CMS Manual System	Department of Health & Human Services (DHHS)				
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)				
Transmittal 11574	Date: August 25, 2022				
	Change Request 12789				

SUBJECT: Sixth General Update to Provider Enrollment Instructions in Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 10 of Pub. 100-08, PIM, with new or clarifying instructions regarding the processing of certain Medicare provider enrollment applications and transactions.

EFFECTIVE DATE: June 24, 2022

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: September 27, 2022

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.2/10.2.1.1/Community Mental Health Centers (CMHCs)
R	10/10.2/10.2.1.2/Comprehensive Outpatient Rehabilitation Facilities (CORFs)
R	10/10.2/10.2.1.6/Home Health Agencies (HHAs)
R	10/10.2/10.2.1.6.1/HHA Ownership Changes
R	10/10.2/10.2.1.11/Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)
R	10/10.2/10.2.1.14/Skilled Nursing Facilities (SNFs)
R	10/10.2/10.2.2.1/Ambulatory Surgical Centers (ASCs)
R	10/10.2/10.2.2.4/Independent Diagnostic Testing Facilities (IDTFs)
R	10/10.2/10.2.2.8/Portable X-Ray Suppliers (PXRSs)
R	10/10.2/10.2.3.12/Physician Assistants
N	10/10.4/10.4.2.3.4/Denial Based on Survey Failure
R	10/10.4/10.4.3/Voluntary and Involuntary Terminations
R	10/10.4/10.4.8/Deactivations
R	10/10.6/10.6.1.1.3.1/Step 1 - Initial Review of the CHOW Application
R	10/10.6/10.6.1.3/Voluntary Terminations
R	10/10.6/10.6.12/Opting-Out of Medicare
R	10/10.7/Model Letters
R	10/10.7/10.7.4/DME Approval Letter Templates
R	10/10.7/10.7.5/Part A/B Certified Provider and Supplier Approval Letter Templates
R	10/10.7/10.7.5.1/Part A/B Certified Provider and Supplier Letter Templates – Post-Transition
N	10/10.7/10.7.5.1.1/Additional Certified Provider and Certified Supplier Letters

III. FUNDING:

For Medicare Administrative Contractors (MACs):

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

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-08 | Transmittal: 11574 | Date: August 25, 2022 | Change Request: 12789

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IMPLEMENTATION DATE: September 27, 2022

I. GENERAL INFORMATION

A. Background: Chapter 10 of Pub. 100-08, PIM, outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR will clarify several provider enrollment topics, mostly involving certified providers and certified suppliers.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		Α	/B N	MAC	DME	Shared-System Maintainers			Other	
		A	В	ННН		FISS	MCS	VMS	CWF	
					MAC					
12789.1	The contractor	X		X						
	shall use the									
	appropriate letter									
	in Section 10.7.5.1									
	in Chapter 10 of									
	Pub. 100-08 in									
	Home Health									
	Agency 36-month									
	rule situations									
	where no exception									
	applies.									
12789.2	As stated in		X							
	Section									
	10.2.2.4(A)(2)(ii)									
	in Chapter 10 of									
	Pub. 100-08, the									
	contractor shall not									
	establish its own									
	additional									
	certification,									
	credentialing, or									
	similar technician									
	requirements for									
	indirect									
	independent									
	diagnostic testing									

Number	Requirement	Responsibility								
		A/B MAC		DME Shared-System Maintainers					Other	
		A	В	ННН		FISS	MCS	VMS	CWF	
					MAC					
	facilities above and									
	beyond the									
	requirements in 42									
	Code of Federal									
	Regulations §									
	410.33(c)(2).									
12789.3	The contractor	X	X	X						
	shall abide by the									
	instructions in									
	Section 10.4.2.3.4									
	in Chapter 10 of									
	Pub. 100-08									
	regarding provider									
	enrollment denials									
	based on a certified									
	provider or									
	supplier survey									
	failure.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsibility	7	
			A/	Έ	DME	CEDI
			MA	AC		
					MAC	
		A	В	ННН		
	None					

IV. **SUPPORTING INFORMATION**

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

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: $\ensuremath{\mathrm{N/A}}$

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. 11574; Issued: 08-25-22)

Transmittals for Chapter 10

10.4.2.3.4 – Denial Based on Survey Failure 10.7.5.1.1 – Additional Certified Provider and Certified Supplier Letters

10.2.1.1 - Community Mental Health Centers (CMHCs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

A CMHC is a facility that provides mental health services. A CMHC must perform certain "core services." These are:

- 1. Outpatient services (This includes services for (a) children, (b) the elderly, (c) persons who are chronically mentally ill, and (d) certain persons who have been discharged from a mental health facility for inpatient treatment.)
- 2. 24-hour-a-day emergency psychiatric services;
- 3. Day treatment or other partial hospitalization (PH) services, or psychosocial rehabilitation services; and
- 4. Screening for patients being considered for admission to state mental health facilities.

NOTE: Partial hospitalization is the only core service for which a CMHC can bill Medicare as a CMHC. Thus, while a facility must furnish certain "core" services in order to qualify as a CMHC, it can only get reimbursed for one of them – partial hospitalization. However, the facility may still be able to enroll in Medicare as a Part B clinic if it does not perform partial hospitalization services.

In some instances, these core services can be furnished under arrangement. This generally means that the facility can arrange for another facility to perform the service if, among other things, CMS determines that the following conditions are met:

- The CMHC arranging for the particular service is authorized by State law to perform the service itself;
- The arranging CMHC accepts full legal responsibility for the service; and
- There is a written agreement between the two entities

While the CMHC generally has the option to furnish services under arrangement, there is actually an instance where the facility must do so. If the CMHC is located in a state that prohibits CMHCs from furnishing screening services (service (4) above), it must contract with another entity to have the latter perform the services. Any such arrangement must be approved by the SOG Location. (See CMS Pub. 100-07, State Operations Manual, chapter 2, section 2250 for additional information on core services and arrangements.)

A CMHC must provide mental health services principally to individuals who reside in a defined geographic area (service area); that is, it must service a distinct and definable community.

B. Initial Enrollment and Certification

1. Introduction

As of October 29, 2014, CMHCs are required to meet the conditions of participation outlined in 42 CFR Part 485, subpart J. CMHCs, like many other types of certified providers and certified suppliers, are therefore required to undergo a state survey as part of the certification and enrollment process. The SOG Location no longer performs the site visit nor does the

CMHC need to submit the previously-required attestation statement. Except as otherwise noted in this chapter 10 or in another CMS directive, CMHC initial applications shall – on and after October 29, 2014 - be processed in the same manner as those for all other certified providers.

2. Processing Instructions for CMHC Initial Form CMS-855A Applications

In the past, the SOG Location had vital functions in reviewing CMHC requests for Medicare participation and finalizing CMS' decision. With the transition of certain SOG activities to the state agencies, the contractors, and CMS PEOG, however, the operational process of reviewing CMHC requests for participation and enrollment now generally involves (and with exceptions) the following:

- The contractor sends the enrollment application (and all supporting documentation) and its recommendation for approval to the state for review
- The state notifies the contractor of its recommendation
- A site visit is performed
- The contractor notifies PEOG of the recommendation. PEOG signs the provider agreement and performs other administrative functions pertaining to the enrollment
- Once PEOG completes the required administrative actions, PEOG will notify the contractor thereof
- The contractor completes processing and notifies the provider of the approval of the transaction using the appropriate model letter (sending a copy thereof to the state).

(<u>Thus</u>, and except as otherwise stated, <u>SOG Locations</u> are no longer involved in the <u>CMHC</u> initial application process for Form <u>CMS-855As.</u>)

Specific details on these steps are outlined in this section 10.2.1.1(B)(2). Said instructions take precedence over any conflicting processing directives in this chapter.

i. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter.
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (C) Ensure that the CMHC has submitted all documentation otherwise required per this chapter. For CMHC initial enrollment, this also includes the following:
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

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

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

ii. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.1(B)(2) prohibits the contractor from returning or rejecting the CMHC application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.1(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

iii. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (B)(3)(a) below need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.1(B)(2)(ii)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (B)(3)(a) below.

If the CMHC fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(ii)(B) above. If the CMHC passes the site visit, the contractor shall (within 3 business days of completing its review of the results) send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

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

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

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

3. Site Visits

a. Initial Enrollment

The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter; the National Site Visit Contractor (NSVC) will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.

b. Practice Locations

Each CMHC location must separately and independently meet the CMHC conditions of participation in 42 CFR Part 485, subpart J. Accordingly, a CMHC must separately enroll each of its practice locations. It cannot have multiple locations on a single application.

If a CMHC is changing its physical location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not switch the provider's enrollment record to "Approved" prior to the completion of the NSVC's site visit and the contractor's review of the results.

c. Revalidation Site Visits

If the CMHC submits a Form CMS-855A revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with section 10.6.20 of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.

C. CMHC 40 Percent Rule

Effective October 29, 2014, under § 485.918(b)(1) a CMHC must provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Social Security Act; this is measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC in the applicable timeframe.

Pursuant to this requirement, a CMHC is required to submit to CMS a certification statement provided by an independent entity (such as an accounting technician). The document must certify that the entity has reviewed the CMHC's client care data for:

- Initial enrollments: The CMHC meets the 40 percent requirement for the prior 3 months.
- Revalidations: The CMHC meets the 40 percent requirement for each of the intervening 12-month periods between initial enrollment and revalidation.

The statement must be submitted as part of any initial enrollment or revalidation (including off-cycle revalidations).

When processing the application, the contractor shall abide by the following:

1. Contractor Does Not Receive the Certification

If the contractor does not receive the certification with the Form CMS-855, the contractor shall develop for the certification as it would with any other form of required supporting documentation. If the CMHC fails to submit the certification within the applicable time period, the contractor shall follow the instructions in section 10.4.1.4.3 of this chapter.

2. Contractor Receives the Certification

If the contractor receives the certification with the Form CMS-855 or timely receives the certification as part of a development request, the contractor shall review the certification to ensure that it complies with § 485.918(b)(1) and the provisions of this section 10.2.1.1(C). If the certification is compliant, the contractor shall continue processing the application; if the certification is not compliant, the contractor shall deny the application or, if it chooses, develop for a revised certification.

Section 10.2.1.1(C) does not apply if the contractor determines that the Form CMS-855 can be returned under section 10.4.1.4.2 of this chapter.

If the contractor exceeds applicable timeliness standards due to the instructions in this section 10.2.1.1(C), the contractor shall accordingly document the provider file consistent with section 10.6.19(H) of this chapter.

