CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10909	**Date: August 10, 2021**
	Change Request 12330

SUBJECT: Fourth General Update to Chapter 10 of Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to -- (1) Incorporate technical and editorial changes into parts of Chapter 10 of Pub. 100-08; and (2) Address any outstanding policy issues in the Chapter 10 sections included in this CR.

EFFECTIVE DATE: August 13, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 13, 2021

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/Table of Contents
R	10/10.2/10.2.7/Opioid Treatment Programs
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.6/10.6.14/Application Fees
R	10/10.6/10.6.20/Screening: On-Site Inspections and Site Verifications
N	10/10.6/10.6.21/Miscellaneous Enrollment Topics

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 10909	Date: August 10, 2021	Change Request: 12330

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I. GENERAL INFORMATION

A. Background: The CMS has recently completed transferring the entirety of Chapter 15 of Pub. 100-08 to Chapter 10 of Pub. 100-08. Chapter 10 outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR will -- (1) Incorporate minor technical and editorial changes into parts of Chapter 10; and (2) Address several outstanding policy issues in the Chapter 10 sections included in the CR. This CR is the fourth in a series of CRs that update various portions of Chapter 10 with technical revisions and any necessary policy changes.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12330.1	The contractor shall confirm that an approved Form CMS-855O enrollment or valid opt-out affidavit does not exist in the Provider Enrollment, Chain and Ownership System (PECOS), prior to processing an initial Form CMS-855O or opt-out affidavit submission.		X							
12330.1.1	The contractor shall return the pending application, if,		X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	pursuant to Business Requirement 12330.1, an approved enrollment or affidavit indeed exists in PECOS.									
12330.2	The contractor shall contact the eligible practitioner (via any means) to clarify if he/she submitted the application to solely bill for emergency services provided to a beneficiary, if a Form CMS-855I is received **and** an opt-out affidavit is active.		X							
12330.3	The contractor shall follow the instructions in Section 10.6.14(H) in Chapter 10 of Pub. 100-08 if an application fee refund is requested and the fee was paid via Automated Clearing House Debit.	X	X	X						
12330.4	Notwithstanding any other instruction to the contrary in Chapter 10 of Pub. 100-08, the contractor shall not order a site visit if the specific location	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	to be visited has already undergone a successful site visit within the last 12 months and the applicable provider/supplier is in an approved status.									
12330.5	Notwithstanding any other instruction to the contrary in Chapter 10 of Pub. 100-08, the contractor shall override the error message in PECOS in the situation described in Section 10.6.20(I) in Chapter 10 of Pub. 100-08.	X	X	X						
12330.6	The contractor shall reactivate the group's reassignments when the group's reactivation application has been approved, if a group practice submits a reactivation application after being deactivated for non-response to a revalidation request.		X							
12330.7	The contractor shall not contact the physician, non-physician practitioner, or contact person directly to confirm either the		X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	change itself or the individual's intent to change his/her specialty when a Form CMS-855 enrollment application is submitted to report a change to a physician's or non-physician practitioner's primary or secondary specialty.									
12330.8	The contractor shall follow the instructions in Section 10.6.21(C) in Chapter 10 of Pub. 100-08 when revoking or deactivating an individual or organization receiving reassigned benefits from an individual practitioner.		X							
12330.9	The contractor shall follow the instructions in Section 10.6.21(D) in Chapter 10 of Pub. 100-08 if it encounters an interstate license compact in its application processing.		X							

III. PROVIDER EDUCATION TABLE

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

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents

*(**Rev.**10909; Issued: 08-10-21)*

Transmittals for Chapter 10

10.6.21 – Miscellaneous Enrollment Topics

10.2.7 - Opioid Treatment Programs

(Rev. 10909; Issued: 08-10-21; Effective: 08-13-21; Implementation: 09-13-21)

