	10/10.3/10.3.2/CMS-20134 – Enrollment Form: Information and Processing
R	10/10.3/10.3.2.1/CMS-20134 (Section 1 - Basic Information)
R	10/10.3/10.3.2.2/CMS-20134 (Section 2 - Identifying Information)
R	10/10.3/10.3.2.3/CMS-20134 (Section 3 - Final Adverse Legal Actions/Convictions)
R	10/10.3/10.3.2.4/CMS-20134 (Section 4 - MDPP Location Information)
R	10/10.3/10.3.2.5/CMS-20134 (Sections 5 & 6 - Owning and Managing Organizations and Individuals)
R	10/10.3/10.3.2.8/CMS-20134 (Section 8 – Billing Agency Information)
R	10/10.3/10.3.2.9/CMS-20134 (Section 13 – Contact Person)
R	10/10.3/10.3.2.11/CMS-20134 (Section 15 – Certification Statement and Authorized Officials)
R	10/10.3/10.3.2.13/CMS-20134 (Section 17 – Supporting Documents)
R	10/10.3/10.3.2.14/Additional Form CMS-20134 Processing Information and Alternatives
R	10/10.3/10.3.3.1/Form CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement
R	10/10.3/10.3.3.2/Form CMS-460 – Medicare Participating Physician or Supplier Agreement
R	10/10.4/10.4.1/General Processing Functions
R	10/10.4/10.4.1.1/Overview of the Process
R	10/10.4/10.4.1.2/Receipt of Application
R	10/10.4/10.4.1.3.1/Initial Steps of Review of Application
R	10/10.4/10.4.1.3.2/Data Verification
R	10/10.4/10.4.1.3.3/Requesting Missing/Clarifying Data/Documentation (Development)

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.4/10.4.1.3.4/Receiving Missing/Clarifying Data/Documentation (Response to Development)
R	10/10.4/10.4.1.3.5/Provider/Supplier Fails to Submit Requested Data/Documentation
R	10/10.4/10.4.1.4.1/Approvals
R	10/10.4/10.4.1.4.2/Returns
R	10/10.4/10.4.1.4.3/Rejections
R	10/10.4/10.4.2/Denials
R	10/10.4/10.4.3/Voluntary and Involuntary Terminations
R	10/10.4/10.4.4/Changes of Information
R	10/10.4/10.4.5/Revalidations
R	10/10.4/10.4.5.1/Revalidation Solicitations
R	10/10.4/10.4.5.2/Non-Responses to Revalidation and Extension Requests
R	10/10.4/10.4.5.3/Receipt and Processing of Revalidation Applications
R	10/10.4/10.4.6/Reactivations
R	10/10.4/10.4.7/Revocations

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: 11891	Date: March 9, 2023	Change Request: 13036

SUBJECT: Second Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0

EFFECTIVE DATE: April 21, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: June 19, 2023

I. GENERAL INFORMATION

A. Background: In preparation for the implementation of PECOS 2.0 in 2023, CMS will be updating Chapter 10 of Pub. 100-08 via several CRs in 2023. Each CR (none of which will be an analysis CR) will revise certain sections of Chapter 10 to incorporate PECOS 2.0 enrollment policies therein. This CR, which is the second CR in this series, will update applicable instructions in Sections 10.1 through Sections 10.4 with these policies. At least one additional CR addressing other PECOS 2.0 enrollment policies will follow in the coming months. Instructions regarding the operational and logistical aspects of the contractors' use of PECOS 2.0 will be issued through guidance outside of the above-referenced series of CRs.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13036.1	The contractor shall follow the PECOS 2.0 instructions in Sections 10.1 through 10.4 of Chapter 10 of Pub. 100-08.	X	X	X						NPEAST, NPWEST
13036.2	The contractor shall observe the situations in Sections 10.1 through 10.4 where the instructions in Section 10.3 in Chapter 10 of Pub. 100-08 supersede those in Sections 10.1 through	X	X	X						NPEAST, NPWEST

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Sections 10.4.									

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. 11891; Issued :03-09-23)

10.2.1.8 - Hospitals and Hospital Units

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(This section 10.2.1.8 applies to "standard" hospitals (as the term "hospital" is defined in § 1861(e)(1)), psychiatric hospitals, hospital units, and transplant programs. It does not apply to critical access hospitals, which are a separate provider type and are not "transitioning.")

A. General Background Information

Hospitals and hospital units are a provider type that enrolls via the Form CMS-855A. An exception to this is when the hospital is requesting enrollment to bill for practitioner services for hospital departments, outpatient departments, outpatient locations, and/or hospital clinics; in this circumstance, a new Form CMS-855B enrollment application is required.

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

1. Receipt of Application

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

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

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

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

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

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

(An authorized official (as defined in § 424.502) must complete, sign, date, and include the Form CMS-1561, though the hospital need not complete those sections of the form reserved for CMS.)

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

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.8(B) prohibits the contractor from returning or rejecting the hospital application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.8(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (D)(1) below need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.1.8(B)(2)(B) above.

(B) Approval Recommended

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

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

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

approval letter.)

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

C. Additional Enrollment Information

1. Swing-Bed Designation

A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital skilled nursing facility (SNF) services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital. Thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional CCN to bill for swing-bed services. (The third digit of the CCN will be the letter U, W, Y or Z.)

In general, and as stated in 42 CFR § 482.58, in order to obtain swing-bed status the hospital must, among other things: (1) have a Medicare provider agreement; (2) be located in a rural area; and (3) have fewer than 100 non-newborn or intensive care beds. Swing-bed hospitals, therefore, are generally small hospitals in rural areas where there may not be enough SNFs, and the hospital is thus used to furnish SNF services.

A separate provider agreement and enrollment for the swing-bed unit is not required. (The hospital's provider agreement incorporates the swing-bed services.) The hospital can add the swing-bed unit as a practice location via the Form CMS-855A.

Additional data on "swing-bed" units can be found in Pub. 100-07, chapter 2, sections 2036 – 2040.

2. Psychiatric and Rehabilitation Units

Though these units receive a state survey, a separate provider agreement and enrollment is not required. (The hospital's provider agreement incorporates these units.) The hospital can add the unit as a practice location to the Form CMS-855A.

3. Multi-Campus Hospitals

A multi-campus hospital (MCH) has two or more hospital campuses operating under one CCN. The MCH would report its various units/campuses as practice locations on the Form CMS-855A. For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

4. Physician-Owned Hospitals

As defined in 42 CFR § 489.3, a physician-owned hospital (POH) means any participating hospital (as defined in 42 CFR §489.24) in which a physician or an immediate family member of a physician has an ownership or investment interest in the hospital. The

ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. (This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements at 42 CFR § 411.356(a) or (b).)

Section 2(A)(4) of the Form CMS-855A asks the applicant to identify whether it is a physician-owned hospital. If the applicant indicates in Section 2(A)(2) that it is a hospital, it must complete Section 2(A)(4). Applicants that are not hospitals need not complete Section 2(A)(4).

At this time, POHs are not required to submit a completed Form CMS-855POH or a completed Attachment 1 of the Form CMS-855A. As stated in the March 12, 2015 announcement in MLN Connects Provider eNews, CMS has extended the deadline for the POH Initial Annual Ownership/Investment Report due to concerns about the accuracy of the data collected in the report. Future instruction regarding the reporting of POH ownership and investment will be provided on the CMS physician self-referral website.

5. Critical Access Hospitals

Critical access hospitals (CAHs) are not considered to be a hospital sub-type for enrollment purposes. CAHs instead must be enrolled as a separate, distinct provider type. Thus, if an existing hospital wishes to convert to a CAH, it must submit a Form CMS-855A as an initial enrollment.

6. Hospital Addition of Practice Location

In situations where a hospital is adding a practice location, the contractor shall notify the provider in writing that its recommendation for approval does not constitute approval of the facility or group as provider-based under 42 CFR § 413.65.

If the contractor makes a recommendation for approval of the provider's request to add a hospital unit, the contractor shall forward the package to the state agency as described in this chapter.

7. Transplant Programs

A transplant program is a component within a transplant hospital that provides transplantation of a particular type of organ to include: heart, lung, liver, kidney, pancreas, or intestine. All organ transplant programs must be located in a hospital that has a Medicare provider agreement. The transplant program will receive a CCN that is separate and distinct from the hospital.

For purposes of Medicare enrollment, a hospital transplant program is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant program, it must check the "other" box in Section 2A2 of the Form CMS-855A, write "transplant program" (and the type(s) thereof, such as liver transplant program, kidney transplant program, etc.) on the space provided, and follow the standard instructions for adding a hospital sub-unit. (If multiple types of transplant programs are listed, the contractor shall (a) treat each as a separate sub-unit for enrollment purposes and (b) process the application in the same fashion it would a hospital application that is reporting/adding multiple sub-units.) No separate enrollment in PECOS need *or will* be created for the transplant center.

D. Section 4 of the Form CMS-855A

Regarding Section 4 of the Form CMS-855A, the hospital must list all addresses where it - and not a separately enrolled provider or supplier it owns or operates, such as a nursing home - furnishes services. The hospital's primary practice location should be the first location identified in Section 4A and the contractor shall treat it as such – unless there is evidence indicating otherwise. NOTE: Hospital departments located at the same address as the main facility need not be listed as practice locations on the Form CMS-855A.

If an enrolled hospital seeks to add or delete a rehabilitation, psychiatric, or swing-bed unit, it should submit a Form CMS-855 change of information request and not, respectively, an initial enrollment application or a voluntary termination application.

E. Non-Participating Emergency Hospitals, Veterans Administration (VA) Hospitals, and Department of Defense (DOD) Hospitals

Non-participating emergency hospitals, VA hospitals and DOD hospitals no longer need to complete a Form CMS-855A enrollment application in order to bill Medicare.

F. Form CMS-855B Applications Submitted by Hospitals

1. Group Practices

If an entity is enrolling via the Form CMS-855B as a hospital-owned clinic/physician practice, the contractor shall contact the applicant to determine whether the latter will be billing any of the listed locations as provider-based. If the applicant will not be billing as provider-based, the contractor shall process the application normally. If, however, the applicant will bill as provider-based, the contractor shall notify the applicant that the hospital must report any changed practice locations to its contractor via the Form CMS-855A.

If the supplier is enrolling as a hospital department (under the "Clinic/Group Practice" category on the Form CMS-855B) or an existing hospital department is undergoing a change of ownership (CHOW), the contractor shall only issue the necessary billing numbers upon notification that a provider agreement has been issued – or, in the case of a CHOW, the provider agreement has been transferred to the new owner. If, however, the supplier is enrolling as a group practice that is merely owned by a hospital (as opposed to being a hospital department), the contractor need not wait until the provider agreement is issued before conveying billing privileges to the group.

2. Individual Billings

Assume an individual physician works for a hospital and will bill for services as an individual (i.e., not as part of the hospital service/payment). However, he/she wants to reassign these benefits to the hospital. The hospital will need to enroll with the contractor via the Form CMS-855B (e.g., as a hospital department, outpatient location).

10.2.2.2 – Home Infusion Therapy Suppliers

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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. *(See section 10.3 of this chapter for certain PECOS application submission policies with respect to enrolling in multiple states within one contractor jurisdiction.)*

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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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. *(This includes applications submitted via PECOS.)* 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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" – Background

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

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

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

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

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

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

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

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

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

iii. Synopsis

In sum:

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

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

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

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

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

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

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

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

B. IDTF Standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

application or, if the supplier is already enrolled in Medicare, the revocation of its Medicare billing privileges.

C. Leasing and Staffing

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

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

D. Sharing of Space and Equipment

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

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

E. Multi-State IDTFs

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

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

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

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

F. One Enrollment per Practice Location

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

IDTF site also contains a mobile unit, the mobile unit must therefore enroll separately from the fixed location.

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

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

G. Interpreting Physicians

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

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

The contractor shall ensure and document that:

- All listed physicians are enrolled in Medicare

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

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

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

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

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

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

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

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

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

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

J. IDTF Technician Licensure and Certification Requirements

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

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

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

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

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

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

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

M. IDTF - Information about Supervising Physicians

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

In addition:

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

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

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

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

P. IDTF - Changes of Supervising Physicians

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

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

Q. Desk and Site Reviews

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

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

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

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

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

R. Mobile Units

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

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

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

- What their responsibilities are; and

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

S. Addition of Codes

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

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

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

physician, non-physician personnel, equipment); and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

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

T. IDTF That Performs Diagnostic Mammography

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

U. IDTF Ownership of CLIA Laboratory

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

10.2.2.10 – Suppliers of Ambulance Services

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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), *10.3,* 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.