3. Special Guidelines

The following additional guidelines concerning certification apply:

- (i) As previously indicated, an appropriate official of the certifying entity must sign the document. (Notarization is not required unless CMS requests it.) Such persons may include accounting technicians, CEOs, officers, directors, etc.
- (ii) The certification should be on the certifying entity's letterhead or should otherwise indicate that the document is clearly from the entity.
- (iii) The contractor shall include the certification in the recommendation package it sends to the state agency.

Unless CMS instructs the contractor otherwise, the appropriate denial bases for failing to comply with § 485.918(b)(1) are §§ 424.530(a)(1) and 485.918(b)(1). The appropriate revocation bases are §§ 424.535(a)(1) and 485.918(b)(1). In cases involving the latter, CMS will determine the appropriate re-enrollment bar length under § 424.535(c) and will notify the contractor thereof.

D. CHOWs and Changes of Information

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

E. Additional Information

For more information on CMHCs, refer to:

- Section 1861(ff) of the Social Security Act
- 42 CFR §§ 410.2, 410.43, and 410.110
- Pub. 100-07, chapter 2, sections 2250 2251F
- 42 CFR § 489.18(b)(1)

10.2.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. Specific examples of such services include:

- Physician services (*)
- Physical therapy (*)
- Occupational therapy
- Respiratory therapy
- Speech pathology
- Social work or psychological services (*)
- Prosthetic/orthotic devices
- Lab services (must meet 42 CFR Part 493 requirements)

(* Services that the CORF must provide)

In addition:

- If the state determines that sufficient functional and operational independence exists, a CORF may be able to share space with another Medicare provider. However, the CORF may not operate in the same space at the same time with another Medicare provider. (See Pub. 100-07, chapter 2, sections 2364 2364C for more information.)
- Like most certified providers, CORFs must be surveyed by the state agency and must sign a provider agreement.
- On occasion, an outpatient physical therapy/speech language pathology location might convert to a CORF; prior to enrolling in Medicare, however, it must be surveyed to ensure that the CORF conditions of participation are met.

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

1. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter.
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (C) Ensure that the CORF has submitted all documentation otherwise required per this chapter. For CORF initial enrollment, this also includes the following:
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

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

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

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.2(B) prohibits the contractor from returning or rejecting the CORF application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.2(B)(2) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) The site visit described in subsection (D)(1) below need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.2(B)(2)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order the site visit described in subsection (D)(1) below.

If the CORF fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(B) above. If the CORF passes the site visit, the contractor (within 3

business days of completing its review of the results) shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

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

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

C. Offsite Locations – Initial Enrollment Applications

Notwithstanding the "single fixed location" language cited in section 10.2.1.2(A) above, there may be isolated cases where CMS or the state permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy, occupational therapy, or speech language pathology services away from the primary location. (This is permitted under 42 CFR § 485.58(e)(2)). The offsite location would not necessarily be separately surveyed but would be listed as a practice location on the CORF's initial Form CMS-855A application.

D. Site Visits

- 1. Initial application The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.
- 2. Revalidation If a CORF submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.
- 3. New/changed location If a CORF is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

E. CHOWs and Changes of Information

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

F. Additional Information

For more information on CORFs, refer to:

- Section 1861(cc) of the Social Security Act
- 42 CFR Part 485, Subpart B
- Pub. 100-07, chapter 2
- Pub. 100-07, Appendix K
- Pub. 100-02, Benefit Policy Manual, chapter 12

10.2.1.6 - Home Health Agencies (HHAs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Background

1. General Information

An HHA is an entity that provides skilled nursing services and at least one of the following therapeutic services: speech therapy, physical therapy, occupational therapy, home health aide services, and medical social services. The services must be furnished in a place of residence used as the patient's home.

Like most certified providers, HHAs receive a state survey (or a survey from an approved accrediting organization) to determine compliance with federal, state, and local laws) and must sign a provider agreement.

There are two potential "components" of an HHA organization:

Parent – The parent HHA is the entity that maintains overall administrative control of its location(s).

Branch – A branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the conditions of participation as an HHA; the branch can thus be listed as practice locations on the main provider's Form CMS-855A. Though the branch receives a 10-digit CCN identifier, it bills under the parent HHA's CCN.

See Pub. 100-07, chapter 2 for more information on branches.

2. Out-of-State HHA Operations

Pub. 100-07, chapter 2, section 2184 states that when an HHA provides services across state lines:

• It must be certified by the state in which its CCN is based.

- The involved states must have a written reciprocal agreement permitting the HHA to provide services in this manner. In those states that have a reciprocal agreement, HHAs are not required to be separately approved in each state; consequently, they would not have to obtain a separate Medicare provider agreement/number in each state. HHAs residing in a state that does not have a written reciprocal survey agreement with a contiguous state are precluded from providing services across state lines; the HHA must establish a separate parent agency in the state in which it wishes to provide services.
- A CMS approved branch office may be physically located in a neighboring state if the state agencies responsible for certification in each state approve the operation.

See section 10.3.1(A)(1)(d)(iii) of this chapter for additional information regarding the enrollment of out-of-state HHA locations.

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

1. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter
- (C) Ensure that the HHA has submitted all documentation otherwise required per this chapter. For HHA initial enrollment, this also includes the following:
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

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

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

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.6(B) prohibits the contractor from returning or rejecting the HHA application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.6(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) A site visit need not be performed. No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.6(B)(2)(B) above.

(B) Approval Recommended

If the state recommends approval, it will typically (though not always) do so via a Form CMS-1539; the contractor may accept any documentation from the state signifying that the latter recommends approval. (Note that the contractor will not receive a formal tie-in notice.) No later than 5 business days after receiving the state's recommendation, the contractor shall commence the following activities:

- (i) Order a site visit
- (ii) Undertake the 3rd capitalization review discussed in section 10.6.1.2.2 of this chapter.
- (iii) Ensure that each entity and individual listed in Sections 2, 5 and 6 of the HHA's Form CMS-855A application is again reviewed against the Medicare Exclusion Database (MED) and the System for Award Management (SAM). (This activity applies: (1) regardless of whether the HHA is provider-based or freestanding; and (2) only to initial enrollments).)

- a. The HHA is still in compliance (e.g., no owners or managing employees are excluded/debarred; capitalization is met; site visit is passed): No later than 3 business days after all of these activities are complete (i.e., the 3-day period begins when the last of the three activities has been completed), the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:
- The Form CMS-855 application (or PECOS Application Data Report) and all applicable documents
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

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

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

b. The HHA is not in compliance (e.g., the HHA does not meet one of the requirements): The contractor shall deny the application in accordance with the instructions in this chapter.

C. Site Visits

- 1. Initial application –The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.
- 2. Revalidation If an HHA submits a revalidation application, the contractor shall order a site visit through PECOS. This is to ensure that the provider is still in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the revalidation application prior to the completion of the NSVC's site visit and the contractor's review of the results.
- 3. New/changed location If an HHA is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information.) This is to ensure that the new/changed location complies with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Nursing Registries

If the HHA checks "Yes" in Section 12B of the Form CMS-855A, the contractor shall ensure that the information furnished about the HHA nursing registry is accurate. (A nursing registry is akin to a staffing agency, whereby a private company furnishes nursing personnel to hospitals, clinics, and other medical providers.)

E. Recommendation before New HHA Location Established

If an HHA is adding a branch or changing the location of its main location or an existing branch, the contractor may make a recommendation for approval to the state prior to the establishment of the new/changed location (notwithstanding any other instruction in this chapter to the contrary). If the contractor opts to make such a recommendation prior to the establishment of the new/changed location, it shall note in its recommendation letter that the HHA location has not yet moved or been established.

F. CHOWs and Changes of Information

HHA changes of ownership shall be processed in accordance with, as applicable, section 10.2.1.6.1 or section 10.6.1.1. HHA changes of information shall be processed in accordance with section 10.6.1.2.

G. Additional Information

For more information on HHAs, refer to:

- Sections 1861(o) and 1891 of the Social Security Act
- 42 CFR Part 484
- 42 CFR § 489.28 (capitalization)
- Pub. 100-07, chapter 2
- Pub. 100-04, chapter 10
- Pub. 100-02, chapter 7

10.2.1.6.1 – HHA Ownership Changes

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Background – 36-Month Rule

1. General Principles

Effective January 1, 2011, and in accordance with 42 CFR § 424.550(b)(1), if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of § 424.510, and
- Obtain a state survey or an accreditation from an approved accreditation organization.

For purposes of § 424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR § 424.502) occurs when an individual or organization acquires more than a 50 percent direct

ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

2. Exceptions

There are several exceptions to § 424.550(b)(1). Specifically, the requirements of § 424.550(b)(1) do not apply if:

- The HHA has submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)
- The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- The HHA is changing its existing business structure such as from a corporation, a partnership (general or limited), or a limited liability company (LLC) to a corporation, a partnership (general or limited) or an LLC and the owners remain the same.
- An individual owner of the HHA dies.

In addition, § 424.550(b)(1) does not apply to "indirect" ownership changes.

3. Timing of 36-Month Period

As indicated earlier, the provisions of 42 CFR § 424.550(b)(1) and (2) (as enacted in "CMS-6010-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule") became effective January 1, 2011. This means these provisions impact only those HHA ownership transactions whose effective date is on or after January 1, 2011. However, the provisions can apply irrespective of when the HHA first enrolled in Medicare. Consider the following illustrations:

- Example 1 Smith HHA initially enrolled in Medicare effective July 1, 2009. Smith underwent a change in majority ownership effective September 1, 2011. The provisions of § 424.550(b)(1) applied to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.
- Example 2 Jones HHA initially enrolled in Medicare effective July 1, 2007. Jones underwent a change in majority ownership effective February 1, 2019. Section 424.550(b)(1) did not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, that Jones underwent another change in majority ownership effective February 1, 2020. Section 424.550(b)(1) applied to this transaction because it took place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2019).
- Example 3 Davis HHA initially enrolled in Medicare effective July 1, 2012. It underwent its first change in majority ownership effective December 1, 2015. This change was not affected by §424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis underwent another change in majority ownership

effective July 1, 2019. This change, too, was unaffected by § 424.550(b)(1), for it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on December 1, 2015). Davis underwent another majority ownership change on July 1, 2020. This change was impacted by § 424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on July 1, 2019).