A. Legislative and Regulatory Background

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

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

1. Accreditation

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

2. Certification

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

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

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

3. Enrollment

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

In the Calendar Year (CY) 2020 Physician Fee Schedule final rule (published in the **Federal Register** on November 15, 2019 (84 FR 62567)), CMS established a new 42 CFR § 424.67 containing requirements that OTPs must meet and continually adhere to in order to enroll (and remain enrolled) in Medicare effective January 1, 2020. Since this latter date, OTPs have enrolled in Medicare consistent with 42 CFR § 424.67 and the general provider enrollment requirements of 42 CFR Part 424, subpart P (42 CFR § 424.500-570). This section 10.2.7 outlines the specific enrollment policies associated with OTP enrollment.

B. OTP Enrollment Process

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

1. Applicable Form CMS-855

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

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

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

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

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

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

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

2. Applicable Fee

An OTP is an "institutional provider" under 42 CFR § 424.502 and thus is required to pay an application fee pursuant to 42 CFR § 424.514. The contractor shall follow the application fee

procedures outlined in chapter 10 of the PIM. A fee is required even when the OTP is changing its enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa.

3. Categorical Screening

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

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

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

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

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

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

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

4. Confirmation of Certification

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

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

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

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

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

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

5. OTP Managing Employees

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

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

6. OTP Personnel

i. Regulatory Background

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

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

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

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

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

ii. Attachment and Verification

Attachment 3 of the Form CMS-855B collects information on the individuals described in § 424.67(b)(1)(i) above. (The Form CMS-855A will eventually be updated to include a similar attachment, after which OTPs completing that form will have to submit the attachment.) OTPs submitting the Form CMS-855B (either the current/revised/new 07/20 version or the prior 07/11 version) must complete this attachment as described in (and subject to) (ii)(A) below and, once enrolled, report any changes to the information thereon (e.g., new or deleted prescribers) consistent with 42 CFR § 424.516(e).

Irrespective of the type of transaction involved (e.g., initial, revalidation, change of information), the contractor shall accept from the OTP:

- The revised version of the Form CMS-855B (which includes the aforementioned OTP attachment) beginning January 4, 2021.

- The prior (07/11) version of the Form CMS-855B through March 31, 2021. (Any such application received by the contractor after March 31, 2021 shall be returned to the OTP consistent with the instructions in this chapter and other applicable CMS guidance.)

Pursuant to the foregoing, the contractor shall adhere to the following policies and instructions in this section (6)(ii).

(A) When to Submit Attachment

(1) General Principles

The OTP need only submit the attachment for the first time as part of (i) an initial Form CMS-855B enrollment, (ii) a Form CMS-855B revalidation (periodic or off-cycle), or (iii) a change from a Form CMS-855A enrollment to a Form CMS-855B enrollment. (For purposes of this requirement, the term "Form CMS-855B" includes the 07/20 version and the 07/11 version (the latter only through March 31, 2021, however).) The OTP is not required to complete it for the first time as part of a change of information request. Consider the following examples:

Example 1 - Smith OTP enrolled in Medicare via the Form CMS-855B in June 2020, prior to the Form CMS-855B being revised to include the attachment. Smith submits a change request in June 2021 to add a new billing agency. Smith need not complete the attachment at this time because Smith's application does not fall within any of the three categories in (A)(i) through (iii) above.

Example 2 - Using Example 1, suppose Smith submitted a Form CMS-855B revalidation application (rather than a change of information) in June 2021. Smith would have to complete the attachment at that time.

Example 3 - Again using Example 1, suppose Smith submitted a Form CMS-855A in March 2021 to change its enrollment from a Form CMS-855B. No attachment need be completed

because the Form CMS-855A lacks an attachment and because no category in (A)(i) through (iii) above applies.

Example 4 - Again using Example 1, assume Smith in August 2020 hired two pharmacists to dispense controlled substances on its behalf. Smith would neither have to report these persons on the attachment nor complete the attachment in full, for no category in (A)(i) through (iii) above applies.