10.2.4 - Other Medicare Part B Services

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Residents and Interns

1. General Background Information

If the applicant is a "resident" in an "approved medical residency program" (as these two terms are defined at 42 CFR § 413.75(b)), the contractor shall refer to Pub. 100-02, chapter 15, section 30.3 for further instructions. (The contractor can also refer to 42 CFR § 415.200, which states that services furnished by residents in approved programs are not "physician services.")

The physician should indicate the exact date on which its residency program, internship, or fellowship was completed, so that the appropriate effective date can be issued.

2. Interns are Ineligible to Enroll in the Medicare Program

An intern cannot enroll in the Medicare program. (For purposes of this requirement, the term "intern" means an individual who is not licensed by the state because he/she is still in post-graduate year (PGY) 1.)

B. Diabetes Self-Management Training

Diabetes self-management training (DSMT) is not a separately recognized provider type, such as a physician or nurse practitioner. A person or entity cannot enroll in Medicare for the sole purpose of performing DSMT. Rather, DSMT is an extra service that an enrolled provider or supplier can bill for, assuming it meets all of the necessary DSMT requirements. If the person or entity enrolls as a provider type (i.e., pharmacy, mass immunizer) that requires the submission of an application fee, the fee shall be submitted with the application.

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. CMS recognizes the American Diabetes Association (ADA) and the Association of Diabetes Care & Education Specialists (ADCES) (formerly known as the American Association of Diabetes Educators or AADE) as approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the appropriate accreditation certificate to its contractor. No Form CMS-855 is required unless the provider or supplier is not in the

Provider Enrollment, Chain and Ownership System (PECOS), in which case a complete Form CMS-855 application must be submitted.

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local Part A/B MAC. This is because A/B MACs, rather than Durable Medical Equipment Medicare Administrative Contractors, pay DSMT claims. Thus, the DMEPOS supplier must separately enroll with its A/B MAC even if it has already completed a Form CMS-855S. If an A/B MAC receives an application from a DMEPOS supplier that would like to bill for DMST, it shall verify with the *applicable NPE contractor* that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- 42 CFR Part 410 (subpart H)

- Publication 100-02, Medicare Benefit Policy Manual, chapter 15, sections 300 – 300.5.1

C. Mass Immunizers Who Roster Bill

An entity or individual who wishes to furnish mass immunization services - but may not otherwise qualify as a Medicare provider - may be eligible to enroll as a "Mass Immunizer" via the Form CMS-855I (individuals) or the Form CMS-855B (entities). Such suppliers must meet the following requirements:

1. They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.

2. They must submit claims through the roster billing process.

3. The supplier, as well as all personnel who administer the shots, must meet all applicable state and local licensure or certification requirements.

The roster billing process was developed to enable Medicare beneficiaries to participate in mass PPV and influenza virus vaccination programs offered by public health clinics and other organizations.

In addition:

- See 42 CFR §§ 424.520(d) and 424.521(a) for information regarding mass immunizer effective dates.

- In Section 4 of the Form CMS-855, the supplier need not list each off-site location (e.g., county fair, shopping mall) at which it furnishes services. It need only list its base of operations (e.g., county health department headquarters, drug store location).

For more information on mass immunization roster billing, refer to:

- Publication 100-02, Benefit Policy Manual, chapter 15, section 50.4.4.2

- Publication 100-04, Claims Processing Manual, chapter 18, sections 10 through 10.3.2.3

D. Advanced Diagnostic Imaging

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1834(e) of the Social Security Act. It required the Secretary to

designate organizations to accredit suppliers – including, but not limited to, physicians, non-physician practitioners, and independent diagnostic testing facilities - that furnish the technical component (TC) of advanced diagnostic imaging services. MIPPA specifically defin*ed* advanced diagnostic imaging procedures as including diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging, such as positron emission tomography (PET). The law also authorizes the Secretary to specify other diagnostic imaging services in consultation with physician specialty organizations and other stakeholders.

The CMS has approved four national accreditation organizations (AOs) – the American College of Radiology, the Inter-societal Accreditation Commission, the Joint Commission, and Rad Site - to provide accreditation services for suppliers of the TC of advanced diagnostic imaging procedures. The accreditation applies only to: (1) the suppliers of the images, not to the physician's interpretation of the image; and (2) those who are paid under the Physician Fee Schedule. All AOs have quality standards that address the safety of the equipment as well as the safety of the patients and staff. Each of these designated AOs submits monthly reports to CMS that list the suppliers who have been or are accredited, as well as the beginning and end-dates of the accreditation and the respective modalities for which they receive accreditation.

Newly enrolling physicians and non-physician practitioners described above do not need to complete the appropriate boxes for Advanced Diagnostic Imaging (ADI) on Internet-based PECOS or the appropriate Form CMS-855. Information for all ADI accredited suppliers is provided to CMS by the approved ADI AOs. The contractor need not verify ADI information submitted on the application.

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

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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. *When processing Form CMS-20134 applications submitted via PECOS, the contractor shall also follow the applicable PECOS instructions in section 10.3 of this chapter. In the event a policy or operational practice in section 10.3.2 et seq. is contrary to that in section 10.3 (e.g., communication mechanisms, validation, documentation submission), the latter takes precedence.*

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

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Reason for Submittal

In this section, the supplier indicates the reason for submittal of the application. Unless otherwise stated in this chapter*, in* another CMS directive, *or as permitted by PECOS*, the supplier may only check one reason for submittal. For example, suppose a supplier is changing its tax identification number (TIN). The supplier must submit two applications: (1) an initial Form CMS-20134 as a new supplier; and (2) a Form CMS-

20134 voluntary termination. Both transactions cannot be reported on the same application.

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, *the PCV*, fax).

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

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

- MDPP preliminary recognition or
- DPRP full recognition

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

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

- Verify that a letter has been submitted for each organizational code provided in Sections 2 and 4 of the Form CMS-20134
- Verify that (1) any letters provided have appropriate letterhead from CDC and (2) each reflects that the organization has met either preliminary or full recognition with an expiration date that has not passed
- Verify that the organization code or codes provided in Sections 2 and 4 of the Form CMS-20134 matches both the organization code on the letter(s) and the organization code on CDC's online registry, which is updated just-in-time and can be found at https://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 *(or electronically saving in PECOS)* confirming

pages from the Centers for Disease Control and Prevention Web site; (2) requesting and receiving from the CDC written confirmation of the supplier's status therewith; or (3) utilizing another third-party verification source. Similarly, if the supplier submits a copy of the applicable recognition but fails to complete the applicable section of the form, the section need not be completed if the data in question can be verified on the recognition itself or via any of the three mechanisms described above in this paragraph. The contractor shall not develop for a correction to the form if the recognition information can be verified as described above.

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

10.3.2.2 – CMS-20134 (Section 2 - Identifying Information)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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 *using the procedures outlined in this chapter (e.g., the PCV for PECOS applications).* The contractor shall accept a particular phone number if it has no reason to suspect that it does not belong to or is not somehow associated with the 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, *the PCV*, 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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Refer to section 10.6.6 of this chapter for information regarding final adverse actions. *Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.6 (e.g., communicating with the provider via the PCV).*

10.3.2.4 – CMS-20134 (Section 4 - MDPP Location Information)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Background

The MDPP location address must be a valid address with the United States Postal Service (USPS). Addresses entered into 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.

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 *applicable* contact person listed on the application and note the verification accordingly in *PECOS.* (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 provider 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; 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 '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.

- 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, *the PCV,* 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 *PECOS.*

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, *the PCV,* 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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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.

Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.7 et seq. (e.g., communicating with the provider via the PCV).

10.3.2.8 – CMS-20134 (Section 8 – Billing Agency Information)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Billing Agency Information section of the Form CMS-20134, refer to section 10.6.8 of this chapter. *Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.8.)*

Note that if the telephone number in Section 8 is blank, the number can be verified with the supplier by telephone, *the PCV*, 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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Regarding the Contact Person section of the Form CMS-20134, see sections 10.3 and 10.6.9 of this chapter. Except as otherwise stated, the PECOS policies in section 10.3 supersede those in section 10.6.9.)

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, *the PCV,* 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 telephone, email, *the PCV,* fax, or mail from the individual supplier, the authorized or delegated official, or a current contact person on file. The contractor shall document 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.)

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

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

*(*Unless indicated otherwise below or in another CMS directive, the instructions in this section apply to (1) signatures on the paper Form CMS-20134, *and (2) signatures for PECOS applications.)*

For paper applications, handwritten (wet) signatures in ink and digital/electronic signatures (digital or electronic signatures such as those created by digital signature options in software, such as Adobe) *are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application*. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

A. 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 *the PCV,* 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 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 *et al.* 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 *person's* signature *or identity.*

B. PECOS Submissions

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

(i) The contractor shall (a) begin processing the application upon receipt via PECOS; (b) perform all required manual validations; and (c) develop for any needed clarifying or missing information or documentation consistent with section 10.3 and all other applicable instructions in this chapter.

(ii) If the supplier submits an invalid certification statement, the contractor shall treat this as missing information and develop for a correct certification statement – preferably via the PCV, email, or fax. (This includes certification statements that are signed by a person unauthorized to do so under 42 CFR Part 424, subpart P.) The contractor shall send one development request that includes a list of all of the data/documentation to be furnished or clarified, including, as applicable, a correct certification statement. The contractor may reject the supplier's application if the supplier fails to furnish said data/documentation within 30 calendar days from the date of the contractor's request.

(iii) For PECOS applications that require development, at least one of the supplier's authorized or delegated officials has to sign any certification statement that must accompany the supplier's response. Obtaining the signatures of the other authorized and delegated officials is not required.

(iv) For PECOS changes of information (as the term "changes of information" is defined in section 10.4.4 of this chapter), if the certification statement is signed by an individual who is not on file with the contractor as an authorized or delegated official of the supplier, the contractor may accept the certification statement. However, it shall develop for information on the person in question consistent with the procedures in this chapter.

(v) The contractor is not required to compare the signature thereon with the same supplier's, authorized official's, or delegated official's signature on file to ensure that it is the same person.

(vi) The contractor shall not request the submission of a driver's license or passport to verify a person's signature or identity.

C. Certification Statement Development

If*, as already mentioned,* the supplier submits an invalid certification statement *(as described in subsections (A) and (B)),* the contractor shall develop for a correct certification statement and send a development letter to the supplier. *The provider must submit the requested certification statement as follows:*

(i) Paper applications -- Via scanned email, fax, or mail. Only the actual signature page is required; the provider need not submit the additional page containing the certification terms. (This also applies to the provider's initial submission of a certification statement. Such instances require the submission of only the signature page and not the certification terms.)

(ii) PECOS applications – Via electronic or uploaded signature.

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; and (2) electronic *or uploaded* signatures *for PECOS applications*.)

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.

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

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(In addition to the instructions in this section 10.3.2.13, refer to: *(1)* the Supporting Documents section of the Form CMS-20134 for information concerning supporting documents; *and (2) section 10.3 of this chapter for instructions regarding the submission of documentation with PECOS applications.)*

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. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The processing alternatives in section 10.3.2.14 are in addition to, and not in lieu of, any other processing alternatives described in this chapter or another CMS directive. These processing alternatives also apply notwithstanding any instruction in this chapter to the contrary. As stated in section 10.3, however, some of the application data elements and verification procedures that have previously been subject to a processing exception/alternative may no longer be so or are moot under PECOS 2.0. (See section 10.3 for a discussion of such data and procedures.) In such situations, the contractor shall disregard the exception/alternative and follow the instructions in section 10.3.

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. *Also, p*er section 10.6.19(H) of this chapter, the contractor shall document in *PECOS* 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.)

10.3.3.1 – Form CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

An EFT agreement (Form CMS-588) authorizes CMS to deposit Medicare payments directly into a provider/supplier's bank account.

A. Processing the Form CMS-588 – Specific Situations

When a Form CMS-588 is received, the contractor shall review the form and develop for any deficiencies or missing information *prior* to approval. *All EFT data shall be entered into PECOS.*

1. Unsolicited Information

If the provider/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 form review.

2. Missing or Incorrect Provider Transaction Access Number (PTAN) or CMS Certification Number (CCN) on the Form CMS-588

If the PTAN and/or CCN is missing or incorrect but the contractor can ascertain the correct number (1) via the supporting documents submitted, (2) elsewhere on the form, or (3) via PECOS, the shared systems, or the provider files, the contractor need not pursue development. (Note that social security numbers and employer identification numbers do not fall within this exception.)