B. Determining the 36-Month Rule's Applicability

If the contractor receives a Form CMS-855A application reporting an HHA ownership change (and unless a CMS instruction or directive states otherwise), it shall undertake the following steps:

Step 1 – Change in Majority Ownership

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and
- The change involves a party assuming a greater than 50 percent ownership interest in the HHA

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of three ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA, this would constitute a change in majority ownership. This is consistent with the verbiage in the aforementioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc. Another example of a change in majority ownership would be if a 50 percent owner obtains any additional amount of ownership (regardless of the percentage) and hence becomes a majority owner; thus, for instance, if a 50 percent owner were to acquire an additional .001 percent ownership stake, he or she becomes a majority owner and the transaction involves a change in majority ownership.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally (which will typically be as a change of information under 42 CFR § 424.516(e)). If it does qualify, the contractor shall proceed to Step 2:

Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's (1) initial enrollment in Medicare or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA – regarding the effective date of the HHA's most recent change in majority ownership, if applicable.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a

change of information under 42 CFR § 424.516(e) or as a potential change of ownership under 42 CFR § 489.18.

If the transfer's effective date falls within one of these 36-month timeframes, the contractor shall proceed to Step 3.

Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall determine whether any of the exceptions in § 424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

- i. The HHA has submitted 2 consecutive years of full cost reports.
- (A) For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. (See 42 CFR § 413.24(h) for a definition of low Medicare utilization.)
- (B) The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer; and (2) accepted by the contractor.
- ii. The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- iii. The HHA is changing its existing business structure such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC and the owners remain the same.
- (A) If the HHA is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its PEOG Business Function Lead (BFL) for guidance.
- (B) For the exemption to apply, the owners must remain the same.
- iv. An individual owner of the HHA dies regardless of the percentage of ownership the person had in the HHA.

Step 4 - Determination

If the contractor concludes that one of the aforementioned exceptions applies (and unless a CMS instruction or directive states otherwise), it may process the application normally; specifically, the contractor shall, as applicable and depending upon the facts of the case, process the application as a change of information under 42 CFR § 424.516(e) (via the instructions in section 10.6.1.2 of this chapter) or as a potential change of ownership under 42 CFR § 489.18 (via the instructions in section 10.6.1.1 of this chapter).

If no exception applies, the contractor shall refer the case to its PEOG BFL for review. Under no circumstances shall the contractor apply the 36-month rule to the HHA and require an initial enrollment based thereon without the prior approval of PEOG. If PEOG agrees with the contractor's determination:

- (1) PEOG will terminate the seller in ASPEN.
- (2) The contractor shall identify the voluntary termination action in PECOS as a deactivation ---- and hence shall deactivate the HHA's billing privileges pursuant to § 424.540(a)(8) ---

with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per \S 424.540(d)(1)(ii)(E), the effective date of the deactivation shall be the date of the sale.

- (3) The contractor shall send to the HHA the "36-Month Rule Voluntary Termination Letter" in section 10.7.5.1. This letter will include, among other things, rebuttal rights regarding the deactivation as well as language stating that, as a result of § 424.550(b)(1), the HHA must:
- Enroll as an initial applicant; and
- Obtain a new state survey or accreditation survey after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the state.

(4) The HHA need not submit a Form CMS-855A voluntary termination application.

Providers and/or their representatives (e.g., attorneys, consultants) shall contact their local MAC with any questions concerning (1) the 36-month rule in general and (2) whether the rule and/or its exceptions apply in a particular provider's case.

C. Additional Notes

The contractor is advised of the following:

- 1. If the contractor learns of an HHA ownership change by means other than the submission of a Form CMS-855A application, it shall notify its PEOG BFL immediately.
- 2. If the contractor determines, under Step 3 above, that one of the § 424.550(b)(2) exceptions applies, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It underwent a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from § 424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA underwent another change in majority ownership that did not qualify for an exception. The HHA thus had to enroll as a new HHA under § 424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership even though the February 2012 change was exempt from § 424.550(b)(1).

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

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

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

As explained in Pub. 100-07, chapter 2 section 2292, there are three types of organizations that may qualify as providers of OPT and OSP services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CCN. The primary purpose of a rehabilitation agency is to improve or rehabilitate an injury or disability and to tailor a rehabilitation program to meet the specific rehabilitation needs of

each patient referred to the agency. A rehabilitation agency must provide, at a minimum, physical therapy and/or speech language pathology services to address those needs of the patients. Social/vocational services are no longer a requirement.

Note that:

- If an OPT/OSP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. An initial Form CMS-855A enrollment application, state survey, and CMS program approval are also required.
- Only those OTP/OSP providers covered under 42 CFR Part 485, Subpart H that furnish OPT/OSP services (as listed above) have provider agreements under 42 CFR § 489.2. Part B physician groups the supplier type that most people normally associate with the term "clinics" do not have certified provider or certified supplier agreements.
- Occupational therapy cannot be substituted for the physical therapy requirement. It may, however, be provided in addition to physical therapy or speech pathology services. (See Pub. 100-07, chapter 2, section 2292A.)

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

1. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter.
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (C) Ensure that the OPT/OSP has submitted all documentation otherwise required per this chapter. For OPT/OSP initial enrollment, this also includes the following:
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

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

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

2. Conclusion of Initial Contractor Review

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

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.1.11(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

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

(B) Approval Recommended

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

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

• The Form CMS-855 application (or PECOS Application Data Report) and all application attachments

- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the provider-signed Form CMS-1561
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

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

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

C. Extension Locations

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

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

If an OPT/OSP provider wants to add an extension site, a Form CMS-855A change of information request should be submitted.

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

D. CHOWs and Changes of Information

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

E. Additional Information

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

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

10.2.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. General Background Information

As stated in Pub. 100-07, chapter 7, section 7004.2, a SNF is a facility that:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or
- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons; while the care and treatment of mental disease is not the primary action of SNFs, the ability to provide appropriate resources and support for these beneficiaries is necessary;
- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under § 1866 of the Social Security Act); and
- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.

Like other certified providers, SNFs receive a state survey and sign a provider agreement.

SNFs cannot have multiple practice locations under one Form CMS-855A enrollment.

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

1. Receipt of Application

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

- (i) Perform all data validations otherwise required per this chapter.
- (ii) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (iii) Ensure that the SNF has submitted all documentation otherwise required per this chapter. For SNF initial enrollment, this also includes the following:
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic

documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

• A signed SNF patient transfer agreement. (See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Facility-Transfer-Agreement-Example.pdf for an example.)

(The SNF must complete, sign, date, and include the Form CMS-1561 and transfer agreement described above, though the SNF need not complete those sections of the forms reserved for CMS. For organizational SNFs, an authorized official (as defined in § 424.502) must sign the forms; for sole proprietorships, the sole proprietor must sign.)

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

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.1.14(B) prohibits the contractor from returning or rejecting the SNF application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

a. Approval Recommendation

If, consistent with the instructions in section 10.2.1.14(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. (This includes sending recommendations via hard copy mail if the state only accepts this method of transmission.) The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

b. Denial

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

3. Completion of State Review

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

a. Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification, therefore, the contractor shall commence the actions described in section 10.2.1.14(B)(2)(b) above.

b. Approval Recommended

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

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

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

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

Within 5 business days of receiving from PEOG the signed provider agreement, transfer agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement to the SNF; (2) send a copy of both the letter and the provider agreement sent to the state and/or AO (as applicable)); (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions; and (3) retain the provider-signed transfer agreement (which CMS does not counter-sign) on file.

C. SNF Distinct Parts

A SNF can be a separate institution or a "distinct part" of an institution. The term "distinct part" means an area or portion of an institution (e.g., a hospital) that is certified to furnish SNF services. The hospital and the SNF distinct part will each receive a separate CCN. Also:

- A hospital may have only one SNF distinct part.
- "Distinct part" designation is not equivalent to being "provider-based."

A SNF distinct part unit must enroll separately (i.e., it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed, and sign a separate provider

agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.)

D. Additional Information

For more information on SNFs, refer to:

- Section 1819 of the Social Security Act
- Pub. 100-07, chapter 7
- Pub. 100-02, chapter 8

10.2.2.1 – Ambulatory Surgical Centers (ASCs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

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

A. Background

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

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

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

- The ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met;
- In the case of deemed status through accreditation by a national accrediting body, where state law requires licensure, the ASC complies with state licensure requirements; and
- The ASC authorizes the release to CMS of the findings of the accreditation survey.

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

B. Processing Instructions for ASC Initial Form CMS-855B Applications

1. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter.
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (C) Ensure that the ASC has submitted all documentation otherwise required per this chapter. For ASC initial enrollment, this also includes the following:
- Form CMS-370 (ASC supplier agreement)
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

(The ASC must complete, sign, date, and include the Form CMS-370, though the ASC need not complete those sections of the form reserved for CMS. For organizational ASCs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if the Form CMS-370 or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.2.1(B) prohibits the contractor from returning or rejecting the ASC application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.2.1(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

The state will: (1) review the recommendation package for completeness; (2) review the contractor's recommendation for approval; (3) perform any state-specific functions; and (4)

contact the contractor with any questions. The contractor shall respond to any state inquiry in Item (4) within 5 business days. If the inquiry involves the need for the contractor to obtain additional data, documentation, or clarification from the ASC, however, the timeframe is 15 business days; if the provider fails to respond to the contractor within this timeframe, it shall notify the state thereof. The contractor may always contact its PEOG BFL should it need the latter's assistance with a particular state inquiry.

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.2.1(B)(2)(B) above.

(B) Approval Recommended

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

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

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the supplier Form CMS-370
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

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

C. Additional Enrollment Information

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

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

When enrolling the ASC, and except as otherwise stated in this chapter or as otherwise instructed by PEOG, the contractor shall use the effective date indicated on the state approval notice/letter (e.g. CMS-1539). This is the date from which the supplier can bill for services.

D. ASCs and Reassignment

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

E. ASCs Changes of Ownership (CHOWs) and Changes of Information

Though ASCs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving ASCs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For ASC CHOW processing instructions, see section 10.6.1.1 of this chapter.

The contractor shall process ASC changes of information in accordance with section 10.6.1.2 of this chapter.

F. Additional General ASC Information

For more information on ASCs, refer to:

- 42 CFR Part 416
- Pub. 100-07, chapter 2, section 2210 and Appendix L. (See Pub. 100-07, chapter 2, section 2210 for information regarding the sharing of space between ASCs and other providers and suppliers.)
- Pub. 100-02, Benefit Policy Manual, chapter 15, sections 260 260.5.3
- Pub. 100-04, chapter 14

G. ASCs and Hospitals

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

- Pub. 100-04, chapter 14, section 10.1
- Pub. 100-02, chapter 15, section 260.1

10.2.2.4 – Independent Diagnostic Testing Facilities (IDTFs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

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

A. Introduction

1. General Background

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

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

2. Place of IDTF Service

i. "Indirect IDTFs" - Background

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

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

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

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

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

- § 410.33(g)(8)) The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF.
- § 410.33(g)(9)) The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public.