Example 5 – Suppose Jones OTP submits an initial enrollment application on March 1, 2021 using the 07/11 version of the Form CMS-855B. The contractor may accept the application, but the latter must include the information on the attachment. (If a paper application is used, the OTP must take the attachment from the 07/20 version, complete it, and submit it with its 07/11 application.) If the OTP in this scenario fails to include the attachment, the contractor shall develop for it using the instructions in this chapter.

Example 6 – Using Example 5, suppose Jones enrolled as an OTP in September 2020. It submits a change of information using the 07/11 version of the Form CMS-855B on February 15, 2021. Jones need not submit the OTP attachment with its change request because no category in (A)(i) through (iii) above applies.

Example 7 – Using Example 6, assume Jones submitted its change request on April 15, 2021 rather than February 15. The contractor shall return the application because the 07/11 version is no longer in use; however, Jones need not submit the OTP attachment at that time because no category in (A)(i) through (iii) above applies.

(2) Submission When Not Required

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

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

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

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

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

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

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

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

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

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

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

(G) Appropriate Attachment Sections

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

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

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

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

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

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

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

7. Provider Agreement

i. Basic Requirement

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

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

ii. Criteria for Inapplicability

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

8. Locations

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

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

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

C. Approval

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

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

2. Process of Approval

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

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

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

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

3. Effective Date of Billing

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

For newly enrolling OTPs that are changing their enrollment from a Form CMS-855B to a Form CMS-855A (or vice versa), the contractor shall apply to the new/changed enrollment the same effective date of billing that was applied to the OTP's initial/former enrollment.

(See 42 CFR § 424.67(c)(2).) To illustrate, suppose an OTP initially enrolled via the Form CMS-855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020 the OTP elects to end its Form CMS-855B enrollment and enroll via the Form CMS-855A pursuant. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS-855A enrollment would be retroactive to April 1, 2020 (though the time limits for filing claims found in § 424.44 would continue to apply).

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

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

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

10.6.12 – Opting-Out of Medicare

(Rev. 10909; Issued: 08-10-21; Effective: 08-13-21; Implementation: 09-13-21)

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

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

A. Who May Opt-*O*ut of Medicare

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

Physicians who are:

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

Non-physician *p*ractitioners who are:

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

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

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

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

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

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, *c*hapter 15, *s*ection 40.9, the affidavit shall state that*,* upon signing the affidavit, the eligible practitioner agrees to the following requirements:

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

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

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

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

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

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

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

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

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

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

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

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

- Full name (first, middle and last),
- Birthdate,

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

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

2. Opting-Out and Ordering*/Certifying/Referring*

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

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

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

3. Adverse Actions

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

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

4. No Dual Status

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

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

returned. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

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

5. Acceptable Opt-Out Affidavit Formats

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Effective Date of an Opt-Out Period

As noted in Pub. 100-02, *c*hapter 15, *s*ection 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

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

2. Non-Participating Practitioners

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

3. Participating *Practitioners*

If *an* eligible practitioner *who* is a participating provider (one *who* accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next

calendar quarter. An opt-out affidavit must be received at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is received within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, *for* the affidavit was not received 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating /supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

D. Emergency and Urgent Care Services

If an eligible practitioner *who* has opted-out provides emergency or urgent care services, he/she must *apply for enrollment via* the Form CMS-855I. Once *he/she* receive*s* his/her PTAN, he/she must submit the claim(s) for any emergency or urgent care service *furnish*ed. *The contractor* shall contact *its* PEOG BFL for additional guidance when this type of situation arises. (See Pub. 100-02, *c*hapter 15, *s*ection 40.28 for more information on *e*mergency and *u*rgent *c*are *s*ervices.)

