CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10674	**Date: March 19, 2021**
	Change Request 12113

Transmittal 10560, dated January 20, 2021, is being rescinded and replaced by Transmittal 10674, dated March 19, 2021, to remove the provider education/MLN instruction deleting business requirement 12113.5. All other information remains the same.

SUBJECT: Second Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to-- (1) Incorporate additional policies and clarifications concerning the enrollment of OTPs in Medicare in Chapter 10 of Publication (Pub.) 100-08; and (2) Address the processing of Form CMS-855B attachments pertaining to prescribing, ordering, and dispensing OTP personnel.

EFFECTIVE DATE: January 4, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 29, 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	10/10.2/10.2.7/Opioid Treatment Programs

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: 10674	Date: March 19, 2021	Change Request: 12113

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SUBJECT: Second Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)

EFFECTIVE DATE: January 4, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 29, 2021

I. GENERAL INFORMATION

A. Background: On November 15, 2019, CMS published a final rule in the Federal Register (FR) titled, "Medicare Program; Calendar Year (CY) 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations" (84 FR 62567). The Final Rule, in part, established policies concerning the enrollment in Medicare of OTPs effective January 1, 2020; these policies were incorporated largely in new 42 Code of Federal Regulations (CFR) § 424.67. One such regulatory provision (42 CFR § 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 who are legally authorized to prescribe, order, or dispense controlled substances on the OTP's behalf. The Form CMS-855B has been revised to collect this information effective January 4, 2021.

This CR has two principal functions. First, it instructs contractors on the processing of the aforementioned Form CMS-855B attachment concerning prescribing, ordering, and dispensing individuals. Second, it further clarifies various OTP enrollment issues the contractors have recently raised; of particular importance are matters pertaining to individuals associated with the OTP who have had adverse legal actions imposed against them.

B. Policy: 42 CFR § 424.67, CY 2020 PFS Final Rule.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12113.1	The contractor shall contact its Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for guidance if the contractor determines that the OTP's medical director does not meet the licensure requirements specified in section 10.2.7(B)(5) in chapter 10 of Pub. 100-08.	X	X							
12113.2	Irrespective of the type of transaction involved, the contractor shall accept from the OTP: (1) The revised version of the Form CMS-855B beginning January 4, 2021; and (2) 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 chapter 10 of Pub. 100-08 and other applicable CMS		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	guidance.)									
12113.3	The contractor shall adhere to the specific instructions in Business Requirements (BRs) 12113.3.1 through 3.7 and the policies described in section 10.2.7(B)(6) in chapter 10 of Pub. 100-08 when processing the Form CMS-855B attachment regarding prescribing, ordering, and dispensing personnel.		X							
12113.3.1	The contractor shall develop (using the procedures outlined in chapter 10 of Pub. 100-08) for any data that is missing or unverifiable on the Form CMS-855B OTP attachment except as stated in BR 12113.3.2. (This includes individuals who the contractor learns (via any means) should be listed on the attachment but were not.)		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12113.3.2	With the exception of names and social security numbers, the contractor should forgo development of missing/unverifiable information on the Form CMS-855B OTP attachment if the data can be located and validated via other means.		X							
12113.3.3	The contractor shall not process the attachment and should either keep it in the provider file or return it to the OTP via the general procedures in chapter 10 of Pub. 100-08 for returning applications if the OTP submits Attachment 3 with its Form CMS-855A application.	X								
12113.3.3.1	Regardless of which optional approach the contractor takes pursuant to BR 12113.3.3, 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	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	by CMS.									
12113.3.3.2	The contractor shall process the attachment consistent with the instructions in section 10.2.7 of chapter 10 of Pub. 100-08 if the OTP submits Attachment 3 with its Form CMS-855B application for the first time as part of a change of information.		X							
12113.3.4	The contractor shall review all individuals listed on the Form CMS-855B OTP attachment against the Medicare Exclusion Database and the System for Access Management. (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 CMS-855B; it need not perform two separate reviews.)		X							
12113.3.5	The contractor shall contact its PEOG BFL for further guidance if the contractor determines in its screening that the individual falls		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	within one of the five categories listed in section 10.2.7(B)(6)(ii)(E) in chapter 10 of Pub. 100-08.									
12113.3.6	The contractor shall develop for the attachment using the instructions in chapter 10 of Pub. 100-08 if an OTP submits the 07/11 version of the Form CMS-855B and fails to include Attachment 3 in the circumstances described in section 10.2.7(B)(6)(A)(1)(i) through (iii) of chapter 10 of Pub. 100-08.		X							
12113.3.7	The contractor shall contact its PEOG BFL for guidance if the contractor becomes aware of one of the individuals described in section 10.2.7(B)(6)(iii) of chapter 10 of Pub. 100-08.		X							
12113.4	In cases where the OTP is changing its Form CMS-855 enrollment type, the contractor shall end-date/deactivate the	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	prior enrollment in the Provider Enrollment, Chain, and Ownership System (PECOS) using the following statuses: (1) The PECOS L & T basis shall be "Voluntary Termination"; and (2) The deactivation reason shall be "Voluntary withdrawal: Applicant voluntarily withdrew from Medicare program."									

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. 10674; Issued: 03-19-21)

10.2.7 - Opioid Treatment Programs

(Rev. 10674 ; Issued:03-19-21 ; Effective:01-04-21 ; Implementation:01-29-21)

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.

*T*he Form CMS-85*5B 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) and the 7/11 version of the Form CMS-855B,* 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).

1. 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.

2. 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).

3. 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.

4. 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).

5. 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.

C. Approval

1. No State Agency or Regional Office (RO) Involvement

Unlike with many entities that complete the Form CMS-855A, there is no *s*tate *a*gency or CMS RO involvement with OTP Form CMS-855A enrollments. Accordingly, no recommendations for approval or other type of referral need be made to the State or RO nor will the CMS RO 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.