3. Missing or Incorrect Social Security Number (SSN) or Employer Identification Number (EIN) Checkbox on the Form CMS-588

If the Form CMS-588 is received and the checkbox for the SSN or EIN is either not checked or is incorrectly checked, the contractor may proceed without further development if the contractor can ascertain the correct option via the supporting documents submitted or elsewhere on the form.

4. Name on Account

As stated on the Form CMS-588, the account to which EFT payments are made must exclusively bear the name of the physician or individual practitioner, or the legal business name (LBN) of the person or entity enrolled with Medicare. Accordingly, the contractor shall accept accounts that (1) solely list the LBN or (2) list the LBN and the Doing Business As name (so long as the LBN is listed first).

B. Form CMS-588 Information Specific to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

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

C. Form CMS-588 Signature Requirements

For paper applications, 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) are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

D. Verification

Providers and suppliers may submit a Form CMS-588 via paper or through PECOS. In either case, the contractor shall ensure that:

(i) All EFT arrangements comply with CMS Pub. 100-04, chapter 1, section 30.2.5.

(ii) The information submitted on the Form CMS-588 is complete and accurate. (Except as otherwise stated in this chapter or another CMS directive, the contractor shall develop for any missing information.)

(iii) The provider/supplier submitted (1) a voided check or (2) a letter from the bank verifying the account information.

(iv) The routing number and account number matches what was provided on the Form CMS-588.

(v) The signature is valid.

(vi) The contractor shall forgo development if the "Part I: Reason for Submission (Individual vs. Group)" section is left blank or an incorrect option is selected but the contractor can make the correct determination based on the provider/supplier's existing file or additional information submitted with the application.

Once it has been processed, the Form CMS-588 will be printed and delivered (along with the voided check and bank letter verifying the account information) to the contractor's financial area for proper processing of the EFT data. If this information cannot be verified and the provider/supplier fails to timely respond to a developmental request, the contractor shall reject the Form CMS-588 and, if applicable, the accompanying Form CMS-855 or Form CMS-20134.

E. Miscellaneous EFT Policies

1. Banking Institutions

All payments must be made to a banking institution. EFT payments to non-banking institutions (e.g., brokerage houses, mutual fund families) are not permitted.

If the provider/supplier's bank of choice does not or will not participate in the provider/supplier's proposed EFT arrangement, the provider/supplier must select another financial institution.

2. Sent to the Wrong Unit

If a provider/supplier submits an EFT change request to the contractor but not to the latter's enrollment unit, the recipient unit shall forward it to the enrollment staff, which shall then process the change. The enrollment unit is responsible for processing EFT changes. As such, while it may send the original EFT form back to the recipient unit, the enrollment unit shall keep a copy of the EFT form and append it to the provider/supplier's Form CMS-855 in the file.

3. Bankruptcies and Garnishments

If the contractor receives a copy of a court order to send payments to a party other than the provider/supplier, it shall contact the applicable SOG Location's Office of General Counsel.

4. Closure of Bank Account

If a provider/supplier has closed its bank/EFT account but will remain enrolled in Medicare, the contractor shall place the provider/supplier on payment withhold until a Form CMS-588 (and Form CMS-855, if applicable) is submitted and approved by the contractor. If such an agreement is not submitted within 90 days after the contractor learned that the account was closed, the contractor shall commence deactivation procedures in accordance with the instructions in this chapter. The basis for deactivation would be § 424.540(a)(2) due to the provider/supplier's failure to submit updated EFT information within 90 days of the change.

5. Reassignments

If a physician or non-physician practitioner is reassigning all of his/her benefits to another supplier and the latter is not currently on EFT, neither the practitioner nor the reassignee needs to submit a Form CMS-588. This is because (1) the practitioner is not receiving payment directly, and (2) accepting a reassignment does not qualify as a change of

information request. If, however, the group later submits a change of information request and is not on EFT, it must submit a Form CMS-588.

6. Final Payments

If a non-certified supplier (e.g., physician; ambulance supplier) voluntarily withdraws from Medicare and needs to obtain its final payments, the contractor shall send such payments to the supplier's EFT account of record. If the account is defunct, the contractor can send payments to the supplier's "special payments" address or, if none is on file, to any of the supplier's practice locations on record. If neither the EFT account nor the aforementioned addresses are available, the supplier shall submit a Form CMS-855 or Form CMS-588 request identifying where it wants payments to be sent.

7. Chain Organizations

Per CMS Pub. 100-04, chapter 1, section 30.2, a chain organization may have payments to its providers be sent to the chain home office. However, *and except as otherwise permitted for PECOS applications under PECOS 2.0,* any mass EFT changes (involving large numbers of chain providers) must be submitted and processed in the same fashion as any other change in EFT data. For instance, if a chain has 100 providers and each wants to change its EFT account to that of the chain home office, 100 separate Form CMS-588s must be submitted *(again, unless PECOS 2.0 permits a consolidated submission for PECOS applications).* If any of the chain providers have never completed a Form CMS-855 before, they must do so at that time.

8. Consolidation of EFT Accounts

The contractor shall follow the instructions in section 10.6.23 of this chapter regarding the consolidation of a provider's or supplier's EFT accounts. These instructions take precedence over any contrary guidance in this chapter.

10.3.3.2 – Form CMS-460 – Medicare Participating Physician or Supplier Agreement

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This agreement establishes that the Medicare provider/supplier accepts assignment of the Medicare Part B payment for all services (1) for which the participant is eligible to accept assignment under the Medicare law and regulations and (2) which are furnished while the agreement is in effect. (This only applies to suppliers that complete the Forms CMS-855B, CMS-855S, and CMS-855I.) The contractor shall follow the instructions in CMS Pub. 100-04, chapter 1, sections 30 through 30.3.12.3 when handling issues related to par agreements and assignment. Queries concerning the interpretation of such instructions shall be referred to the responsible CMS component.

Individual physicians and non-physician practitioners who only reassign benefits to a clinic/group practice inherit the par status established by the clinic/group practice; accordingly, these physicians and non-physician practitioners need not submit the Form CMS-460. However, if the individual physician/practitioner maintains a private practice separate from the reassignment, he/she may designate his/her own par status. See the instructions in CMS Pub. 100-04, chapter 1, section 30 for applying the correct par status to clinic/group practices, organizations and individuals in private practice.

A. PECOS Information

All suppliers must choose to be either par or non-par when enrolling and must maintain the same par status across all lines of business. The contractor shall search PECOS to determine if an enrollment already exists with the enrolling provider/supplier's legal business information (i.e.: legal business name, federal tax identification number).

No par status change shall be made by the contractor without confirmation from the provider/supplier first. In the event that a provider/supplier submits a par agreement and they are currently enrolled as non-par, the contractor must confirm with the provider/supplier that the change in the par status is valid for all lines of business. Likewise, if a provider/supplier does not submit a par agreement, and they are enrolled as par or non-par, the contractor shall confirm that the provider/supplier is not changing their current par status across all lines of business.

B. Valid signatures

For paper applications, 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) are acceptable. For web applications, the supplier can sign it electronically or upload the signature and then submit the application. The contractor shall contact its PEOG BFL for questions regarding electronic signatures.

10.4.1 – General Processing Functions

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This section 10.4.1 et seq. outlines the general methods that contractors shall follow when processing enrollment applications. (More specific processing activities can be found elsewhere in this chapter (e.g., sections 10.3.1 et seq., 10.6.6, etc.)). Should an inconsistency or gap exist between the general procedures outlined in section 10.4.1 et seq. and those of greater specificity in other sections of this chapter, the latter shall take precedence unless otherwise noted*; this includes the instructions in section 10.3 concerning PECOS applications.*

The CMS stresses that nothing in this section 10.4.1 et seq. (except as stated to the contrary) supplants more detailed instructions in this chapter (or another CMS directive) pertaining to, for instance: (1) processing alternatives; (2) referrals to the state agency; (3) processing policies specific to certain CMS applications (e.g., CMS-855, CMS-20134) and certain sections thereof.

All references to "provider" include "supplier" unless stated otherwise.

10.4.1.1 – Overview of the Process

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Typical Steps

In general, the application review and verification process is as follows:

1. Contractor receives application

2. Contractor reviews application and verifies data thereon. *(For PECOS applications, some of this data will have been verified when the provider enters its enrollment information into PECOS.)*

3. If (i) required data/documentation is missing, (ii) data cannot be verified, and/or (iii) there are data discrepancies, contractor requests missing/clarifying information from the provider.

4. If applicable, contractor (i) verifies any newly furnished data or (ii) seeks additional data/clarification from provider

5. Certain situations may require referral to the state agency (the state) and, after receiving information from the state, referral to CMS PEOG before a final determination is rendered.

6. Final determination

Section 10.4.1 et seq. is structured so as to generally follow the preceding six steps.

B. Non-Form CMS-855 and CMS- 20134 Documentation

There are situations where the contractor processes non-Form CMS-855 and CMS- 20134 forms and other documentation relating to provider enrollment. Such activities include*, but are not limited to:*

- EFT agreements (Form CMS-588) submitted alone
- "Do Not Forward" issues
- Par agreements (Form CMS-460)
- Returned remittance notices
- Informational letters received from other contractors
- Diabetes self-management notices
- Verification of new billing services
- Paramedic intercept contracts
- 1099 issues that need to be resolved
- Opt-out affidavits
- *Surety bond updates and cancellations*

The contractor *shall:*

(i) Follow the instructions in section 10.3 regarding the uploading into PECOS of documentation received outside of an application submission; and

(ii) Note in PECOS the date of the document submission with a description of the document. (The specific language lies within the contractor's discretion.)

10.4.1.2 – Receipt of Application

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Acknowledgment of Receipt of Application

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

B. Pre-Screening of Application

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

C. Reassignment Packages

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

In situations where an entity wants to simultaneously (i) enroll a group practice, (ii) enroll the individual practitioners therein, and (iii) reassign benefits accordingly, the instructions below apply. As early in the process as possible, the contractor shall examine the incoming forms to see if a reassignment may be involved; also, the contractor is encouraged (though not required) to have the same analyst handle all three applications in the package.

Only the Form CMS-855Rs are submitted - If a brand-new group with new practitioners is attempting to enroll but submits only the Form CMS-855Rs for its group members (i.e., neither the initial Form CMS-855B nor the initial Form CMS-855Is were submitted), the contractor shall develop for the other forms upon receipt and processing.

Only the Form CMS-855R is submitted and a Form CMS-855A or CMS-855B and Form CMS-855I is already on file – Suppose an individual: (1) submits only the Form CMS-855R without including the Form CMS-855A or Form CMS-855B and Form CMS-855I; and (2) indicates on the Form CMS-855R that he/she will be reassigning all or part of his/her benefits to the CAH II. The contractor shall not develop for the other forms if they are already on file. The contractor shall simply process the Form CMS-855R and reassign it to the Form CMS-855A.

Only the Form CMS-855B is submitted - If a brand-new group wants to enroll but submits only the Form CMS-855B without including the Form CMS-855Is and Form CMS-855Rs for its group members (i.e., the Form CMS-855B arrives alone without the other forms), the contractor shall develop for the other forms if they are not submitted upon receipt and processing of the Form CMS-855B.

Only the Form CMS-855I is submitted – Suppose an individual: (1) submits only the Form CMS-855I without including the Form CMS-855B and Form CMS-855R; and (2) indicates on the Form CMS-855I that he/she will be reassigning all or part of his/her benefits to the group practice. The contractor shall develop for the other forms if they are not submitted upon receipt and processing of the Form CMS-855I.

Only the Form CMS-855I is submitted in CAH situation - Suppose an individual: (1) submits only the Form CMS-855I; and (2) indicates on the Form CMS-855I that he/she will be reassigning all or part of his/her benefits to an existing Part A CAH II. The contractor shall develop for the Form CMS-855R if it is not submitted upon receipt and processing of the Form CMS-855I. Upon receipt of the Form CMS-855R, the contractor shall process the application and reassign the individual to the Part A entity.

Form CMS-855A and Form CMS-855B never submitted - Suppose an individual is joining a group that was enrolled prior to the Form CMS-855A or Form CMS-855B (i.e., the group or CAH II never completed a Form CMS-855). The contractor shall develop for a Form CMS-855A from the CAH II or Form CMS-855B from the group. Once the group or CAH II's or

group's application is received and processed, the contractor shall process the new reassignment.