E. Termination of an Opt-Out Affidavit

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

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

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

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

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

1. General Policies

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

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

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

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

The *contractor* shall issue an Opt-Out Renewal Alert Letter (found in *s*ection 10.7.1*4*(*E*) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. *For this purpose,* CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The *contractor* shall access the report monthly through the Share Point Ensemble site. The *contractor* shall *also* review the opt-out report for opted-out eligible practitioners that will auto-renew in the next *three*-and-a-half months. *In addition, the contractor* shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date*;* the eligible practitioner *will thus* ha*ve* at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

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

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

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

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

renewal date, *the contractor* shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

H. Failure to Properly Cancel or Terminate Opt-Out

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

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

10.6.14 – Application Fees

(Rev. 10909; Issued: 08-10-21; Effective: 08-13-21; Implementation: 09-13-21)

A. Background

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

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

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR § 424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations), Form CMS-855S, Form CMS-20134 or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. A physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

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

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

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

B. Contractor Activities Upon Receipt

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

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

2. *Outcomes*

a. The provider has neither paid the fee nor submitted the hardship exception request-- *T*he contractor shall send a development letter to the provider notifying it that: *(i)* it has 30 days from the date of the letter to pay the application fee via Pay.gov and any other items that may be missing or needed; and *(ii)* failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

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

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

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

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

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

C. Fee Amount

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

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

D. Non-Refundable

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

1. A hardship exception request that is subsequently approved;

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

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

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

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

E. Format

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

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

F. Practice Locations

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

G. Other Application *Fee Policies*

1. PECOS Enrollment Records - The fee is based on the Forms CMS-855 and CMS-20134 application submission, not on how enrollment records are created in PECOS. For instance, suppose a hospital submits an initial Form CMS-855A. In the Identifying Information/hospital type section of the application, the hospital indicates that it has a psychiatric unit and a rehabilitation unit. Separate PECOS enrollment records must be

created for each unit. However, only one application fee is required because only one Form CMS-855A application was submitted.

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

3. **Change of Ownership via Form CMS-855B, *Form CMS-20134,* or Form CMS-855S -** A provider or supplier need not pay an application fee if the application is reporting a change of ownership via the Form CMS-855B, *Form CMS-20134,* or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

4. Reporting a *C*hange in *T*ax *I*dentification *N*umber

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

***5*. Requesting a Reactivation**

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

***6*. Changing the Physical Location of an Existing Practice Location**

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

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

H. Refund Requests

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

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

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

There may be isolated instances where, at the end of a calendar year, a provider pays the fee amount for that year (Year 1) *but* the submission date (for Internet-based PECOS applications) or the application postmark date (for paper applications) falls in the beginning of the following year (Year 2). Assuming that Year 2's fee is higher than Year 1's, the provider *must* pay the Year 2 fee. *T*he contractor shall *thus:* (1) send an e-mail to its PEOG BFL requesting a full refund of the fee and including any pertinent documentation in support of the request; and (2) send a letter to the provider notifying it that *(i)* it has 30 days from the date of the letter to pay the correct fee amount (i.e., the Year 2 amount) via Pay.gov and *(ii)* failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

J. Hardship Exception

1. Background

A provider requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 *or Form CMS-20134* application is submitted, the hardship exception letter must accompany the application; if the application is submitted via Internet-based PECOS, the hardship exception letter must accompany the certification statement. Hardship exception letters shall not be considered if they were submitted separately from the application or certification statement, as applicable. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider*;* and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

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

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

a. Considerable bad debt expenses,

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

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

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

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

Upon receipt of a hardship exception request with the application or certification statement, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG BFL. CMS has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. CMS will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 10.6.14(K) below.

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

K. Appeals of Hardship Determinations

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

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

The reconsideration request should be mailed to:

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

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

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

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

If CMS denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If CMS approves the reconsideration request, it will notify the provider of this

via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

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

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

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

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

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

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

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

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

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

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

10.6.20 – Screening: On-Site Inspections and Site Verifications

(Rev. 10909, Issued: 08-10-21; Effective: 08-13-21; Implementation: 09-13-21)

A. DMEPOS Suppliers and IDTFs

The scope of site visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

(For purposes of this section 10.6.20, the term "contractor" refers to the Medicare Administrative Contractor; the term "SVC" refers to the site visit contractor.)