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

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

iii. Synopsis

In sum:

- (A) IDTFs that perform direct, in-person testing on beneficiaries must still meet all requirements and standards in 42 CFR § 410.33. Also, the personnel performing these tests must comply with the requirements in § 410.33(c)(1).
- (B) Indirect IDTFs need not meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). The personnel performing these tests must comply with the requirements in § 410.33(c)(2) rather than § 410.33(c)(1).
- (C) If an IDTF performs both direct and indirect tests:
- It must meet the standards in § 410.33(g)(6), (g)(8), and (g)(9). An IDTF must exclusively and only perform tests involving no beneficiary interaction, treatment, or testing in order to be exempt from § 410.33(g)(6), (g)(8), and (g)(9). Thus, even if the overwhelming majority of the IDTF's tests are those described in the previous sentence, the aforementioned exemptions are inapplicable if the IDTF conducts any tests requiring direct, in-person patient interaction.
- Personnel performing direct patient interaction tests must meet the requirements of § 410.33(c)(1). Personnel conducting indirect, non-person tests must meet the requirements of § 410.33(c)(2). If a particular technician at an IDTF performs both categories of tests, he or she must meet § 410.33(c)(1)'s requirements for the direct, in-person tests and § 410.33(c)(2)'s requirements for the indirect, non-in-person tests.

- (D) The contractor will typically be able to determine during application processing whether the IDTF is an "indirect IDTF." This can be done via, for instance, reviewing: (1) the site visit results; or (2) the tests reported in Attachment 2 of the Form CMS-855B. In this matter, the contractor shall abide by the following:
- Unless there is evidence that the IDTF only performs indirect tests, the contractor may assume that the supplier is not an "indirect IDTF."
- If the contractor determines that the IDTF performs both indirect and direct tests, it shall follow the instructions described in this subsection (A)(2).

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

B. IDTF Standards

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

- 1. Operates its business in compliance with all applicable federal and state licensure and regulatory requirements for the health and safety of patients (\S 410.33(g)(1)).
- The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by state and/or federal agencies to make certain that guidelines and regulations are being followed and to ensure that businesses are furnishing quality services to Medicare beneficiaries.
- The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. No exemptions to applicable state licensing requirements are permitted, except when granted by the state.
- The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate state or federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.
- 2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and final adverse actions must be reported to the contractor within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days (§ 410.33(g)(2)).

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

3. Maintain a physical facility on an appropriate site. (For purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient

privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.) (§410.33(g)(3)).

- IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.
- The requirements in 42 CFR § 410.33(g)(3) take precedence over the guidelines in section 10.3.1(B)(1)(d) of this chapter pertaining to the supplier's practice location requirements.
- The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).
- 4. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—
- (i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;
- (ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request; and
- (iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days. (§ 410.33(g)(4)).
- 5. Maintain a primary business phone under the name of the designated business. The IDTF must have its –
- (i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.
- (ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance. (§ 410.33(g)(5)).

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

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

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

- (ii) Notify the CMS designated contractor in writing of any policy changes or cancellations. (§ 410.33(g)(6))
- 7. Agree not to directly solicit patients; this includes but is not limited to a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician who: (a) is furnishing a consultation or treating a beneficiary for a specific medical problem; and (2) uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth in § 410.32(a)(3). (§ 410.33(g)(7))
- By the signature of the authorized official in Section 15 of the Form CMS-855B, the IDTF agrees to comply with 42 CFR § 410.33(g)(7).
- The supplier is prohibited from directly contacting any individual beneficiary for the purpose of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.
- There is no prohibition on television, radio, or Internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.
- 8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:
- (i) The name, address, telephone number, and health insurance claim number of the beneficiary.
- (ii) The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.
- (iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision. ($\S 410.33(g)(8)$)
- 9. Openly post these standards for review by patients and the public. (§ 410.33(g)(9))
- 10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change. (\S 410.33(g)(10))
- 11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers' suggested maintenance and calibration standards. (§ 410.33(g)(11))
- 12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable federal or state licenses or certifications of the individuals performing these services. (§ 410.33(g)(12))
- 13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days. (§ 410.33(g)(13))
- 14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must---
- (i) Be accessible during regular business hours to CMS and beneficiaries; and

- (ii) Maintain a visible sign posting its normal business hours. (§ 410.33(g)(14))
- 15. With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:
- (i) Sharing a practice location with another Medicare-enrolled individual or organization;
- (ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or
- (iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (§ 410.33(g)(15))
- 16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed-base location. (§ 410.33(g)(16))
- 17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act (§ 410.33(g)(17)) (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as an agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

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

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

C. Leasing and Staffing

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

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

D. Sharing of Space and Equipment

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

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

E. Multi-State IDTFs

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

- a. Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the states in which it operates; and
- b. Operate in compliance with all applicable federal, state, and local licensure and regulatory requirements with regard to the health and safety of patients.

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

F. One Enrollment per Practice Location

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

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

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

G. Interpreting Physicians

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

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

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

The contractor shall ensure and document that:

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

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

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

2. Changes of Interpreting Physicians

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

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

H. Effective Date of IDTF Billing Privileges

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

- (1) The filing date of the Medicare enrollment application that was subsequently approved by the contractor; or
- (2) The date the IDTF first started furnishing services at its new practice location.

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

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

If an IDTF undergoes an ownership change that results in a new enrollment (e.g., a new federal tax information number (TIN) results from this change), the contractor should use the

transfer of ownership/business date as indicated by the IDTF, instead of establishing a new effective date.

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

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

J. IDTF Technician Licensure and Certification Requirements

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

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

K. IDTF - Changes of Technicians

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

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

L. IDTF Supervising Physicians – General Principles

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

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

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

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

M. IDTF - Information about Supervising Physicians

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

In addition:

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

N. IDTF - General, Direct, and Personal Supervision

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

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

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

O. IDTF - Attestation Statement for Supervising Physicians

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

that all codes listed in Section 2 are covered through the use of multiple supervising physicians.

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

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

P. IDTF - Changes of Supervising Physicians

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

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

Q. Desk and Site Reviews

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

- The information listed on Attachment 2 of the Form CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and enrollment requirements.
- To the extent applicable, the IDTF meets the criteria outlined in sections 10.6.20(A) and 10.6.20(B) of this chapter.
- The IDTF meets the supplier standards in 42 CFR § 410.33.

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

R. Mobile Units

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

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

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

S. Addition of Codes

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

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

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

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

T. IDTF That Performs Diagnostic Mammography

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

U. IDTF Ownership of CLIA Laboratory

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number may own both an IDTF and an independent CLIA laboratory. In such a situation, they should be separately enrolled and advised to bill separately. The contractor

shall also advise its claims unit to ensure that the CLIA codes are not being billed under the IDTF provider number.

10.2.2.8 – Portable X-Ray Suppliers (PXRSs)

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

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

A. Background

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

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

A PXRS does not have a supplier agreement.

B. Processing Instructions for PXRS Initial Form CMS-855B Applications

1. Receipt of Application

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

- (A) Perform all data validations otherwise required per this chapter.
- (B) Ensure that the application(s) is complete consistent with the instructions in this chapter.
- (C) Ensure that the PXRS has submitted all documentation otherwise required per this chapter. For PXRS initial enrollment, this also includes the following:
- Form CMS-1880 (Request for Certification as Supplier of Portable X-Ray Suppliers)
- Form CMS-1561 (Health Insurance Benefit Agreement, also known as a "provider agreement")
- Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)

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

Notwithstanding the foregoing, if the Form CMS-1561, the Form CMS-1880, or the Form HHS-690 evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete. For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

2. Conclusion of Initial Contractor Review

(Nothing in this section 10.2.2.8(B) prohibits the contractor from returning or rejecting the PXRS application if otherwise permitted to do so per this chapter. When returning or rejecting the application, the contractor shall follow this chapter's procedures for doing so.)

(A) Approval Recommendation

If, consistent with the instructions in section 10.2.2.8(B) and this chapter, the contractor believes an approval recommendation is warranted, the contractor shall send the recommendation to the state pursuant to existing practice and this chapter's instructions. The contractor need not copy the SOG Location or PEOG on the recommendation. Unless CMS directs otherwise, the contractor shall also send to the provider the notification letter in section 10.7.5.1(E) of this chapter.

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

(B) Denial

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

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) A site visit need not be performed. No later than 5 business days after receiving this notification, the contractor shall commence the actions described in section 10.2.2.8(B)(2)(B) above.

(B) Approval Recommended

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

No later than 5 business days after receipt of the recommendation from the state, the contractor shall order a site visit as described in this chapter.

If the PXRS fails the site visit, the contractor shall follow the denial procedures addressed in subsection (B)(2)(B) above. If the PXRS passes the site visit, the contractor shall (within 3

business days of completing its review of the results) send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents:

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments.
- A copy of the Form CMS-1539 or similar documentation received from the state
- A copy of the supplier-signed Form CMS-1880
- A copy of the draft approval letter, with the effective date shown on the Form CMS-1539 (or similar documentation) included in the draft letter. (See section 10.7.5.1 for the model approval letter.)

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

Within 5 business days of receiving from PEOG the signed provider agreement, effective date, and CCN, the contractor shall: (1) send the approval letter and a copy of the CMS-countersigned provider agreement (CMS-1561) to the PXRS; (2) send a copy of both the approval letter and the provider agreement to the state and/or AO (as applicable); and (3) switch the PECOS record from "approval recommended" to "approved" consistent with existing instructions.

C. Site Visits

- 1. Initial application –The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not convey Medicare billing privileges to the provider prior to the completion of the NSVC's site visit and the contractor's review of the results.
- 2. New/changed location If a PXRS is (1) adding a new location or (2) changing the physical location of an existing location, the contractor shall order a site visit of the new/changed location through PECOS no later than 5 business days after the contractor receives the approval recommendation from the state but before the contractor sends to PEOG the applicable e-mail described in section 10.6.1.2(A)(3) of this chapter. (See the latter section for more information. This is to ensure that the new/changed location is in compliance with CMS's enrollment requirements. The scope of the site visit will be consistent with sections 10.6.20(A) and 10.6.20(B) of this chapter. The NSVC will perform the site visit. The contractor shall not make a final decision regarding the change of information application prior to the completion of the NSVC's site visit and the contractor's review of the results.

D. Reassignment

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

E. Practice Location Information

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

• Whether it furnishes services from a "mobile facility" or "portable unit." (A PXRS can be either, though it usually is a portable unit.) A "mobile facility" typically describes a vehicle that travels from place to place to perform services <u>inside</u> the vehicle. Examples of such vehicles include mobile homes and trailers. A portable unit involves a supplier

transporting medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.