10.4.1.3.1 – Initial Steps of Review of Application

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Opening Review – Basic Activities

Except as stated otherwise in this chapter (see sections *10.3, 10.3.1 et seq., and* 10.4.1 for more details) or when a processing alternative applies, the contractor shall undertake the following:

1. Confirmation of Completion - Ensure that the provider has completed all required data elements on the Form CMS-855, Form CMS-20134, or opt-out affidavit (including all effective dates) and that all supporting documentation has been furnished. The contractor shall also ensure that the provider has completed the application in accordance with the instructions (1) in this chapter and in all other CMS directives and (2) on the Form CMS-855 or Form CMS-20134. (The instructions on the Form CMS-855 or Form CMS-20134 shall be read and applied in addition to, and not in lieu of, the instructions in this chapter and all other applicable CMS directives.)

2. Verification - Verify and validate all information the provider furnished on the Form CMS-855, Form CMS-20134, or opt-out affidavit (assuming a data source is available*). (For PECOS applications, note that PECOS will automatically verify certain information. See section 10.3 of this chapter for more information.)*

3. State Agency - Coordinate with the state and/or SOG Location as needed.

4. Exclusion/Debarment – *Follow the instructions in section 10.6.6 of this chapter with respect to reviewing the MED and SAM.*

B. Paper Applications

1. General Background Information

The contractor shall begin processing the application upon receipt and shall develop for missing certification statements and all other missing information (including the application fee) upon review. This includes but is not limited to:

- Ensuring that all required data elements on the application have been completed and that all required supporting documentation has been submitted

- Ensuring that the provider submitted a valid and dated certification statement signed by an appropriate individual (e.g., the enrolling physician for Form CMS-855I applications)

- Validating all data on and submitted with the application (assuming that a data source is available)

- *As applicable, and consistent with section 10.3 of this chapter, e*ntering into PECOS all information contained on the application.

*Except as otherwise prescribed in section 10.3 of this chapter, t*he contractor may begin the verification process at any time.

2. Photocopying Pages

The contractor may accept photocopied pages in any Form CMS-855 or Form CMS-20134 it receives so long as the application contains a valid signature. For example, suppose a corporation wants to enroll five medical clinics it owns. The Section 5 data on the Form CMS-855B is exactly the same for all five clinics. The contractor may accept photocopied Section 5 pages for these providers. However, valid signatures must be furnished in Section 15 of each application.

3. White-Out & Highlighting

The contractor shall not write on or highlight any part of the original Form CMS-855 or Form CMS-20134 application or any supplementary pages the applicant submits (e.g., copy of license). Provider usage of white-out is acceptable, although the contractor should contact the applicant to resolve any ambiguities. In addition, the contractor must determine whether the amount of white-out used on a particular application is within reason. For instance, if an entire application page is whited-out, the contractor should request that the page be resubmitted.

C. PECOS Applications

The contractor shall begin processing the application upon receipt and shall develop for *additional/clarifying/*missing *data consistent with the instructions in section 10.3 and other pertinent sections of this chapter.*

10.4.1.3.2 – Data Verification

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Means of Verification

*Except as s*tated otherwise in this chapter or in another CMS directive, the contractor shall verify and validate – via the most cost-effective methods available, *including via PECOS (as described and directed in section 10.3)* - all information furnished by the provider on or with its application, assuming a data source is available. The general purpose of the verification process is to ensure that all of the data furnished on the Form CMS-855 or Form CMS-20134 is accurate.

Examples of verification techniques include, but are not limited to: (i) site visits; (ii) third-party data validation sources; (iii) state professional licensure and certification websites (e.g., medical board sites); (iv) federal licensure and certification websites (if applicable); (v) state business web sites (e.g., to validate "doing business as" name); and (vi) Yellow Pages (e.g., to verify certain phone numbers).

The list of verification techniques identified in this section 10.4.1.3.2 is not exhaustive. *Except as prescribed otherwise in section 10.3,* if the contractor is aware of another means of validation that is as cost-effective and accurate as those listed, it may use it. However, all SSNs and NPIs listed on the application shall be verified through PECOS. The contractor shall not request an SSN card or driver's license to verify an individual's identity or SSN.

B. Overall Verification Principles

Unless stated otherwise in this chapter or in another CMS directive, the following apply:

1. A data element is considered "verified" when, after attempting at least one means of validation, the contractor is confident that the data is accurate. (The contractor shall use its best judgment when making this assessment.)

2. The contractor need only make one verification attempt (i.e., need only use one validation technique) before either: (i) concluding that the furnished data is accurate; or (ii) requesting clarifying information if the data element cannot be verified (though the contractor is encouraged to make a second attempt using a different validation means prior to requesting clarification).

C. Concurrent Reviews

(For PECOS application submissions, note that PECOS's automatic verifications of applications from related entities shall take precedence – e.g., in terms of length of time between application submissions, depth of the relationship between the associated parties – over the instructions in this section 10.4.1.3.2(C).)

If the contractor receives multiple Form CMS-855 or Form CMS-20134s for related entities, it can perform concurrent reviews of similar data. For instance, suppose a chain home office submits initial Form CMS-855As for four of its chain providers. The ownership information (Sections 5 and 6) and chain home office data (Section 7) is the same for all four providers. The contractor need only verify the ownership and home office data once; it need not do so four times – once for each provider. However, the contractor shall document in each provider's *PECOS record* that a single verification check was made for all four applications.

For purposes of this requirement: (1) there must be an organizational, employment, or other business relationship between the entities; and (2) the applications must have been submitted within a few weeks of each other. As an illustration, assume that Group Practice A submits an initial Form CMS-855B on January 1. Group Practice B submits one on October 1. Section 6 indicates that Joe Smith is a co-owner of both practices, though both entities have many other owners that are not similar. In this case, the contractor must verify Mr. Smith's data in both January and October. It cannot use the January verification and apply it to Group B's application because: (1) the applications were submitted nine months apart; and (2) there is no evidence that the entities are related.

D. Contacting another Contractor

During the verification process, the contractor may need to contact another Medicare contractor for information regarding the provider. The latter contractor shall respond to the former contractor's request within three business days absent extenuating circumstances.

E. Proof of Life Documentation

When an enrollment record is updated to reflect an erroneous date or report of death, the contractor shall request documentation that supports "proof of life" (e.g., Retirement, Survivors, and Disability Insurance document issued by SSA). If the provider cannot obtain such documentation, the contractor shall submit a request to its PEOG BFL containing the provider's name, date of birth, and SSN so that CMS can confirm proof of life with SSA.

10.4.1.3.3 – Requesting Missing/Clarifying Data/Documentation (Development)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

This section 10.4.1.3.3 addresses the contractor's solicitation of missing/clarifying information/documentation and/or a valid certification statement. The policies herein apply except as otherwise stated in this chapter *(e.g., section 10.3)* or another CMS directive.

A. Only One Request Needed

The contractor need only make one request. Of course, the contractor should respond to any of the provider's telephone calls, e-mails, etc., resulting from the request. Yet the contractor need not – on its own volition – make an additional request unless the contractor uncovers missing data (or data that must be clarified) that it failed to detect prior to sending the original development letter.

To the extent possible, the contractor should avoid contacting the provider for missing/clarifying data/documentation until it has attempted to validate all of the data on the application. This will obviate the need to contact the provider each time the contractor discovers an issue.

B. Commencement of Timeframe

The provider has 30 calendar days to furnish the information or documentation the contractor requested. This 30-day clock commences on the day on which the contractor sends the development request *(e.g., via the PCV)*.

C. Telephonic Requests

Unless otherwise stated in this chapter or in another CMS directive, telephonic requests for missing/clarifying data/documentation are generally not permitted for paper or PECOS applications; it is important that requests for information or clarification be formalized in writing. However, in cases where CMS permits telephonic requests for such data, the contractor shall adhere to the following:

1. A telephonic request is made when the contractor: (1) speaks with an appropriate provider official, or (2) leaves a message either with an appropriate official's staff (e.g., his/her executive assistant) or with an appropriate official's voice mail service. In situation (2), the contractor shall leave the name and telephone number of an appropriate individual at the contractor site who the official can contact; otherwise, the contact does not qualify as a legitimate request for clarification.

2. When leaving a message, the contractor shall also state that the requested data/clarification must be furnished within 30 days.

3. Telephone requests shall be made on weekdays between 9 am and 5 pm of the provider's time zone.

4. The 30-day clock begins on the day (1) of the telephone conversation with the appropriate official, or (2) the message is left.

5. All telephone activity that falls within this subsection (C) shall be documented in PECOS consistent with the instructions in section 10.6.19(H) of this chapter.

D. Inability to Contact Provider

If the contractor cannot, for the reasons listed in (i) through (iii) below, communicate with the provider to request information/documentation, it shall attempt one alternative means of communication:

(i) The mailed letter is returned because the provider is not at that address;

(ii) The contractor cannot e-mail *(e.g., via the PCV)* the letter to the provider because of issues with the recipient's e-mail system; or

(iii) The provider's fax number is repeatedly busy

If an alternative communication, too, cannot be completed for one of the above reasons, the contractor need not make another attempt to obtain the data and may reject the application once the applicable 30-day period expires. However, it is strongly advised that the contractor make a third attempt to contact the provider prior to taking this step, especially if it appears the provider is acting in good faith. (The contractor shall document *in PECOS* each attempt to contact the provider.)

(With respect to e-mail *(including via the PCV)*, an alternative communication includes sending an e-mail to another listed contact person, delegated official, or authorized official.)

E. Development Reasons and Elements of Letter

1. Paper Applications

a. Reasons to Develop

Development is necessary if the provider or supplier: (i) submits an application with at least one missing required data element; (ii) fails to submit at least one required document; (iii) submits an invalid certification statement; (iv) writes "N/A" (or a variation thereof) in response to a question that requires a "yes" or "no" answer; or (v) submits the full application via fax or e-mail unless the contractor has provided for an exception based on extenuating circumstances *or the submission via this means is otherwise authorized by CMS*. (If the contractor instructs the provider to submit the application via fax or e-mail, the contractor shall inform its PEOG BFL.)

Development is also required if the contractor determines that clarification is needed regarding certain information (e.g., particular data cannot be verified or there are data inconsistencies).

b. Elements of a Development Letter

If any of the development reasons in section 10.4.1.3.3(E)(1)(a) above apply, the contractor shall send a development letter to the provider – preferably via *the PCV*, e-mail or fax - that contains, at a minimum, the applicable elements in (i) through (vi) below. (See section 10.7 et seq. of this chapter for these model letters.)

i. A list of all of the missing required data/documentation, an explanation of the certification statement's deficiencies, and/or the issues/information to be clarified.

ii. A request that the provider submit the missing data/documentation, clarification, and/or revised certification statement within 30 calendar days.

iii. Unless the only data that is missing is documentation, a request that the provider submit an appropriately signed and dated certification statement. (This certification statement will cover both the submission of any missing data as well as any deficiencies associated with the original certification statement.) The provider may submit the certification statement via scanned e-mail, fax or mail.

(A new certification statement is not required if the only missing material is documentation or if the requested clarification does not require any changes to the provider's Form CMS-855 or CMS-20134 application.)

iv. If missing data is involved, the contractor shall direct the provider to the CMS Web site at which the CMS-855 or CMS-20134 forms can be found.

v. A fax number and mailing address to which the missing/clarifying data/documentation/correct certification statement can be sent to the contractor. An e-mail address may be included if applicable.

vi. The name and phone number of a contact person at the contractor site. An e-mail address may be included if applicable.

2. PECOS Applications

a. Reasons to Develop

Development is necessary if the provider or supplier: (i) submits an application with at least one required data element *that needs clarification; or* (ii) fails to submit at least one required document.

b. Elements of a Development Request

When developing for more information, the contractor shall send a request to the provider *via the PCV* containing:

(i) A list of all missing documentation *or* information to be clarified;

(ii) A request that the provider submit the data/materials in question within 30 calendar days; and

(iii) The name and phone number (an e-mail address is optional) of a contact person at the contractor site.

The contractor shall not attempt to contact the provider for the missing/clarified information *or documentation* prior to sending the *PCV request* referenced above, though the contractor is free to make a follow-up contact with the provider after sending the *PCV request.*

10.4.1.3.4 - Receiving Missing/Clarifying Data/Documentation (Response to Development)

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(Note that references to missing information will generally only apply to paper applications.)

A. Requirement to Furnish All Missing/Clarifying Material

The provider must furnish <u>all</u> missing/clarifying data/documentation the contractor requested within the 30-day timeframe. Whether the provider furnished all information is a decision resting solely with the contractor. Should the provider furnish some (but not all) of the requested data/clarification within the specified time period, the contractor need not contact the provider again to request the remaining information. For instance, suppose the contractor *requested clarification regarding data the provider furnished* in Sections 3, 4, and 5 of the

Form CMS-855A. The provider only *clarified* the Section 3 data. The contractor may reject the application without attempting another contact.