B. Other Provider and Supplier Types

For all provider and supplier types – other than DMEPOS suppliers and IDTFs – that *must undergo* a site visit *pursuant to* this section 10.6.20 and *§* 424.518, the SVC will perform such visits consistent with the procedures in this section 10.6.20. This includes the following:

(1) Documenting the date and time of the visit, and including the name of the individual attempting the visit;

(2) Photographing the provider's or supplier's business for inclusion in the provider/supplier's file. All photographs will be date/time stamped;

(3) Fully documenting observations made at the facility, which could include facts such as (a) the facility was vacant and free of all furniture, (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company;

(4) Writing a report of the findings regarding each site verification; and

(5) Including a signed site visit report stating the facts and verifying the completion of the site verification.

In terms of the extent of the visit, the SVC will determine whether the following criteria are met: *(i) t*he facility is open*; (ii) p*ersonnel are at the facility*; (iii) c*ustomers are at the facility (if applicable to that provider or supplier type*); and (iv) t*he facility appears to be operational. This will require the site visitor(s) to enter the provider or supplier's practice location/site, rather than simply conducting an external review. If any of the *four* elements *((i) through (iv))* listed above are not met, the contractor will, as applicable - and using the procedures outlined in this chapter and in existing CMS instructions - deny the provider's enrollment application pursuant to § 424.530(a)(5)(i) or (ii), or revoke the provider's Medicare billing privileges under § 424.535(a)(5)(i) or (ii).

C. Operational Status

When conducting a site verification to determine whether a practice location is operational, the *SVC* shall make every effort to limit its verification to an external review of the location. If the *SVC* cannot determine whether the location is operational based on *this* external review, *it* shall conduct an unobtrusive site verification by limiting its encounter with provider or supplier personnel or medical patients.

The contractor must review and evaluate the site visit results received from the SVC prior to making a final determination. If it is determined *(*during the review and evaluation process*)* that *the* location is non-operational based on the site visit results but there is reason to proceed with the enrollment, the *contractor* shall provide the appropriate justification in the comment section of the Validation Checklist in PECOS. *(F*or example, a second site visit

determined the location to be operational; the provider only renders services in patient's homes; etc.).

If the *contractor* is unsure of how to proceed based on *its* evaluation of the site visit results, *it* shall contact *its* Provider Enrollment *&* Oversight Group (PEOG) Business Function Lead (BFL) and copy *its c*ontracting *o*fficer's *r*epresentative (COR).

D. Timing

Site verifications should be done Monday through Friday (excluding holidays) during their posted business hours. If there are no hours posted, the site verification should occur between 9 a.m. and 5 p.m. If, during the first attempt, there are obvious signs that *the* facility is no longer operational*,* no second attempt is required. If, on the first attempt*,* the facility is closed but there are no obvious indications *that* the facility is non-operational, a second attempt on a different day during *the* posted hours of operation should be made.

E. Documentation

*As indicated previously, w*hen conducting site verifications to determine whether a practice location is operational, the *SVC* shall:

(i) Document the date and time of the attempted visit and include the name of the individual attempting the visit;

(ii) As appropriate, photograph the provider/supplier's business for inclusion in the provider/supplier's file on an as-needed basis. All photographs should be date/time stamped;

(iii) Fully document all observations made at the facility (e.g., the facility was vacant and free of all furniture, a notice of eviction or similar documentation was posted at the facility, the space is now occupied by another company*, etc.*); and

(iv) Write a report of its findings regarding each site verification.