- Its base of operations. This is from where personnel are dispatched and where equipment is stored. It may or may not be the same address as the practice location.
- All geographic locations at which services will be rendered.
- Vehicle information if the services will be performed <u>inside</u> or <u>from</u> the vehicle. Unless stated otherwise in this chapter or in another CMS directive, copies of all licenses and registrations must be submitted as well.

F. Additional Enrollment Information

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

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

When enrolling the PXRS, and except as otherwise stated in this chapter or as otherwise instructed by PEOG, the contractor shall use the effective date that is indicated on the state approval letter/notice. This is the date from which the supplier can bill for services.

G. PXRS Changes of Ownership (CHOWs) and Changes of Information

Though PXRSs are not mentioned in 42 CFR § 489.18, CMS generally applies the CHOW provisions of § 489.18 to them. CHOWs involving PXRSs are thus handled in accordance with the principles in § 489.18 and Pub. 100-07, chapter 3, sections 3210 through 3210.5(C). For PXRS CHOW processing instructions, see section 10.6.1.1 of this chapter. The contractor shall process PXRS changes of information in accordance with section 10.6.1.2 of this chapter.

H. Additional Information

For more information on PXRSs, refer to:

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

10.2.3.12 – Physician Assistants

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

(The physician assistant (PA) enrollment instructions in this section 10.2.3.12 supersede all other PA-specific instructions in this chapter.)

A. PA Requirements Under § 410.74

Current federal regulations at 42 CFR §§ 410.74 discuss the requirements that a PA must meet.

Among the requirements for coverage of PA services outlined in 42 CFR §§ 410.74(a) are that the PA (as listed in §§ 410.74(a)(2)):

- (i) Meets the qualifications set forth in § 410.74(c);
- (ii) Is legally authorized to perform the services in the state in which they are performed;
- (iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;
- (iv) Performs the services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and PAs (including explicit supervisory or collaborative practice requirements) describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Social Security Act. For states with no explicit state law and scope of practice rules regarding physician supervision of a PA's services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physician(s) when furnishing professional services; and
- (v) Performs the services: (A) in all settings in either rural and urban areas; or (B) as an assistant at surgery.

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

- (1) Have graduated from a PA educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or
- (2)(i) Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and (ii) be licensed by the state to practice as a PA. (The PA need not be currently NCCPA-certified.)

B. PA Employer

Prior to January 1, 2022, payment for the PA's services could only be made to the PA's employer, not to the PA himself/herself. That is, the PA could not individually enroll in Medicare to receive <u>direct</u> payment for his or her services. This also meant that the PA could not reassign his or her benefits to the employer, for the employer must receive direct payment anyway. Pursuant to the CY 2022 Physician Fee Schedule Final Rule, however, a PA may:

- Individually enroll in Medicare (e.g., as a sole proprietorship, professional corporation)
- Receive direct payment for his/her services
- Establish PA groups (e.g., LLCs)
- Reassign his/her benefits to his/her employer.

The previous requirement that the PA's employer must bill for his/her services has hence been eliminated.

C. PA Enrollment Information

With the aforementioned change concerning PA employers (and except as stated in this subsection (C)), the contractor is advised of and/or shall adhere to the below policies, which are effective January 1, 2022. Although these policies can be applied to PA applications that are pending or in process as of January 1, 2022, it is important that the contractor adhere to the effective date instructions in subsection (C)(2)(e) below.

1. Newly enrolling, revalidating, and reactivating PAs shall complete the applicable Form CMS-855I sections to the same extent as would any other individual practitioner who is able to individually enroll in and bill Medicare.

2. Transactions

- a. <u>Initial Enrollment</u> If a PA is initially enrolling in Medicare and does not intend to reassign his/her benefits, he/she need not complete Section 2(I) of the Form CMS-855I. (The PA's practice location information, however, shall be furnished.)
- b. <u>Initial Enrollment</u> If a PA is initially enrolling in Medicare and intends reassign his/her benefits, the PA shall complete Section 2(I) with the name, PTAN (if assigned), NPI, and EIN of the employer/entity/supplier to which benefits will be reassigned. <u>With PECOS</u> <u>unable to accommodate Form CMS-855R PA reassignments at this time, Section 2(I) will effectively constitute a reassignment application in the interim</u>. (For purposes of this section 10.2.3.12, such situations will be labeled "PA payment arrangements.") Reassigned payments can therefore be made to the employer/entity/supplier listed in Section 2(I), similar to how employers have previously been paid for PA services.

Regarding verification, the contractor:

- Shall follow this chapter's existing instructions for validating PA employer information rather than those for Form CMS-855R submissions
- Shall apply the Form CMS-855I's effective date to the PA payment arrangement
- Consistent with existing policy concerning PA employers, shall confirm that the employer/entity/supplier is enrolled in Medicare
- Need not secure the employer/entity/supplier's signature to effectuate the PA payment arrangement (as occurs with Form CMS-855R reassignees)
- If Section 2(I) is blank, the contractor can assume that the PA seeks direct payment. If there is evidence to the contrary, however, the contractor can (via any means) ask the PA whether reassignment is or is not desired. If it is, the contractor shall develop for the completion of Section 2(I).

c. Change Request Involving Section 2(I)

On and after January 1, 2022, the contractor shall continue to pay the employer/entity/supplier listed in Section 2(I) unless or until the PA submits a Form CMS-855I that removes or changes the employer/entity/supplier. The contractor need not contact every enrolled PA upon the January 1, 2022 effective date to determine whether the PA wishes to continue his/her existing payment arrangement or instead receive payment directly. It is the PA's responsibility to report or change this data, if applicable, via the Form CMS-855I.

Form CMS-855Rs shall not be submitted to establish, change, or terminate a PA payment arrangement. If a Form CMS-855R is nonetheless submitted, the contractor shall not return the form; instead, the contractor shall place it in the provider file and develop with the PA for a Form CMS-855I change request that updates Section 2(I).

If, after a change request or other Form CMS-855I transaction, no employers/entities/suppliers are left in Section 2(I), payments shall be made directly to the PA.

d. Form CMS-855B

Effective January 1, 2022, PAs can establish PA group practices and be enrolled via the Form CMS-855B. The contractor shall process the Form CMS-855B in the same fashion it would any other group practice application, and the application shall be completed to the same extent as would any other such application. PA payment arrangements to the group (e.g., Section 2(I)) shall be processed consistent with the instructions in this subsection (C).

e. Effective Date

The effective date under § 424.520(d) and § 424.521(a) for PAs enrolling as sole proprietors/solely-owned entities and/or PA groups shall be on or after January 1, 2022 -- even if the application was received prior to that date and the effective date might thus otherwise be before January 1, 2022. In this latter situation, an effective date of January 1, 2022 is appropriate.

10.4.2.3.4 – Denial Based on Survey Failure (Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

(The instructions in this section 10.4.2.3.4 apply only if both of the following requirements are met:

- (i) The situation involves a certified provider/supplier initial enrollment denial based on the provider/supplier's failure of its state/accreditation survey (e.g., section 10.4.2.3.4 is inapplicable to revocations, changes of information involving a survey, etc.); and.
- (ii) The certified provider/supplier type in question has "transitioned" (as that term is described in this chapter).

Except as otherwise stated, section 10.4.2.3.4 takes precedence over any other instruction in this chapter to the contrary. (For instance, if a SNF fails its survey and the state notifies the contractor thereof, the contractor shall follow the instructions in this section 10.4.2.3.4 rather than those in section 10.2.1.14(B)(3)(a) of this chapter.) All other denials (e.g., survey denials for non-transitioned providers; denials for transitioned providers for reasons other than a survey failure) shall be handled consistent with the instructions in this chapter.)

A. Traditional Process – Survey Failure

The longstanding process for state/accreditation survey failures typically involved the following:

- (i) The SOG Location notifies the provider/supplier of the survey failure
- (ii) The provider/supplier is given up to two additional opportunities for resurvey within 6 months of the SOG notification in (i) above

- (iii) As applicable, no provider agreement, tie-in notice (CMS-2007), final denial notice, etc. from the SOG Location is issued unless or until the provider/supplier passes or fails the remaining survey(s) or the aforementioned 6-month period expires
- (iv) Depending on the results of (iii), the SOG Location issues a tie-in approval/denial notice to the contractor
- (v) The contractor finalizes the application
- (vi) The SOG Location handles any resulting reconsideration.

Regarding paragraph (A)(ii) above: (1) the applicant may submit no more than two additional requests for survey/certification; and (2) no more than 6 months may elapse between the date of the SOG Location's first denial and the CMS's receipt of the second request. Note, however, that isolated cases can arise when a subsequent survey is completed within the 6-month period but the SOG Location does not receive the results until after the 6-month period expires. This is acceptable because the actual survey would have occurred timely. Thus, references to a "6-month period" in this section 10.4.2.3.4 includes isolated instances where the SOG Location is awaiting survey results beyond the expiration of this period.

B. Revised Process for Transitioned Certified Providers/Suppliers

<u>Event 1 – Provider/Supplier Fails Initial Survey</u>

- (i) The state notifies the SOG Location and the contractor (typically via the CMS-1539) of the survey failure and the specific requirements the provider/supplier failed.
- (ii) Within 5 business days of receiving this notification copy from the state, the contractor shall send to the provider/supplier the denial letter in section 10.7.5.1.1 of this chapter. (Notwithstanding any other instruction in this chapter to the contrary, this particular letter need not be sent via certified mail.) The state, accreditation organization (if applicable), and SOG Location shall be copied on the letter.
- (iii) The letter shall include the reason(s) for the survey failure (from the CMS-1539) and reconsideration rights for said failure; the SOG Location will handle any reconsideration.
- (iv) The 6-month clock commences on the date of the letter in (B)(ii) above.
- (v) Once this letter is sent, no further action by the contractor is required at this time and the provider/supplier need not submit a new or revised application because of the survey failure. The enrollment application is not finalized but instead remains pending until the provider/supplier passes the survey or the six-month period has expired.

Event 2 – The 6-Month Period - Reconsiderations

- (i) If the provider/supplier submits a reconsideration and the survey failure is overturned because of a successful survey, the SOG Location will notify the provider/supplier thereof. (The SOG Location will also notify the contractor of the reversal via a CMS-1539 (or other approval notice).) The contractor shall follow the instructions in paragraph (i) in Event 3 below.
- (ii) If the survey failure is upheld on reconsideration, the SOG Location will notify the provider/supplier and the contractor thereof. The contractor need not take further action at

this time. During the above-referenced 6-month period, the state will perform no more than two additional surveys.