B. Format of Furnishing Missing/*Clarifying* Data

1. Paper Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider shall: (1) provide the missing/clarification information (excluding documentation) on the applicable Form CMS-855 or CMS-20134 page(s) and (2) submit the material via mail, fax, *the PCV,* or scanned e-mail. A newly signed and dated certification statement must accompany the Form CMS-855 or CMS-20134 page(s) containing *any* missing data – unless the only missing information is supporting documentation, in which case no new certification statement is needed. The provider may submit the certification statement via scanned e-mail, fax, *the PCV,* or mail (paper submissions) along with *any* missing information.

2. PECOS Applications

Unless stated otherwise in this chapter or in another CMS directive, the provider *must furnish the clarifying data/documentation and/or missing/clarifying documentation via PECOS. (See section 10.3 for more information.)*

C. Format of Clarifying Data

(For both paper and PECOS applications, the provider must submit any missing/clarifying data or documentation and any required new certification statement within 30 days of the original request for clarification (rather than 30 days from the date of any follow-up request to provide the data.))

1. Paper Applications

In cases where clarifying (as opposed to missing) information is requested, the contractor may accept the clarification by e-mail, fax, the PCV, or letter. If the provider furnishes the clarification via telephone, the contractor shall – unless another CMS directive states otherwise - request that the provider furnish said clarification in writing (preferably via e-mail).

If the *furnished* clarification requires the provider to change or alter data that must be reported on the paper Form CMS-855 *or* CMS-20134, the contractor shall instruct the provider (via a follow-up e-mail or fax) to (1) submit the revised data on the applicable paper CMS-855 or CMS-20134 or PECOS application and (2) furnish a new certification statement. *The provider must submit the certification statement via scanned PCV, e-mail, fax, or mail.*

2. PECOS Applications

The provider must furnish any clarifying information or missing documentation via the PCV if no updates to its PECOS application are needed (e.g., no documentation need be uploaded, no changes to its Section 4 enrollment data are required). If application updates and/or documentation are required, the contractor shall instruct the provider (via the PCV) to (1) submit the clarified information via PECOS and (2) furnish a new certification statement in PECOS. (Paper certification statements are not permitted.)

Consider the following illustrations:

EXAMPLE 1: The contractor notifies the provider via an e-mailed letter on March 1 of a discrepancy regarding its ownership information on the *paper* Form CMS-855A. The provider e-mails the contractor on March 3 and explains the discrepancy. Based on this e-mail, the contractor determines that the provider must correct its ownership data in Section 5 of its Form CMS-855A. The contractor sends a follow-up e-mail to the provider on March 7 instructing the provider to do so. The provider must submit the revised data on the Form CMS-855 or CMS-20134 (with a new certification statement) by March 31 (not April 6, or 30 days from the date of the follow-up e-mail).

EXAMPLE 2: The contractor notifies the provider via *a PCV-transmitted letter* on March 1 of a discrepancy regarding *certain* ownership information on *its PECOS* Form CMS-855A. The provider telephones the contractor on March 6 and explains the discrepancy to the contractor's satisfaction. Although the discrepancy does not require the provider to make any revisions to its Form CMS-855A, the contractor shall request that the provider furnish its explanation in writing *via the PCV* no later than 30 days from its March 1 e-mail (or March 31), not 30 days from the date of its March 6 request for the written explanation.

EXAMPLE 3: The contractor notifies the provider via *a PCV-transmitted letter* on March 1 of a discrepancy regarding *certain* ownership information on its *PECOS* Form CMS-855A. Determining (based on the contractor's *notification*) that the ownership information it provided was incorrect, it submits a revised Section 5 of its Form CMS-855A to the contractor with a new certification statement *via PECOS* but without any accompanying explanation of the change. The contractor receives the revised Section 5 on March 12. If the contractor determines that the discrepancy has been resolved via the revised submission, it need not contact the provider for a written explanation. (This is because the clarification was furnished in writing via the Form CMS-855 or CMS-20134 itself.) If, however, the contractor would like a written explanation or otherwise needs clarification about the submission, it may request that the provider submit a written explanation *via the PCV* no later than March 31.

D. Maintenance of Received Material

Paper Applications – The contractor shall maintain all missing/clarifying information or documentation received (including new certification statements) *in PECOS via the uploading process described in section 10.3.*

PECOS Applications – The contractor shall maintain in PECOS all clarifying information/documentation and/or missing documentation.

10.4.1.3.5 – Provider/Supplier Fails to Submit Requested Data/Documentation

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

If, in the contractor's view, the provider failed to submit all of the requested data/documentation and/or a valid certification statement *if required* (*e.g.,* as a correction to the original certification statement, as part of a request for missing data*, etc.),* the contractor may:

- Reject the application if the 30-day period has elapsed,
- Wait until the 30-day period has elapsed and then reject the application, or
- Extend the 30-day period no more than an additional 30 days if (1) it appears that the provider is making a good-faith effort to comply with the development letter and/or (2) the provider furnished most of the requested data. For instance, suppose the contractor requested

5 pieces of *clarifying* information. The provider timely submitted 4 of them and furnished a signed certification statement. Since the provider appears to be acting in good faith, the contractor is encouraged to continue working with the provider.

If the provider fails to fully respond to a second request, the contractor may either: (1) reject the application if the original 30-day period has elapsed, (2) wait until the 30-day period has elapsed and then reject the application, or (3) make a third request using the procedures described above.

10.4.1.4.1 – Approvals

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

(This section 10.4.1.4.1 does not apply in situations where another CMS instruction contains alternative direction.)

A. Non-Certified Suppliers and Individual Practitioners

(This section 10.4.1.4.1(A) does not apply to ambulatory surgical centers, portable x-ray suppliers, *DMEPOS suppliers, MDPP suppliers,* or providers and suppliers that complete the Form CMS-855A.)

If the contractor approves a supplier's enrollment, it shall notify the supplier via letter of the approval. The letter shall follow the content and format of the applicable model letter in section 10.7 et seq. of this chapter.

The contractor shall send the approval letter via e-mail, mail, or fax *for paper applications (and the PCV for PECOS applications)* within 5 business days of approving the enrollment application in PECOS. (This timeframe should allow for *the* updating the enrollment information in the shared systems (MCS, FISS or VMS)). For all applications other than the Form CMS-855S, the contractor shall send the letter to the supplier's contact person if one is listed; otherwise, the contractor may send the letter to the supplier at the supplier's correspondence address or special payment address.

B. Certified Providers and Certified Suppliers

(This section 10.4.1.4.1(B) only applies to: (1) initial Form CMS-855A applications or CHOW, acquisition/merger, or consolidation applications submitted by the new owner; and (2) initial ambulatory surgical center and portable x-ray supplier applications. Note also that this subsection (B) contains only general instructions regarding certified provider/supplier approvals. Instructions in other chapter 10 sections (e.g., sections 10.2.1 et seq., 10.2.2 et seq., *section 10.3,* 10.6.1 et seq.) may contain more specific direction, such as with the processing of FQHC applications. Except as stated otherwise, these more specific instructions take precedence over those in this section 10.4.1.4.1(B)). *To illustrate, processes for "transitioned" provider initial enrollment (e.g., hospitals, HHAs) are described in provider-specific sections of section 10.2.1, et seq.) and take precedence over those in this section 10.4.1.4.1(B).*

If the contractor decides to recommend approval of the provider or supplier's application, the contractor shall send a recommendation letter to the applicable state agency, with a copy to the SOG Location. The recommendation letter shall follow the guidance and format of the applicable template letter in section 10.7 et seq. of this chapter. The contractor may also include an explanation of any special circumstances, findings, or other information that the state should know about. The letter can be sent to the state/SOG Location via mail, fax, or e-mail.

Also, the contractor:

(i) Shall send either a photocopy (not the original), faxed version, or e-mail version of the final completed Form CMS-855 to the state agency, along with all updated Form CMS-855 pages, explanatory data, documentation, correspondence, final sales agreements, etc. (which can also be sent via mail, fax, or e-mail). If the Form CMS-855, associated documentation, and recommendation letter are mailed, they should be included in the same package.

(ii) Shall not send a copy of the Form CMS-855 to the SOG Location unless the latter specifically requests it or if the transaction in question is one for which state involvement is unnecessary.

(iii) Notify the applicant that the contractor has completed its initial review of the application. The notification can be furnished via e-mail, *the PCV,* or via the letter identified in Section 10.7.5 of this chapter (which may be sent to the applicant's contact person). The contractor may, but is not required to, send a copy of its recommendation letter to the provider as a means of satisfying this requirement. However, the contractor should not send a copy to the provider if the recommendation letter contains sensitive information.

C. DMEPOS Suppliers

As stated in 42 CFR § 424.57(b), a DMEPOS supplier must, among other things, meet the following conditions to be eligible to receive payment for a Medicare-covered item: (i) the supplier has submitted a complete Form CMS-855S (including all supporting documentation) to *the applicable contractor*); and (ii) the item was furnished on or after the date the *contractor* issued to the supplier a DMEPOS supplier number conveying Medicare billing privileges.

D. Medicare Diabetes Prevention Program (MDPP) Suppliers

As stated in 42 CFR § 424.205(d), an MDPP supplier must, among other things, not have an ineligible coach on its roster. Though the MDPP supplier's effective date for billing privileges is the date a successful Form CMS-20134 application was submitted, the contractor must notify MDPP suppliers of their application approval because some MDPP suppliers may not begin furnishing services until receiving such information.

If the contractor approves an MDPP supplier's enrollment, it shall notify the supplier via letter of the approval. The letter shall follow the content and format of the applicable model letter in section 10.7 et seq. of this chapter.

Absent a CMS instruction or directive to the contrary, the contractor shall send the approval letter within 5 business days of approving the enrollment application in PECOS. The letter shall be sent to the supplier's contact person if one is listed; otherwise, the contractor may send the letter to the supplier's correspondence address or special payment address.

For claims submitted by MDPP suppliers prior to the date of enrollment, the contractor shall follow the instructions in Pub. 100-04, chapter 1, section 70, with respect to the claim filing limit. Payments cannot be made for services furnished prior to the date the applicant submitted an application or CAP that resulted in successful enrollment.

E. Additional Copies of Approval Letters

With the exception of Form CMS-855S applications, if any contact person listed on a provider/supplier's enrollment record requests a copy of the provider/supplier's Medicare approval letter, the contractor shall send it to the contact person via e-mail, *the PCV*, fax, or

mail. (This excludes certification letters *from the state or SOG Location,* for the contractor does not generate these approvals. *Also, see section 10.3 of this chapter for information regarding those contact persons for PECOS applications/enrollments who can and cannot receive documents or information pertaining to a specific application.)*

For *Form* CMS-855S application approval letters, *suppliers may contact their applicable NPE East or NPE West contractor for a copy thereof.*

10.4.1.4.2 - Returns

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Reasons/Grounds for Return

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

Notwithstanding any other directive to the contrary in this chapter or another CMS directive, the contractor (including the NSC) may immediately return the enrollment application to the provider only in the instances described below and which are outlined in § 424.526(a)(1) through (13). Except as otherwise indicated in the specific return reason, this policy applies to all applications identified in this chapter (e.g., initial applications, change requests, Form CMS-855O applications, Form CMS-588 submissions, change of ownership (CHOW) applications, revalidations, reactivations, etc.) (*Note that some of these return reasons may no longer apply or will be rendered moot with the advent of PECOS 2.0)*:

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

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

(3) The seller or buyer in a CHOW submitted its Form CMS-855A or Form CMS-855B application more than 90 days prior to the anticipated date of the sale.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Procedures for Returning the Application

If the contractor returns the application, the following apply:

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

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

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

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

See section 10.3 of this chapter for more information regarding the return of applications.

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

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

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

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

D. Reactivations

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

E. Revalidations

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

10.4.1.4.3 - Rejections

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Background

1. Rejection Reasons

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

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

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

(ii) The application is unsigned or undated.

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

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

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

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

(vii) The paper application is completed in pencil.

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

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

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

(Note that certain rejection grounds are inapplicable to PECOS applications (e.g., Form CMS-855 application was completed in pencil, certification statement is missing)).

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

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

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

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

submit the fee (or a waiver) within 30 days of the request, the contractor can reject the application.

2. Applicability

a. Development

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

b. Transaction and Form Types

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

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

B. Timeframe

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

C. Incomplete Responses

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

EXAMPLE: A provider submits a Form CMS-855A in which Section 3 is blank. On March 1, the contractor requests that Section 3 be fully completed. On March 14, the provider submits an application with the Final Adverse Action History question completed. However, the report of each adverse action, date, applicable body, and resolution data fields remains blank. The contractor need not make a second request for this data to be furnished. It can reject the application on March 31, or 30 days after its initial request was made.