F. Determination

If a provider/supplier is determined not to be operational or in compliance with the regulatory requirements for its provider/supplier type, the contractor shall revoke the *provider/supplier's* Medicare billing privileges - unless the provider/supplier has submitted a change *of information request* that notified the contractor of a change in practice location. Within 7 calendar days of CMS or the contractor determining that the provider/supplier is not operational, the contractor shall update PECOS or the applicable claims processing system (if the provider*/supplier* does not have an enrollment record in PECOS) to revoke Medicare billing privileges and issue a revocation notice to the provider/supplier. The contractor shall afford the provider/supplier applicable appeal rights in the revocation notification letter.

For non-operational status revocations, the contractor shall use either 42 CFR § 424.535(a)(5)(i) or 42 CFR §424.535(a)(5)(ii) as the legal basis for revocation. Consistent with 42 CFR § 424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider or supplier is no longer operational. The contractor shall establish a 2-year enrollment bar for *providers/*suppliers that are not operational.

For regulatory non-compliance revocations, the contractor shall use 42 CFR § 424.535(a)(1) as the legal basis for revocation. Consistent with 42 CFR § 424.535(g), the date of revocation is the date on which CMS or the contractor determines that the provider/supplier is no longer in compliance with regulatory provisions for their provider/supplier type. The

contractor shall establish a 2-year enrollment bar for providers/suppliers that are not in compliance with provisions for their provider/supplier type.

G. Site Visits Performed by the National Supplier Clearinghouse (NSC)

The NSC shall continue to conduct onsite inspections consistent with its Statement of Work and any instructions issued by the NSC project officer.

H. Multiple Site Visits

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall not order a site visit if the specific location to be visited has already undergone a successful site visit within the last 12 months and the applicable provider/supplier is in an approved status.

Consider the following illustrations:

Example 1 - A single-site home health agency (HHA) undergoes a revalidation site visit on February 1. The HHA submits a change of information request on July 1 to add a branch location. The contractor shall order this site visit because the visit will occur at a location (i.e., the branch location) different from the main location (i.e., the location that underwent the February 1 revalidation visit).

Example 2 - A DMEPOS supplier undergoes a revalidation site visit on April 1. It submits an initial Form CMS-855S application on May 1 to enroll a second location. The new location shall undergo a site visit because: (1) it is different from the first (revalidated) location; and (2) it is/will be separately enrolled from the first location.

Example 3 - A physical therapy (PT) group has three locations – X, Y, and Z. As part of a revalidation, the contractor elects to order a site visit of Location Y, rather than X or Z. The visit was performed on June 1. On October 4, the group submits a Form CMS-855B to report a change of ownership, thus requiring a site visit under this chapter. However, the contractor shall not order a visit for Location Y because this site has been visited within the past 12 months. Location X or Location Z must instead be visited.

Example 4 - An IDTF undergoes an initial enrollment site visit on July 1. On September 24, it submits a Form CMS-855B application to change its practice location; this mandates a site visit under this chapter. The site visit shall be performed even though the initial visit took place within the past 12 months. This is because the second visit will be of the new location, whereas the first visit was of the old location.

I. Certified Providers/Suppliers – Address Validation Error

Notwithstanding any other instruction to the contrary in this chapter, the contractor need not order a site visit for a certified provider/supplier prior to making a recommendation to the state agency or CMS Survey & Operations Group location if an address validation error is received in PECOS. The contractor shall override the error message and notate in the referral package that the address was unverifiable. This avoids multiple site visits being performed (that is, pre-enrollment, survey, and post enrollment).

10.6.21 – Miscellaneous Enrollment Topics

(Rev. 10909; Issued: 08-10-21; Effective: 08-13-21; Implementation: 09-13-21)

This section 10.6.21 addresses additional provider enrollment policies. Except as otherwise stated, the instructions in this section supersede any other instructions to the contrary in this chapter.

A. Group and Reassignment Reactivation

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

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

B. Specialty Changes

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

C. Reassignments Related to Revoked or Deactivated Reassignee

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

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

D. Interstate License Compacts

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

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

At present, there are interstate compacts involving physicians, physical therapists, occupational therapists, speech language pathologists, nurse practitioners, and psychologists. More are possible.

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