Event 3 – Final Decision

The state or SOG Location will notify the contractor of the final outcome of the 6-month period (e.g., survey is finally passed, provider fails subsequent survey). This could occur either before or after the exact date on which the 6-month period expired. The contractor is not required to internally track this 6-month period but need only wait for the state's or SOG Location's notification of the final outcome.

(i) Notice of Approval

If the state or SOG Location sends notice of its approval of the provider/supplier (e.g., subsequent survey passed; failure of the first survey was overturned on reconsideration), the contractor shall complete its processing of the application consistent with the instructions in this chapter regarding transitioned providers/suppliers. (To illustrate, if the provider is an HHA, the contractor shall follow the instructions in section 10.2.1.6(B).) In sending the appropriate approval letter, however, the contractor shall delete all references therein to provider agreement reconsiderations. This is because the provider/supplier has no further appeals rights related to the provider agreement.

(ii) Notice of Denial

If the state or SOG Location sends notice of its denial of the provider/supplier (e.g., the provider failed a subsequent survey(s); the provider did not file a reconsideration request regarding the first failed survey and/or no second survey was performed), the contractor shall follow the current denial instructions in this chapter for transitioned providers/suppliers.

10.4.3 – Voluntary and Involuntary Terminations

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Voluntary Terminations of Certified Providers and Certified Suppliers

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

B. Voluntary Terminations of Non-Certified Suppliers

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

- 1. Timeframes The contractor shall process such voluntary terminations in accordance with the timeframes in section 10.5 et seq. of this chapter.
- 2. Submission Non-certified suppliers may only submit voluntary termination requests via the paper or Internet-based Form CMS-855/20134. They cannot do so via letter.
- 3. Reassignments/PTANs When processing a voluntary termination of a reassignment, the contractor shall contact the group to confirm that: (1) the group member PTAN is being terminated from all locations; and (2) if multiple group member PTANs exist for multiple group locations, each PTAN is terminated. However, if a group has one PTAN with multiple addresses, the contractor need not contact the group to confirm the termination.

- 4. PECOS and Deactivations The contractor shall identify the voluntary termination action in PECOS as a deactivation with a status reason of "Voluntarily Withdrawal from the Medicare Program." Per 42 CFR § 424.540(a)(7), and unless stated otherwise in this chapter or in another CMS directive, the effective date of the deactivation (for system purposes) shall be the day after the date on which the supplier voluntarily withdrew from Medicare
- 5. Reassignments When processing a voluntary termination of a reassignment, the contractor shall terminate non-certified suppliers effective the day after that which the supplier requested on its termination application. (Note that this is different from a voluntary termination of the provider/supplier itself as addressed in subsection (B)(4) above.)
- 6. Special Payments Upon receipt of a non-certified supplier voluntary termination request, the contractor may ask the supplier to complete the "Special Payments" portion of Section 4 of the Form CMS-855/20134 so that future payments can be sent thereto. If the supplier has no special payments address already on file, the addition should be included in the same transaction as the termination (i.e., one transaction incorporating both items). If the supplier wants to change its existing special payments address, the transaction should be treated as a separate change request (i.e., one termination and one change request). The supplier is not required to submit a Form CMS-588 in conjunction with a termination.

C. Involuntary Terminations – Certified Providers/Suppliers

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

1. Notification from State or SOG Location

If the contractor receives a notice from the state or SOG Location that involuntarily terminates a certified provider/supplier's Medicare participation because the provider/supplier no longer meets the conditions of participation, the contractor need not send a letter to the provider/supplier stating that its Medicare participation has been terminated. The state or SOG Location will issue such a letter and afford appeal rights. The contractor shall follow the applicable instructions in section 10.4.7 et seq. of this chapter with respect to revoking the provider/supplier's enrollment, since the provider/supplier is no longer compliant with Medicare enrollment regulations. (NOTE: The contractor must identify in its revocation letter the exact provision within said statute(s)/regulation(s) with which the provider/supplier is non-compliant.)

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

2. Revocation Letter

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

3. Additional Information

For more information on voluntary terminations, refer to:

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

10.4.8 – Deactivations

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Bases for Contractor Action

Unless indicated otherwise in this chapter or in another CMS instruction or directive, the contractor shall – without prior approval from its PEOG BFL - deactivate a provider/supplier's entire enrollment record and Medicare billing privileges when:

- (i) The provider/supplier fails to respond to a revalidation request.
- (ii) The provider/supplier fails to respond timely to a revalidation development request.
- (iii) The provider/supplier is enrolled in an approved status with neither an active reassignment nor practice location for 90 days or longer. (The deactivation basis shall be 42 CFR § 424.540(a)(4), which permits deactivation if the provider/supplier is not in compliance with all enrollment requirements. See sections 10.4.8(B) and (D) below for more information on this new deactivation ground.)
- (iv) The provider/supplier deactivates an EFT agreement and remains enrolled but does not submit a new EFT agreement within 90 days. (The deactivation basis shall be 42 CFR § 424.540(a)(4).)
- (v) The provider/supplier is deceased, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the provider's/supplier's death; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(6) below.)
- (vi) The provider or supplier is voluntarily withdrawing from Medicare, and a situation arises where: (1) a particular instruction in this chapter calls for deactivation due to the voluntary withdrawal; and (2) said directive does not require obtaining PEOG approval prior to the deactivation. (See reference to 42 CFR § 424.540(a)(7) below.)

The contractor shall not take deactivation action except as specified and permitted in this chapter or other CMS directives.

B. Regulatory Reasons for Deactivation in § 424.540(a)

1. Grounds

Section 424.540(a) lists eight deactivation grounds:

Section 424.540(a)(1) - The provider/supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12-month period will begin the 1st day of the 1st month without a claim submission through the last day of the 12th month without a submitted claim.

Section 424.540(a)(2) - The provider/supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under Title 42. (For example, a provider/supplier type falling within the purview of § 424.516(e)(1) and (2) failed to report a change in ownership or control within (i) 30 calendar days of when the change occurred, or (b) 90 calendar days of when the change occurred for all other information on the enrollment application.)

If the provider/supplier submits a change of information and (a) it appears the change was not reported within 90 days of the change, (b) the contractor did not previously take administrative action against the provider/supplier, and (c) no revocation action is applicable, the contractor should process the change of information without deactivating the provider/supplier's enrollment.

<u>Section 424.540(a)(3)</u> - The provider/supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

<u>Section 424.540(a)(4)</u> - The provider/supplier is not in compliance with all enrollment requirements. (See section 10.4.8(D) below for more information.)

<u>Section 424.540(a)(5)</u> - The provider's/supplier's practice location is non-operational or otherwise invalid. (See section 10.4.8(D) below for more information.)

Section 424.540(a)(6) - The provider/supplier is deceased.

Section 424.540(a)(7) - The provider/supplier is voluntarily withdrawing from Medicare.

<u>Section 424.540(a)(8)</u> - The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

C. Effective Dates

(See § 424.540(d) for regulations concerning deactivation effective dates.)

The effective dates of *a* deactivation are as follows:

- a. Non-Billing (§ 424.540(a)(1)) Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the deactivation is imposed.
- b. Section 424.540(a)(2), (3), and (4) (see subsection (B) above) Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/ supplier became non-compliant (e.g., the day after the expiration of the 90-day period in which the provider was required to report a change of information).
- c. Section 424.540(a)(5) Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider's/supplier's practice location became non-operational or otherwise invalid.
- d. <u>Section 424.540(a)(6)</u> Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of death of the provider/supplier.
- e. <u>Section 424.540(a)(7)</u> Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date on which the provider/supplier voluntarily withdrew from Medicare.

f. <u>Section 424.540(a)(8)</u> - Unless stated otherwise in this chapter or in another CMS directive, the effective date is the date of the sale. (Note that PEOG will ultimately determine this effective date during its review of the case per subsection (F) below.)

(See subsection 10.4.8(E) below for *additional* information on § 424.540(a)(7). *See subsection 10.4.8(F) below for additional information on § 424.540(a)(8)).*

D. Sections 424.540(a)(4) and (a)(5)

(This section 10.4.8(D) is inapplicable to the situations described in section 10.4.8(A)(iii) and (iv). These two scenarios do not require any referral to PEOG; the contractor can take deactivation action on its own volition.)

The grounds for deactivation under § 424.540(a)(4) and (a)(5) mirror the revocation reasons described in, respectively, § 424.535(a)(1) and (a)(5). When sending a potential § 424.535(a)(1) and (a)(5) revocation case to PEOG for review per section 10.4.7.1(A) of this chapter, PEOG will determine whether a revocation or a deactivation (under § 424.540(a)(4) or (a)(5)) is appropriate. The contractor shall not deactivate a provider or supplier under § 424.540(a)(4) or (a)(5) unless PEOG specifically directs the contractor to do so. Moreover, the contractor need not refer a potential § 424.540(a)(4) and (a)(5) deactivation case to PEOG outside of the situation described in per section 10.4.7.1(A).

E. Section 424.540(a)(7)

See section 10.6.1.3 of this chapter for information regarding certified provider/supplier voluntary terminations and section 10.4.3(B) for information on non-certified supplier voluntary terminations.

F. Section 424.540(a)(8)

See section 10.2.1.6.1 of this chapter for information regarding seller CHOWs.

G. Miscellaneous

- 1. Except for deactivations under § 424.540(a)(8) (see § 424.550(b)(1)) and § 424.540(a)(7), the deactivation of Medicare billing privileges does not affect a provider/supplier's participation agreement.
- 2. Prior to deactivating an HHA's billing privileges for any reason (including under the "36-month rule"), the contractor shall refer the matter to its PEOG BFL for review and approval. The only exception for PEOG BFL review and approval is *a* deactivation due to failure to comply with a revalidation request.
- 3. <u>Notwithstanding any other instruction to the contrary in this chapter</u>, the provider/supplier may submit a rebuttal for deactivations imposed pursuant to § 424.540(a)(7) or (8). For these two rebuttal reasons, the contractor shall abide by the rebuttal policies in section 10.4.8.1. Note, however, that any such rebuttal only applies to the deactivation of billing privileges and not to the provider agreement termination.