D. Creation - *Paper Applications Only*

If the contractor cannot *complete the intake or data entry process* in PECOS because of missing data and the application is subsequently rejected, the contractor shall *disposition the application* accordingly *in PECOS consistent with existing CMS guidance*.

E. Other Impacts of a Rejection

1. Changes of Information and CHOWs

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

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

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

F. Reactivations

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

G. Revalidations

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

H. Additional Rejection Policies

1. Resubmission after Rejection

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

2. Applicability

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

3. Physicians and Non-Physician Practitioners

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

4. Notice

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

5. Copy of Application

Paper Applications - If the contractor rejects an application, it shall either (1) keep the original application and all supporting documents or (2) *maintain the scanned submission* of the application and documents *in PECOS* and return the originals to the provider. If the contractor chooses the former approach and the provider requests a copy of its application, the contractor may fax or mail it to the provider.

PECOS – Since the application was submitted electronically via PECOS and all supporting documents were uploaded consistent with section 10.3 of this chapter, the contractor need not return any documents to the provider.

10.4.2 - Denials

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In executing the instructions in section 10.4.2 et seq. of this chapter, the contractor shall also adhere to:

(i) The supplemental and superseding instructions in section 10.6.6 of this chapter concerning final adverse actions (e.g., referrals to PEOG);

(ii) The letter formats and verbiage in section 10.7 et seq. of this chapter;

(iii) *The PECOS 2.0 instructions in section 10.3 of this chapter;* and

(iv) Any other directive that, per CMS, explicitly pre-empts any instruction(s) in section 10.4.2 et seq. of this chapter.

If any instruction in categories (i) through (*iv*) above conflict with that in section 10.4.2 et seq., the instruction in (i), (ii), (iii), *or (iv)* applies. In addition, the contractor shall adhere to any instruction in (i), (ii), (iii), *or (iv)* above that addresses a denial-related matter not discussed in section 10.4.2 et seq.

10.4.3 – Voluntary and Involuntary Terminations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Voluntary Terminations of Certified Providers and Certified Suppliers

For information regarding certified provider/supplier voluntary terminations, see section 10.6.1.3 of this chapter.

B. Voluntary Terminations of Non-Certified Suppliers

The contractor shall adhere to the following when processing voluntary terminations of non-certified suppliers.

1. Timeframes – The contractor shall process such voluntary terminations in accordance with the timeframes in section 10.5 et seq. of this chapter.

2. Submission – Non-certified suppliers may only submit voluntary termination requests via the paper *application process* or *PECOS*. They cannot do so via letter.

3. Reassignments/PTANs - When processing a voluntary termination of a reassignment, the contractor shall contact the group to confirm that: (1) the group member PTAN is being terminated from all locations; and (2) if multiple group member PTANs exist for multiple group locations, each PTAN is terminated. However, if a group has one PTAN with multiple addresses, the contractor need not contact the group to confirm the termination.

4. PECOS and Deactivations - The contractor shall identify the voluntary termination action in PECOS as a deactivation with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per 42 CFR § 424.540(a)(7), and unless stated otherwise in this chapter or in another CMS directive, the effective date of the deactivation (for system purposes) shall be the day after the date on which the supplier voluntarily withdrew from Medicare

5. Reassignments - When processing a voluntary termination of a reassignment, the contractor shall terminate non-certified suppliers effective the day after that which the supplier requested on its termination application. (Note that this is different from a voluntary termination of the provider/supplier itself as addressed in subsection (B)(4) above.)

6. Special Payments - Upon receipt of a non-certified supplier voluntary termination request, the contractor may ask the supplier to complete the "Special Payments" portion of Section 4 of the Form CMS-855/20134 so that future payments can be sent thereto. If the supplier has no special payments address already on file, the addition should be included in the same transaction as the termination (i.e., one transaction incorporating both items). If the supplier wants to change its existing special payments address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The supplier is not required to submit a Form CMS-588 in conjunction with a termination.

C. Involuntary Terminations – Certified Providers/Suppliers

In the event an instruction in section 10.6.1 et seq. of this chapter contradicts guidance in this section 10.4.3(C), the section 10.6.1 et seq. guidance takes precedence.

1. Notification from State or SOG Location

If the contractor receives a notice from the state or SOG Location that involuntarily terminates a certified provider/supplier's Medicare participation because the provider/supplier no longer meets the conditions of participation, the contractor need not send

a letter to the provider/supplier stating that its Medicare participation has been terminated. The state or SOG Location will issue such a letter and afford appeal rights. The contractor shall follow the applicable instructions in section 10.4.7 et seq. of this chapter with respect to revoking the provider/supplier's enrollment, since the provider/supplier is no longer compliant with Medicare enrollment regulations. **(NOTE:** The contractor must identify in its revocation letter the exact provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.)

The contractor shall record the revocation in PECOS using the status reason of "Non-Compliance: Provider/Supplier Type Requirements Not Met." The contractor shall not identify the involuntary termination action in PECOS as a Deactivation with a status reason of "Voluntarily Withdrawal from the Medicare Program." In addition, the contractor shall end-date the entity's enrollment record in PECOS in the same manner as it would upon receipt of a termination notice from the SOG Location.

2. Revocation Letter

Per subsection (C)(1) above, the contractor shall issue a revocation letter to the certified provider/supplier using 42 CFR § 424.535(a)(1) as the legal basis for the revocation. The letter shall also contain the effective date of the revocation, appeal rights, and the length of the reenrollment bar as determined by CMS and indicated to the contractor. (See section 10.7 et seq. of this chapter for the applicable revocation letter.) The contractor shall e-mail a copy of the letter to the SOG Location using the same e-mail address it normally uses when communicating with the SOG Location's survey and certification staff.

3. Additional Information

For more information on voluntary terminations, refer to:

- Section 1866(b)(1) of the Social Security Act
- 42 CFR § 489.52(b)
- Pub. 100-07, chapter 3, section 3046 (SOM)

10.4.4 – Changes of Information

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. General Information

Unless as stated otherwise in this chapter, the following apply:

(i) The instructions in this section 10.4.4 apply to Part A and Part B enrollments.

(ii) In the event an instruction in section*s* 10.6.1 et seq. *or 10.6.22 et seq.* of this chapter contradicts that in this section 10.4.4, the section 10.6.1 *et seq. or 10.6.22* et seq. guidance takes precedence (e.g., *transitioned* certified provider/supplier change of information instructions in section 10.6.1.2 of this chapter).

(iii) Except as otherwise specified in this chapter or another CMS directive, if an enrolled provider/supplier is adding, deleting, or changing information under its existing tax identification number, it must report the change using the applicable Form CMS-855 or CMS-20134. (Letterhead is impermissible.) The provider/supplier shall: (a) furnish the changed data in the applicable section(s) of the form; and (b) sign and date the certification statement.

(iv) The timeframes for reporting changes are generally addressed in § 424.516.

B. Time Requirements to Report Changes of Information via a Form CMS-855/20134 Application

1. Physicians/Non-Physicians/Groups

Pursuant to § 424.516(d), change of information requirements apply to physicians, non-physician practitioners, and physician and non-physician practitioner organizations (i.e., clinic/group practices). These supplier types must report the following changes within 30 days: (1) a change of ownership; (2) adverse legal action; and (3) a change in practice location. All other changes must be reported within 90 days.

2. DMEPOS Suppliers

Per 42 CFR §§ 424.57(c)(2) and 424.516(c), DMEPOS suppliers must report any change to their enrollment information within 30 days.

3. IDTFs

Per 42 CFR §§ 410.33(g)(2) and 424.516(b), IDTFs must report any change in adverse legal actions, ownership, location, and general supervision within 30 days. All other changes must be reported within 90 days.

4. MDPP Suppliers

Per 42 CFR §§ 424.205(d)(5) and 424.516(e), an MDPP supplier must update its enrollment application within 30 days of any change of ownership, change to its coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), or change in final adverse action history. All other changes must be reported within 90 days.

5. All Other Provider/Supplier Types

Consistent with 42 CFR § 424.516(e), all other provider/supplier types not specifically referenced in § 424.516(b) through (e) are subject to the following reporting timeframes:

(i) Changes of ownership or control (including changes in authorized official(s) or delegated official(s)) – 30 days

(ii) All other changes – 90 days

(In addition, and per § 424.516(e)(3), an air ambulance supplier must report a revocation or suspension of its license or certification to the contractor within 30 days of the revocation/suspension. The following FAA certifications must be reported: (a) specific pilot certifications including, but not limited to, instrument and medical certifications; and (b) airworthiness certification.)

C. Signatories and Notifications

1. Signer Not on Record - If the signer has never been reported in Section 6 of the Form CMS-855 or CMS-20134, Section 6 must be completed in full with information about the individual. (This policy applies regardless of whether the provider/supplier already has a Form CMS-855/20134 on file.) The contractor shall conduct all required validations concerning the individual.

2. Notifications – For changes of information that do not require state agency or SOG Location approval (e.g., Form CMS-855I changes, Form CMS-855B changes not involving ambulatory surgical centers or portable x-ray suppliers, minor Form CMS-855A/B certified provider/supplier changes), the contractor shall:

(i) Furnish written, e-mail, *PCV,* or fax confirmation to the provider that the change has been made; and

(ii) Document *PECOS* (per section*s 10.3 and* 10.6.19 of this chapter) with the date and time the confirmation was made. If, however, the transaction only involves an area code/ZIP code change, the contractor need not send confirmation to the provider that it has processed the change.

3. Confirmation of Change in Practice Location Address

In cases where a provider submits a Form CMS-855 or Form CMS-20134 request to change its practice location address, the contractor shall contact the location currently associated with the provider in PECOS or MCS to verify that the provider/supplier is no longer there and did in fact move.

D. Change in Special Payments Address

Note that the instructions in this subsection (D) are in addition to, and not in lieu of, those in section 10.6.23 and vice versa.

1. Submitted Change - If the provider/supplier submits a change to its special payments address, the contractor shall verify the change by contacting the individual physician/practitioner (Form CMS-855I changes), an authorized or delegated official (Form CMS-855A, Form CMS-855B, and Form CMS-20134 changes), or the contact person listed in Section 13 (for Form CMS-855A, Form CMS-855B, Form CMS-20134, and Form CMS-855I changes). If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

2. Revalidation - When processing a revalidation application, the contractor shall (unless another CMS directive instructs otherwise) follow the instructions in sections 10.4.4(D) and 10.4.4(C)(3) above, respectively, if the practice location address or special payment address on the application is different from that currently associated with the provider in PECOS or MCS.

E. Provider or Supplier Changing Specialty Type

With the exception of individual physicians *and certain situations described in section 10.3 of this chapter,* providers and suppliers who wish to change their enrolled provider/supplier type must terminate their current enrollment and submit an initial enrollment application (Screening and an application fee (if applicable) applies for the new enrollment.)

F. Changes Involving Complete Form CMS-855 or CMS-20134 Applications

A provider must submit a complete Form CMS-855 or CMS-20134 application if it (1) submits any change request and (2) does not have an established enrollment record in PECOS. (For purposes of this requirement, the term “change request” includes EFT changes.) It is immaterial whether: (1) the provider or another party (e.g., local government changes street name) was responsible for triggering the changed data; or (2) the signer of the change request or EFT form already has a signature on file with the contractor.

If the contractor receives a change request from a provider that is not in PECOS, the contractor shall develop for the entire application consistent with the procedures described in this chapter (i.e., the contractor shall treat the transaction as a request for additional information). Consistent with existing policies for requesting additional data, the provider has 30 calendar days from the date of the contractor's request to furnish a complete Form CMS-855 or CMS-20134. During this period, the contractor should "hold" (i.e., not process) the change request until the entire application arrives; no L & T record shall be created in PECOS at this point.

If the provider fails to submit a complete application within the aforementioned 30-day period, the contractor shall follow the instructions in section 10.4.1.4.3 of this chapter.

If the provider submits the application, the contractor shall process it in accordance with the instructions in this chapter and all other applicable CMS directives. This includes:

(i) Processing the complete application consistent with the timeframes for initial applications outlined in this chapter.

(ii) Validate all data elements on the Form CMS-855 or CMS-20134 consistent with the instructions in this chapter pertaining to initial applications. The contractor shall not approve the change request until it has verified all data on the complete Form CMS-855 or CMS-20134 *consistent with the instructions in this chapter.*

(iii) Creating a record in PECOS prior to approving the change request. (The receipt date should be the date on which the complete application was received, not the date on which the initial change request was received.) The transaction should be treated as an initial enrollment in PECOS; internally, the contractor shall treat it as a change of information. As the complete application will presumably incorporate the changed data reported on the original Form CMS-855 or CMS-20134 change request, the contractor shall not take two separate counts (one initial and one change request) for the transaction. *(NOTE: Any PECOS 2.0 policies or procedures that are contrary to those in this subparagraph (iii) take precedence over the latter.)*

G. Incomplete or Unverifiable Changes of Information

(The contractor shall follow the instructions in this section 10.4.4(G) if it cannot process the submitted change request to completion.)