10.6.1.1.3.1 – Step 1 - Initial Review of the CHOW Application (Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Process

Upon receipt of a Form CMS-855 CHOW application, the contractor shall undertake the following (in whichever order the contractor prefers):

- (i) Perform all data validations otherwise required per this chapter.
- (ii) Ensure that the submitted application(s) is complete consistent with the instructions in this chapter.
- (iii) Ensure that the provider has submitted all documentation otherwise required per this chapter. For CHOW purposes, this also includes the following:
- (a) Legal Documentation of CHOW The legal documents that governed the transaction, such as a sales agreement, bill of sale, or transfer agreement. (See section 10.6.1.1.3.1.1 below for more information on such documents.)
- (b) Form CMS-1561 (Health Insurance Benefit Agreement). (In lieu of the Form CMS-1561, rural health clinics (RHCs) must submit the Form CMS-1561A and ambulatory surgical centers (ASCs) must submit the Form CMS-370.) (See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List for more information.) These forms are generally known as "provider agreements" and "supplier agreements," as applicable.
- (c) Evidence of state licensure, if applicable. (This can be furnished consistent with existing instructions in this chapter concerning submission of evidence of state licensure.)
- (d) Evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal, as applicable. (Evidence should be either written or electronic documentation.) (See https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf for more information.)
- (e) Applicable CMS Form that requests certification in Medicare. (These include, for example, CMS-377 for ASCs, CMS-3427 for end-stage renal disease (ESRD) facilities, etc.) (See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List for more information.)
- (f) Form CMS-1539 Medicare/Medicaid Certification and Transmittal (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS011722).
- (g) Form CMS-2567 Statement of Deficiencies and Plan of Correction (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS008860).
- (h) For skilled nursing facilities (SNFs), a signed patient transfer agreement. (See https://www.cms.gov/Medicare/Provider-Enrollment-and-
 https://www.cms.gov/Medicare/Provider-Enrollment-and-
 https://www.cms.gov/Medicare/Provider-Enrollment-and-
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 https://www.cms.gov/Medicare/Provider-Enrollment-and-
 https://www.cms.gov/Medicare/Prep/Downloads/Facility-Transfer-Agreement-Example.pdf
 https://www.cms.gov/Medication-transfer-Agreement-Example.pdf
 https://www.cms.gov

(The provider must complete, sign, date, and include the applicable CMS forms described in this subsection (A)(iii); the provider need not, of course, complete those sections of the forms that are reserved for CMS. For organizational providers, an authorized official (as defined in § 424.502) must sign the forms; for sole proprietorships, the sole proprietor must sign.)

Notwithstanding the foregoing, if any document in subsection (A)(iii)(b), (d), (e), (f), (g), or (h) above is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon; the contractor shall instead notify the state in its recommendation letter which document(s) was/were missing or otherwise incomplete.

For all other missing or incomplete required documentation, the contractor shall follow the normal development instructions in this chapter.

Note that if the application is rejected and this results in the expiration of the applicable time period for reporting the change (e.g., 30 days), the contractor shall e-mail its PEOG BFL notifying him/her of the rejection. PEOG will determine whether the provider's/supplier's billing privileges should be deactivated under § 424.540(a)(2) or § 424.550(b)(2) or revoked under § 424.535(a)(1) or (a)(9). PEOG will notify the contractor of its decision.

- (iv) Ascertaining whether a formal § 489.18 CHOW has occurred This involves performing all necessary background research, which can include:
- Reviewing the sales or lease agreement
- Reviewing the ownership information in Sections 2, 5, and 6 of the Form CMS-855A (or Sections 5 and 6 of the Form CMS-855B)
- Reviewing whether the provider checked "Yes" or "No" to the question in Section 2 of the Form CMS-855A concerning the acceptance of assignment of the provider agreement.
- Contacting the provider(s) to request clarification of the sales agreement, etc. (Unless otherwise stated in this chapter, the provider must furnish any such clarification in writing; e-mail is acceptable.)
- (v) As applicable, take into account the supplemental instructions in sections 10.6.1.1.3.1(B), 10.6.1.1.3.1.1 and 10.6.1.1.4 of this chapter.

B. Additional Instructions

- 1. <u>TIN Change</u> While a CHOW is typically accompanied by a TIN change, this is not always the case. On occasion, the TIN remains the same; conversely, sometimes the provider is changing its TIN but not its ownership. In short, while a change of TIN (or lack thereof) is evidence that a CHOW may or may not have occurred, it is not the most important factor; rather, the change in the provider's ownership arrangement is the central issue. Hence, the contractor <u>shall</u> review the sales/lease agreement closely, for this will help indicate whether a CHOW has occurred. <u>Again, CMS stresses that the terms and conditions of the sales</u> agreement are the primary indicator of the existence or non-existence of a CHOW.
- 2. Request for Information and/or Clarification If, after its initial review under subsection (A), the contractor remains uncertain as to whether a CHOW has taken place, the contractor: (i) reserves the right to request any clarifying information from the provider (e.g., additional documentation concerning the sale); and/or (ii) may contact its PEOG BFL or the SOG Location for assistance. (This may include situations where, for instance, (i) the provider believes that the transaction is merely a stock transfer but the contractor disagrees, and (ii) the contractor is uncertain whether the provider is accepting assignment.)
- 3. <u>Acceptance of Assignment</u> Regardless of the provider's response to the Form CMS-855 question concerning whether the provider accepts assignment, the contractor shall review the sales/transfer agreement and any other documentation to confirm whether the provider's response is consistent with the agreement. (For example, if the provider responds "no" to the question, the contractor shall review the sales agreement to ensure consistency.) If an inconsistency is discovered, the contractor shall contact the provider for clarification.
- 4. <u>Situations Requiring Referral to PEOG</u> The contractor shall refer the case and all supporting documentation (e.g., sales agreement) to its PEOG BFL in either of the following situations:

- The provider reports a CHOW based strictly on a relinquishment by the owner of all authority and responsibility for the provider organization without a § 489.18-level change of ownership. (For instance, the sales agreement indicates that the provider is selling only 10% of its ownership stake but the provider claims the transaction is a CHOW because it is relinquishing all control of the provider to the party to which its 10% ownership share is being sold.)
- It appears the owner of a provider is entering into a franchise agreement with a corporate chain (and thus uses the chain's name).

10.6.1.3 – Voluntary Terminations

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

The CMS Provider Enrollment & Oversight Group (PEOG) and Medicare Administrative Contractors have assumed a number of enrollment-related functions previously handled by state agencies (hereafter occasionally referenced as "state") and CMS Survey & Operations Group Locations (SOG Locations) concerning certified provider and certified supplier voluntary terminations. This section 10.6.1.3 instructs the contractor on how to process such transactions. Unless stated otherwise, these instructions take precedence over those in section 10.4.3 of this chapter.

Except as stated otherwise in this chapter, this section does not apply to voluntary terminations pursuant to an HHA change in majority ownership under § 424.550(b)(1). Instructions concerning the handling of these transactions are in section 10.2.1.6.1 of this chapter.

A. Background

Consistent with the principles of 42 CFR § 489.52(a) (and except as otherwise required), a certified provider/supplier that wishes to terminate its agreement with Medicare must send written notice of its intention to the SOG Location, the state agency, or the contractor within the timeframes addressed in § 489.52. Under CMS Publication (Pub.) 100-07, chapter 2, section 2005F, the notice is a letter on letterhead with an authorized signature.

Submission of a Form CMS-855 voluntary termination application is not mandatory but is highly preferred. Providers and suppliers are encouraged to continue to submit this form.

Section 10.6.1.3(B) below discusses various scenarios that the contractor may encounter in processing certified provider/supplier voluntary terminations. These should be reviewed and considered in conjunction with the policies in section 10.6.1.3(C) below, particularly those in subsections (C)(2), (C)(3), (C)(6), and (C)(7).

B. Situations and Scenarios

1. Termination Reported to Contractor Via Form CMS-855 <u>or</u> Letter with No Prior Notice from State Agency or SOG Location

If the contractor receives a Form CMS-855 voluntary termination application <u>or</u> a voluntary termination letter (but not both) directly from a certified provider/supplier without having received any termination notification from the state/SOG Location, the following apply:

(i) The contractor shall: (a) process the application/letter consistent with the timeframes for voluntary terminations in section 10.4.3 of this chapter; and (b) as applicable, follow the instructions in section 10.6.1.3(C) below.

(NOTE: If the application/letter is from a skilled nursing facility (SNF), the contractor shall

contact the state agency to determine whether the SNF complies with the requirements of 42 CFR §§ 483.15(c)(8) and 483.70(l). These two provisions address the SNF's required notice to the state of an impending closure and patient safety. If the state indicates that the SNF is not compliant, the contractor shall contact its PEOG Business Function Lead (BFL) for guidance; if compliance is confirmed, the contractor can proceed as normal.)

- (ii) Prior to finalizing its processing of the Form CMS-855 or letter submission, the contractor shall e-mail a copy of the draft approval letter (see the applicable model letter in section 10.7.5.1) containing the appropriate termination effective date, reason for termination, and source of the termination notice (i.e., Form CMS-855 or letter) to PEOG at MedicareProviderEnrollment@cms.hhs.gov, with "S&C Voluntary Termination" in the e-mail's subject line.
- (iii) PEOG will update the Automated Survey Process Environment (ASPEN) system, notify the contractor thereof, and, if the provider/supplier is deemed, provide the contractor the name and e-mail address of the applicable accreditation organization (AO).
- (iv) Within 3 business days of receiving of the aforementioned notice from PEOG, the contractor shall: (1) e-mail a copy of the final signed approval letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed); and (2) deactivate the provider/supplier in the Provider Enrollment, Chain and Ownership System (PECOS) pursuant to the instructions/guidance in section 10.6.1.3(C)(9) below.

2. Termination Reported to Contractor Via Form CMS-855 <u>and</u> Letter with No Prior Notice from State Agency or SOG Location

If the contractor receives a Form CMS-855 voluntary termination application <u>and</u> a voluntary termination letter directly from a certified provider/supplier without having received any termination notification from the state/SOG Location, the following apply:

- (i) If the Form CMS-855 and letter arrive either simultaneously or before the contractor begins processing one of them, the contractor has the discretion to determine which submission to process. It need not process both of them; the submission that the contractor does not process may be returned (consistent with the instructions in this chapter) or placed in the provider/supplier file, and the contractor need take no further action thereon.
- (ii) If the contractor receives both submissions and it has begun processing one of them, the contractor shall continue processing that document. The contractor can return the other submission (consistent with the instructions in this chapter) or place it in the provider/supplier file; no further action thereon is required.
- (iii) Regardless of whether (2)(i) or (ii) applies, the contractor shall process the submission consistent with the instructions in section 10.6.1.3(B)(1) above.