There can be instances where a provider has an enrollment record in PECOS and submits a change request but: (1) fails to timely respond to the contractor's request for additional or clarifying information; or (2) the changed information cannot be validated. The contractor in these situations shall reject the change request in accordance with section 10.4.1.4.3 of this chapter. Moreover, if the changed information is of such materiality that the contractor cannot determine whether the provider still meets all enrollment requirements, the contractor shall refer the matter to its PEOG BFL for guidance. Examples include but are not limited to: (i) change in the provider's lone practice location; (ii) change in ownership; or (iii) change in EFT information.

H. Change of EFT Information

(Note that the instructions in this subsection (H) are in addition to, and not in lieu, those in section 10.6.23 and vice versa.)

If the provider submits a Form CMS-588 request to change the bank name, depository routing transit number, or depository account number, the contractor shall contact the individual physician/practitioner (for Form CMS-855I enrollees), an authorized or delegated official on record (for Form CMS-855A, CMS-855B, and Form CMS-20134 enrollees), or the Section 13 contact person on record (for Form CMS-855A, Form CMS-855B, Form CMS-20134 and Form CMS-855I enrollees) to verify the change. If the contractor cannot reach, as applicable, the individual physician/practitioner or an authorized or delegated official, it shall confirm the change with the contact person.

I. Special Instructions for Certified Providers, ASCs, and Portable X-ray Suppliers

1. Timeframe for State Review

In situations where state *and/or SOG Location* review of the change of information is required (see section*s* 10.6.1.2 *and 10.6.22.1*), the contractor may (via any means) advise the provider that it may take several months for the request to be approved.

2. Post-Recommendation Changes

If an applicant submits a change request after the contractor recommends approval of the provider's initial Form CMS-855 application but before the state or SOG Location (as applicable) notifies the contractor that, respectively, it recommends approval of or approves the initial application, the contractor shall process the newly-submitted data as a separate change of information. The contractor shall not take the changed information/corrected pages and, immediately upon receipt, send them directly to the state/SOG Location for incorporation into the existing application.

In entering the change request into PECOS, the contractor shall use the date on which it received the change request in its mailroom as the actual receipt date in PECOS; the contractor shall not use the date on which the contractor received the aforementioned state/SOG Location approval/recommendation. The contractor shall explain the situation in *PECOS.*

J. Critical Access Hospital (CAH) Addition of New Provider-Based Locations

Regulations found at 42 CFR § 485.610(e)(2) and in the State Operations Manual state that the CAH's provider-based location must meet certain distance requirements from the main campus of another hospital or CAH.

The contractor shall contact the appropriate SOG Location while processing the Form CMS-855A to verify that the CAH's new provider-based location is more than 35 miles (15 miles in the case of mountainous terrain or an area with only secondary roads) from the main campus of another hospital or CAH. The contractor may not make a recommendation for approval without receiving a response from the SOG Location.

If the SOG Location finds that CAH's new provider-based location meets the distance requirements, the contractor shall continue processing the application normally. If the SOG Location determines that the location does not meet the distance requirements, the contractor shall reject the application and issue to the CAH the applicable rejection letter outlined in section 10.7 et seq.

The SOG Location will provide the CAH with three options if the location does not meet the distance requirements:

1. The CAH keeps the new provider-based location, which will cause an involuntary

termination in 90 days (as outlined in the Pub. 100-07, chapter 3, section 3012).
2. The CAH terminates the new provider-based location and continue its enrollment as a CAH.
3. The CAH keeps the new provider-based location but converts to a hospital (as outlined in Pub. 100-07, chapter 2, sections 2256G and 2256H).

For each option, the contractor shall keep the CAH's enrollment in an approved status in PECOS. For Option #1 above, the contractor will receive notice from the SOG Location of the termination, which will lead to revocation of the CAH's enrollment. For Option #2, the CAH's enrollment remains approved and the contractor shall expect no further communication from the SOG Location. If the CAH chooses Option #3 to convert to a hospital, the contractor will receive a Form CMS-855A to terminate the CAH's enrollment and a new Form CMS-855A to enroll as a hospital.

10.4.5 – Revalidations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

Consistent with section 6401(a) of the Patient Protection and the Affordable Care Act (ACA), all existing providers and suppliers are required to revalidate their enrollment information under new enrollment screening criteria. Providers and suppliers are normally required to revalidate their Medicare enrollment every 5 years (every 3 years for DMEPOS suppliers). However, CMS reserves the right to perform off-cycle revalidations as deemed necessary.

Except as otherwise stated in this chapter or another CMS directive, the contractor shall follow the guidance in sections 10.4.5 through 10.4.5.3 of this chapter when processing revalidation applications. This guidance takes precedence over all other instructions in this chapter concerning revalidation processing unless, again, another CMS directive specifies otherwise. *The contractor shall note, however, that some of the instructions in section 10.4.5 et seq. may not apply to PECOS revalidation applications. This is because, as stated in section 10.3(C) of this chapter:*

(1) PECOS automatically handles revalidation tracking and revalidation requests and prevents the submission of PECOS revalidation applications outside of the revalidation window.
(2) PECOS establishes timeframes and then queues mailings based on revalidation history and enrollment dates (although CMS can modify timeframes and request off-cycle revalidations at any time; this includes those for large group revalidations.) All PECOS revalidation requests will be staggered so that revalidations are submitted and processed within 7 months of the provider's due date. This will eliminate the potential for unsolicited revalidation applications submitted outside of the 7-month window and permit a more structured and streamlined revalidation process.
(3) Failure to respond to a revalidation request would result in an automatic pend, deactivation, etc.

Accordingly, the contractor can disregard those instructions in section 10.4.5 et seq. that obviously do not apply to a particular situation.

10.4.5.1 – Revalidation Solicitations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. *Background*

Under previous practice, CMS identif*ied* the providers and suppliers required to revalidate during each cycle. CMS communicate*d* when new lists bec*a*me available through the appropriate channels, at which time the contractor obtain*ed* the list from the CGI Share Point

Ensemble website. *With the advent of PECOS 2.0, PECOS will automatically: (i) determine when a provider/supplier is due to periodically revalidate its enrollment; and (ii) send a revalidation notice to the provider/supplier. Note that this new process of revalidation solicitation applies both to providers/suppliers that currently submit applications via (or otherwise utilize) PECOS or via paper. For the former group, solicitations will be sent via the PCV. For the latter, solicitations will be e-mailed via PECOS, and the affected provider/supplier may submit its revalidation application via paper; it is not required to use PECOS.*

B. Sending Revalidation Letters

Based on the due date identified *in PECOS, PECOS will* send a revalidation notice (using the applicable letter in section 10.7 et seq. of this chapter) between 90 to 105 days prior to the *provider/supplier's* revalidation due date. The initial revalidation letter *will* include a generic provider enrollment signature.

C. Interaction with Change Request

If the contractor receives a *change of information* (COI) application from the provider after *PECOS has mailed to the provider a* revalidation notice, the contractor shall *ensure that the received revalidation application contains the changed information.*

If the contractor receives *paper* revalidation and COI applications concurrently, the contractor shall merge the two applications and process accordingly. *If the two applications were PECOS applications, they should be processed as two separate transactions.*

If the provider submits an application marked as a revalidation but that only includes enough information to be considered a COI, the contractor shall (1) develop for a complete application containing the missing data elements and (2) treat it as a revalidation.

D. Interaction with a Change of Ownership (CHOW)

PECOS will not commence revalidation action regarding a provider/supplier that is undergoing a CHOW that: (1) the contractor is currently processing; or (2) is pending review with the state agency.

E. Reassignment Applications Received After Revalidation Letter Mailed

If a reassignment application has been received *after a revalidation letter has been sent to the affected provider/supplier*, the contractor shall process the reassignment application. The supplier need not report the newly established reassignment/employment arrangement on the revalidation application, and the contractor shall not develop for *this* information; this is because the arrangement was established after the revalidation notice was issued. However, the contractor shall maintain the reassignment/employment arrangement information in the enrollment record when processing the revalidation application; this information shall not be overridden. If the supplier fails to respond to the revalidation request, all reassignments shall be end-dated, including the newly established reassignment. Consider the following illustration:

EXAMPLE: Dr. Doe submits a Form CMS-855R application to add a new reassignment to Browns Medical Center *after receiving a revalidation request*. He submits his revalidation application to his contractor but does not include the reassignment for Browns Medical Center because the contractor is still processing the Form CMS-855R and has not yet approved the reassignment. The contractor finalizes the reassignment changes and then proceeds with processing the revalidation application. The contractor shall not develop for

the new reassignment to Browns Medical Center and shall maintain the reassignment in the provider's enrollment record when processing the revalidation application.

F. Revalidation Extension Requests

The contractor shall only accept extension requests from a provider that was not given the full 7 months' advance notice prior to their revalidation due date. The contractor shall *not* accept extension requests from providers for any other reason.

The provider/supplier may submit its request in writing (fax/e-mail*/PCV* permissible) or via phone, though the individual provider, authorized/delegated official, or *appropriate* contact person shall make the request. *(See section 10.3 of this chapter for information regarding contact persons for PECOS applications.)*

G. Additional Letter Data

In addition to the PCV e-mailing revalidation correspondence, the contractor – in any circumstance required per this chapter -- shall print and mail the following PCV-generated letters: (1) revalidation notification letters (e.g., the first letter came back as undeliverable (see subsection (B)(2) above)); (2) pend letters; and (3) deactivation letters.

(NOTE: As a general rule, the PCV can, among other things: (1) automatically send emails (e.g., revalidation); (2) send e-mails upon request (e.g., development); (3) generate letters/store letters; (4) send letters to a print queue; and (5) accept document uploads,)

10.4.5.2 – Non-Responses to Revalidation and Extension Requests

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

A. Phone Calls

The contractor may (but is not required to) continue to contact providers via telephone, e-mail, *or the PCV* to communicate non-receipt of revalidation applications. The contractor shall document *in PECOS* all such communications with the provider.

B. Pend Status and *Deactivation Actions*

PECOS will automatically pend (i.e., hold payment to) a provider*/supplier that* fails to respond to a revalidation request *within the required timeframe. The pend will last until the final disposition of the application, and PECOS will notify the provider/supplier of the pend.* If the provider does not submit the revalidation within this period, *PECOS will automatically deactivate the provider and notify the contractor thereof. Within 10 business days of receiving this notification, the contractor shall send the appropriate deactivation letter to the provider using the procedures in this chapter. The deactivation basis is 42 CFR § 424.540(a)(3). Per § 424.540(d)(1)(ii)(A), the deactivation effective date shall be the date on which PECOS deactivated the provider (that is, the date on which the provider became non-compliant).*

No later than 5 business days after sending the aforementioned deactivation letter --- and if the deactivated supplier is a physician – the contractor shall search his/her associate record to determine if he/she serves as a supervising physician on any independent diagnostic testing facility (IDTF) enrollment. If he/she does, the contractor shall disassociate him/her as the supervising physician for that entity. If he/she is the only supervising physician on file for the IDTF, the contractor shall develop for an active supervising physician to bring the IDTF into compliance. The contractor shall give the IDTF 30 days to respond. Failure to provide an

active supervising physician in the designated timeframe shall result in revocation of the IDTF's billing privileges for non-compliance with the IDTF standards.

10.4.5.3 – Receipt and Processing of Revalidation Applications

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

The provider may submit its revalidation application via paper or PECOS, though the latter is encouraged so as to allow for more expedited processing.

For paper applications, the contractor shall input the relevant data in PECOS consistent with longstanding practice and with the policies in this chapter, including those in section 10.3.

Note that some of the instructions in this section 10.4.5.3 et seq. may be inapplicable to PECOS (e.g., developing for missing sections of the Form CMS-855 revalidation application).

A. General Situations

1. Unsolicited Applications

An unsolicited revalidation application is one received outside of the PECOS revalidation request addressed in section 10.4.5.1. The contractor shall return such applications using the applicable sample return letter in section 10.7 et seq. within 20 business days of receipt. *If the application was received more than 7 months prior to the provider/supplier's revalidation due date, the contractor shall use § 424.526(a)(8) as the return basis. If § 424.526(a)(8) does not apply to the situation, the contractor shall use § 424.526(a)(7) as the basis, for the application was inapplicable to or not needed for the transaction involved.*

If applicable, the contractor shall also submit a request to CMS to have the application fee returned to the provider.

2. Signatures

The contractor may only accept revalidation applications signed by the individual provider or the authorized or delegated official.

3. Sub-Units

Any certified provider sub-unit that has a separate provider agreement must revalidate on a separate Form CMS-855A. It cannot revalidate via the main provider's Form CMS-855A. If the sub-unit has a separate CMS Certification Number (CCN) but not a separate provider agreement (e.g., hospital psychiatric unit, HHA branch), the sub-unit can disclose the revalidation on the main provider's Form CMS-855A; this is because the sub-unit is a practice location of the main provider and not a separately enrolled entity. Separate fees, too, are not required.

4. Collapse of PTANs

If the provider requests to collapse its PTANs per a revalidation, the contractor shall process said requests if appropriate (based on payment localities, etc.).

5. Voluntary Withdrawal

(This subsection (A)(5) does not apply to certified providers/suppliers. See section 10.6.1.3 of this chapter for instructions concerning certified provider/supplier voluntary terminations.)

If a non-certified supplier wishes to voluntarily withdraw from Medicare (including deactivating all active PTANs), the contractor shall accept this request via phone, U.S. mail, or fax from the individual supplier or the authorized/delegated official (on letterhead); the contractor shall not require the non-certified supplier to complete a Form CMS-855 or CMS-20134 application. If the contractor makes the request via telephone, the contractor shall document the telephone conversation *in PECOS* and take the appropriate action in PECOS.

B. Development Required

(Note that some of the instructions in this subsection (B) will be inapplicable to PECOS applications. See section 10.3 for more information.)

1. General Instructions

If a revalidation application requires development (e.g., missing application fee, *clarification or documentation needed*, missing reassignments), the contractor shall notify the provider via mail, telephone, *the PCV,* fax, or e-mail. The contractor shall develop for all of the *required* information in one development request. The provider has 30 days to respond to the contractor's request. *For paper applications, the provider* may submit the information via mail, fax, or e-mail containing scanned documentation; this includes missing signatures and dates. *For PECOS applications, the provider must submit the information via PECOS.* (Note that the provider may submit a full Form CMS-855I or Sections 1, 2, 4, & 15 of the Form CMS-855I to report missing reassignments any time prior to their revalidation due date*; this includes* post-revalidation application approval.)

If the contractor can verify licensure and/or educational requirements (e.g., non-physician practitioner's degree or diploma) online, the contractor shall not require the provider to submit this documentation. If the supporting documentation currently exists in the provider's file, the provider need not submit that documentation again with their revalidation application; the contractor may utilize the existing documentation for verification. Residency information is not required as part of a revalidation. In addition, the contractor need not develop for data that is missing *or needs clarification* on the provider's revalidation application if the provider *accurately* disclosed *(meaning no clarification is needed)* the information (1) elsewhere on the application or (2) in the supporting documentation submitted with the application, though with the exception of the following items:

(i) Adverse legal action data
(ii) LBN
(iii) Tax identification number (TIN)
(iv) NPI-legacy number combinations
(v) Supplier/Practitioner type
(vi) DBA name
(vii) Effective dates of sale/transfer/consolidation or indication of acceptance of assets/liabilities

The contractor shall not require providers to include the PTAN(s) in Section 2 or 4 of the revalidation application---provided that the provider included the information needed (NPI, TIN, LBN, DBA, etc.) for the contractor to appropriately make the association. If the PTAN was not submitted but is needed to make the connection, the contractor shall use the shared systems, PECOS, or its provider file(s) as a resource before developing with the provider.

The contractor shall not develop for the EFT form if the provider has the 05/10 or 09/13 version of the Form CMS-588 on file. If provider submits an EFT form with a bank letter or

voided check, the contractor may verify that the LBN matches and develop to process the application accordingly. *Note that the instructions in section 10.6.23 apply to revalidations.*

If the supporting documentation currently exists in the provider's file, the provider 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. In addition, per the instructions in this chapter, the contractor shall document in *PECOS* that it found the missing information elsewhere in the enrollment package, with previously submitted applications, or with documentation currently uploaded in PECOS. (This excludes information that the contractor must verify at the current point in time (e.g., a license without a primary source verification method).) In addition, the contractor shall not utilize information submitted along with opt-out applications for enrollment application processing or vice-versa.

If a revalidation response is received for a single reassignment within an enrollment record that has multiple reassignments, the contractor shall develop with the contact person (or the individual provider if a contact is not listed) for the remaining reassignments not accounted for. If no response is received within 30 days, the contractor shall revalidate the single reassignment and deactivate the reassignments within the enrollment records that were not revalidated.

If other missing information is not received within 30 days, the contractor shall deactivate the provider within 25 days after the development due date and notify the provider of the deactivation using the applicable sample letter in section 10.7 et seq. of this chapter. After deactivation, the provider must submit an entirely new application in order to reactivate their PTANs. The contractor may use any supporting documentation received (if needed) for subsequent application submissions.

The deactivation date shall be consistent with the latter of: (1) the revalidation due date; or (2) the date on which the deactivation occurred due to non-response or incomplete response to a development request for all provider business structures (e.g., organizations, sole proprietors, sole owners, etc.).

2. Illustrations

Consider the following examples that address the instructions in section 10.4.5.3(B)(1):

SCENARIO #1 - *PECOS* issues a revalidation notice to the provider and includes reassignments and/or employment arrangements for Groups A, B & C. The provider submits the revalidation application but only addresses the reassignment for Group A. The contractor develops with the contact person for the missing reassignments and/or employment arrangements for Groups B & C. The provider responds with the reassignment information for Groups B & C prior to the development due date. Since the revalidation application remains in progress, the provider may submit a full Form CMS-855I or Sections 1, 2, 4, & 15 of the Form CMS-855I to report the missing reassignment information (even post-revalidation application approval). Here, the contractor processes the revalidation application to completion, and the provider experiences no break in billing.

SCENARIO #2 - The contractor issues a revalidation notice to the provider and includes reassignments and/or employment arrangements for Groups A, B & C. The provider submits the revalidation application to the contractor but only addresses the reassignment for Group A. The contractor develops with the contact person for the missing reassignments and/or employment arrangements for Groups B & C. No response is received within 30 days, and

the revalidation due date has passed. In this situation, Group A's reassignment is revalidated, and the contractor shall deactivate Group B & C's reassignments and/or employment arrangements effective with the date on which the contractor took deactivation action due to non-response or incomplete response to a development request. The approval letter shall identify the reassignments and/or employment arrangements that were revalidated and those that were terminated with the effective date of the reassignment or termination. The provider must submit a full application (Form CMS-855R) to reactivate the reassignment. The reactivation effective date is based on the receipt date of the CMS-855R.

In Scenario #2, therefore: (i) the provider experiences a break in billing but the contractor only deactivates the non-response reassignments and/or employment arrangements; and (ii) the contractor revalidates the other reassignments and/or employment arrangements.)

Contractor-initiated development letters*, however,* shall include a provider enrollment analyst's name and phone number for provider contacts.

C. Revalidation Received after a Pend is Applied

If the contractor receives a revalidation application after applying a pend, it shall remove the pend within 15 business days of receiving the revalidation application, even though the submitted application has not been processed to completion. This will release all held paper checks, SPRs, and EFT payments.

The contractor shall process the revalidation application using current processing instructions and mail, fax, or e-mail *(via the PCV for PECOS applications)* a decision letter to the provider to notify the latter that the contractor has processed the revalidation application.

D. Revalidation Received After a Deactivation Occurs

1. General Guidance

The contractor shall require a deactivated provider to submit a new, full application to reactivate their enrollment record. The contractor shall process the application as a reactivation. The provider shall maintain their original PTAN; however, the contractor shall reflect a gap in coverage (between the deactivation and the reactivation) on the existing PTAN using A/R codes in MCS and based on the application's receipt date. The provider will not receive reimbursement for dates of service in which they were non-compliant with Medicare requirements (deactivated for non-response to revalidation). The contractor shall reactivate group members (with the group enrollment) who had their reassignment associations terminated when the contractor deactivated the group. The effective dates assigned to the reassigned providers should align with the group's effective date per standard reactivation instructions.

2. Certified Providers and Certified Suppliers

Unless CMS instructs otherwise, the contractor shall allow a certified provider/supplier to maintain its original PTAN and effective date when the reactivation application is processed. (As stated in § 424.540(c), a deactivation does not terminate a certified provider/supplier agreement.) In addition, when processing the revalidation application after a deactivation occurs, the contractor shall not require the deactivated certified provider/supplier to obtain a new state surveyor accreditation as a condition of revalidation.

E. Finalizing the Revalidation Application

Prior to processing the revalidation application to completion, the contractor shall:

(i) Ensure that a site visit (if applicable to the provider in question) occurs.

(ii) Ensure that the provider meets all applicable federal regulatory requirements regarding licensure, certification, and/or educational requirements.

(iii) Revalidate the provider's information based on the data in PECOS.

(iv) Verify the practice locations, although the contractor need not contact each location separately. The contractor shall: (1) verify the location(s) by contacting the contact person listed on the application; and (2) note the validation accordingly in the contractor's verification documentation per the instructions in this chapter.

(v) Ensure that the appropriate record type and finalization status are identified in PECOS.

(vi) Ensure that an enrollment record is not marked as revalidated in PECOS if responses have been received for some PTANs but not all PTANs have been addressed (meaning that no action has been taken on the non-response PTANs, e.g., end-dated). If all PTANs have been addressed (e.g., revalidated, end-dated), the enrollment can be marked as revalidated.

(vii) Ensure that PECOS and the claims systems remain consistent. The contractor shall not directly update the shared systems without first updating PECOS when processing a revalidation (unless instructed otherwise in another CMS directive).

(viii) When processing is complete, issue an approval letter to the contact person (or the provider if no contact person is listed) via mail, fax, *the PCV,* or e-mail. (For PECOS If the provider has reassignments that were terminated due to non-response, the approval letter shall contain the reassignments that were terminated due to non-response and the effective date of termination (i.e., the revalidation due date or the development due date).

F. Revalidation Reporting

Unless CMS requests it, the contractor *need no longer* submit reports *to CMS regarding its revalidation activities, for the revalidation data is captured in PECOS.*

10.4.6 – Reactivations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

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

1. Limited

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

2. Moderate

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

3. High

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

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

If the contractor approves a Part B non-certified supplier's reactivation application, the reactivation effective date shall be the date the contractor received the application that was processed to *approval.* In addition, upon reactivating a Part B non-certified supplier, the contractor shall issue a new PTAN; *for PECOS applications (and as indicated in section 10.3 of this chapter), PECOS will automatically issue a new PTAN.*

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

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

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

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

E. Reactivation Effective Date

Per 42 CFR § 424.540(d)(2), the effective date of a reactivation of billing privileges under this section is the date on which the contractor received the provider's or supplier's reactivation submission that the contractor processed to approval. Under 42 CFR § 424.540(e), however, the provider or supplier may not receive payment for services or items furnished while deactivated. This means that the contractor shall not add a retroactive back-billing period (e.g., 30 days) to the reactivation effective date. To illustrate, suppose the contractor establishes a reactivation effective date under § 424.540(d)(2) of October 30, the date the contractor received the ultimately approved reactivation submission. The contractor under § 424.540(e) cannot establish an effective date earlier than October 30 to allow for additional retroactive billing.

F. Miscellaneous Policies

1. Previous Withdrawn Status

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

2. Deactivation for Non-Billing

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

3. Contractor Timeliness Standards

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

10.4.7 – Revocations

(Rev. 11891; Issued: 03-09-23; Effective: 04-21-23; Implementation: 06-19-23)

In executing the instructions in section 10.4.7 et seq. of this chapter, the contractor shall also adhere to:

(i) All supplemental and any superseding instructions in section 10.6.6 of this chapter concerning final adverse actions (e.g., referrals to PEOG);

(ii) The letter formats and verbiage in section 10.7 et seq. of this chapter;

(iii) The PECOS 2.0 instructions in section 10.3 of this chapter; and

(iv) Any other directive that, per CMS, explicitly pre-empts any instruction(s) in section 10.4.7 et seq. of this chapter.

If any instruction in categories (i) through (i*v*) above conflict with that in section 10.4.7 et seq., the instruction in (i), (ii), (iii), *or (iv)* applies. In addition, the contractor shall adhere to any instruction in (i), (ii), (iii), *or (iv)* above that addresses a revocation-related matter not discussed in section 10.4.7 et seq.