3. Notice of Voluntary Termination Received from State Agency and/or SOG Location without the Contractor Having Received a Form CMS-855 or Letter Directly From the Provider/Supplier

Although many voluntary termination submissions from certified providers/suppliers are via the Form CMS-855, there are occasions where the provider/supplier will only notify the state agency and/or SOG Location. The contractor will typically learn of this when it receives a Form CMS-1539 ("Medicare/Medicaid Certification and Transmittal") and/or other written notification from the state/SOG Location. (The state uses the Form CMS-1539 to communicate findings to the SOG Location with respect to a facility's compliance with health and safety requirements.) In such situations, the following apply:

(i) The contractor may accept from the state/SOG Location written documentation other than the Form CMS-1539. This includes, for example, a Form CMS-2007 or even a voluntary termination letter of the type described in sections 10.6.1.3(B)(1) and (B)(2) above; indeed, the provider/supplier sometimes sends its termination letter directly to the state/SOG Location and the latter simply forwards it to the contractor.

If the contractor has questions concerning said documentation, it shall contact the state/SOG Location for clarification. (This could include situations when it is unclear: (1) whether a termination is involved; (2) which provider/supplier is to be terminated; or (3) if the state forwards to the contractor a termination request that the state received from the provider, whether the state considers it to be a valid termination request.).

- (ii) Upon receipt of the Form CMS-1539 (or other/additional state/SOG Location document), the contractor need not develop with the provider/supplier for a Form CMS-855A/B voluntary termination application or a letter. Instead:
- (A) The contractor shall abide by the applicable instructions in section 10.6.1.3(C) below (e.g., section (C)(6) regarding effective dates; section (C)(7) concerning cessations of business). If the notice from the state was a voluntary termination letter from the provider/supplier (as described in section 10.6.1.3(B)(3)(i) above), the contractor shall pay particular attention to the instructions in section 10.6.1.3(C)(3) below.
- (B) The contractor shall e-mail a copy of the draft approval letter (see section 10.7.5.1 of this chapter) containing the appropriate termination effective date, reason for termination, and source of the termination notice to MedicareProviderEnrollment@cms.hhs.gov, with "S&C Voluntary Termination" in the subject line.
- (C) PEOG will update ASPEN, notify the contractor thereof, and, if the provider/supplier is deemed, provide the contractor the name and e-mail address of the applicable AO.
- (D) Within 3 business days of receiving of the aforementioned notice from PEOG, the contractor shall: (1) e-mail a copy of the final signed letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed); and (2) deactivate the provider/supplier in PECOS pursuant to the instructions/guidance in section 10.6.1.3(C)(9)) below.
- 4. Notification of Termination Received from the State Agency and/or SOG Location and Directly from the Provider/Supplier Via the Form CMS-855 and/or Letter

The contractor shall adhere to the instructions in this section (B)(4) in the following situations:

- (i) The contractor receives notification of termination (i.e., via Form CMS-1539 or other documentation) from the state/SOG Location after the provider/supplier has been deactivated in PECOS pursuant to the latter's Form CMS-855/letter voluntary termination submission Within 10 calendar days of receiving the state/SOG Location notification, the contractor shall inform the state/SOG Location via e-mail that the provider/supplier has already been deactivated in PECOS and terminated in ASPEN. No further action by the contractor is necessary.
- (ii) The contractor receives notification of termination from the state/SOG Location while the contractor is processing a Form CMS-855/letter voluntary termination submission but before the provider/supplier has been deactivated in PECOS The contractor shall: (i) continue processing the application/letter normally and to completion,

consistent with the instructions in this section 10.6.1.3; and (ii) e-mail a copy of the final signed letter to the provider/supplier, SOG Location, state agency, and AO (if the provider/supplier is deemed) after the provider/supplier has been deactivated in PECOS.

- (iii) The contractor receives notification of termination (i.e., via Form CMS-1539 or other documentation) from the state/SOG Location before the contractor received or began processing the provider's/supplier's Form CMS-855/letter voluntary termination submission The contractor:
- (A) Shall follow the instructions in section 10.6.1.3(B)(3) above
- (B) Need not contact the provider/supplier about its Form CMS-855/letter submission prior to the completion of all of the steps in section 10.6.1.3(B)(3)(ii) above
- (C) Either in the termination approval letter (which the contractor may modify for the purpose) sent to the provider/supplier or via a simultaneous or separate e-mail to the provider/supplier, the contractor shall notify the provider/supplier that its submission to the contractor was not processed due to the provider/supplier's prior notification to the state/SOG Location. (If this communication is sent separately from the approval letter or the e-mail containing the letter, the contractor shall send the separate e-mail no later than 10 calendar days after sending the letter.)
- (iv) The contractor receives notification of termination from the state/SOG Location and a separate voluntary termination Form CMS-855/letter from the provider/supplier without having begun the processing of either The contractor has the discretion to determine which submission to process. It need not process both of them; the submission that the contractor does not process may be returned (consistent with the instructions in this chapter) or placed in the provider/supplier file, and the contractor need take no further action thereon.

C. Additional Certified Provider/Supplier Voluntary Termination Policies

- 1. Completion of Form CMS-1539 The state completes the Form CMS-1539. In Part II thereof, the following fields contain: (i) 26-Termination Action "00"; Code for a voluntary termination; and (ii) 28 –Termination Date; this is the effective date of the voluntary termination.
- 2. <u>Required Contents of Voluntary Termination Letter Received Directly from Provider/Supplier</u> If the contractor is processing a voluntary termination letter it received directly from the provider/supplier (as opposed to receiving it from the state/SOG Location), the contractor shall ensure that the letter:
- Is on the provider/supplier's letterhead
- Contains the provider/supplier's legal business name, NPI, and CMS Certification Number (CCN)
- States with sufficient clarity (in the contractor's judgment) that the provider/supplier wishes to terminate its Medicare provider/supplier agreement and/or enrollment. (No exact, uniform, standard language from the provider/supplier is necessary; the letter must merely furnish adequate notice of the provider/supplier's intentions).
- Is signed and dated by an authorized representative of the provider/supplier. This person need not be on file as an authorized or delegated official of the provider/supplier. The contractor shall accept the person's signature if it has no reason to suspect that he/she lacks the authority to act on the provider/supplier's behalf. If it has doubts, however, it may contact its PEOG for guidance.

(The applicable regulations do not require that the letter contain the termination effective date or the reason for the termination. For purposes of ascertaining the effective date and reason, the contractor shall follow the instructions in section 10.1.3(C)(6).)

If the letter does not meet all of the above requirements, the contractor shall develop with the provider/supplier for the missing or deficient information. Development shall be consistent with the general developmental instructions in this chapter (e.g., 30 days for provider/supplier to respond) except as follows:

- The contractor may develop for the missing or clarifying information via any means, even by telephone. No application development letter is required.
- Except as stated in sections 10.6.1.3(C)(3) and (C)(6) below, all missing or clarifying data must be furnished via a new letter signed by an authorized representative (who need not be the same person who signed the original letter).

If the provider/supplier fails to respond fully and completely to the aforementioned request within the required timeframe, the contractor shall contact its PEOG BFL for guidance and include a copy of the initial provider/supplier letter in the e-mail to PEOG.

(See section 10.6.1.3(C)(3) below for instances where the guidance in this section 10.6.1.3(C)(2) may apply to voluntary termination letters submitted to the state/SOG Location rather than to the contractor.)

- 3. <u>Provider/Supplier's Voluntary Termination Letter Received Directly from the state/SOG Location Without the Contractor Having Received a Termination Notification from the Provider/Supplier As explained in section 10.6.1.3(B)(3) above, the contractor may receive a provider/supplier's voluntary termination letter directly from the state/SOG Location without having received any termination notification (i.e., letter or Form CMS-855) from the provider/supplier. If the contractor encounters this situation, the contractor shall adhere to the following:</u>
- (i) Provider/Supplier Voluntary Termination Letter Received from State/SOG Location Without Other Confirming Documentation If the letter is unaccompanied by a Form CMS-1539 or other documentation signifying that the state/SOG Location (1) considers the termination letter as valid or (2) otherwise accepts the termination request, the contractor shall contact the state via e-mail for clarification on these issues. If the state indicates that it considers the provider/supplier as having terminated its provider/supplier agreement, the contractor shall process the termination consistent with the instructions in section 10.6.1.3(B)(3); any missing or unclear information (e.g., reason for the termination, effective date, CCN) shall be obtained from the state and/or SOG Location. If the state is merely forwarding the provider/supplier letter to the contractor for processing without making any determination as to whether the termination is valid, the contractor shall process the letter consistent with the instructions in section 10.6.1.3(B)(1) and (C)(2).
- (ii) Provider/Supplier Voluntary Termination Letter Received from State/SOG Location With Additional Documentation Confirming that the State Considers the Provider/Supplier As Having Terminated Its Agreement The contractor shall process the termination consistent with the instructions in section 10.6.1.3(B)(3).
- 4. <u>Tie-Out Notices</u> SOG Locations no longer issue tie-out notices (Form CMS-2007) for voluntary terminations.
- 5. <u>Special Payments</u> Upon receipt of a Form CMS-855 voluntary termination application or a voluntary termination letter directly from the provider/supplier per the instructions in this section 10.6.1.3, the contractor may (but is not required to) ask the provider/supplier to

complete or update the "Special Payments" portion of Section 4 of the Form CMS-855 so that future payments can be sent thereto. If the provider/supplier is <u>adding</u> a special payment address, it should be included in the same transaction as the voluntary termination action (i.e., one transaction incorporating both items). If the provider/supplier is <u>changing</u> its existing special payments address, the transaction constitutes a separate change request (i.e., one termination and one change request). The provider/supplier is not required to submit a Form CMS-588 in conjunction with a termination.

- 6. <u>Termination Effective Dates and Termination Reasons</u> As noted previously, § 489.52(b) outlines the applicable effective dates for voluntary terminations. The contractor shall adhere to the following instructions regarding these dates as well as certain situations pertaining to termination reasons:
- (i) The contractor receives a Form CMS-855 or voluntary termination letter per section 10.6.1.3(B)(1) or (B)(2) (i.e., the contractor receives a termination submission from the provider/supplier before receiving notification from the state/SOG Location):
- (A) If the provider/supplier's submission is missing either the effective date of termination or the reason for the termination (or if either data element is not sufficiently clear to the contractor), the contractor shall develop with the provider/supplier for the missing/unclear data. The contractor may develop for the information via any means, even by telephone; no development letter is required. The provider/supplier must furnish the data via e-mail or other written format, but a new letter is not required. If the provider/supplier fails to submit the requested data within 30 days, the contractor shall contact its PEOG BFL for guidance. If the provider/supplier submits the data, the following effective dates apply:
- (1) The termination reason is that the provider/supplier has ceased business (which includes non-operational status) The termination effective date in ASPEN is that on which the provider/supplier stopped providing services to the community. (See section 10.6.1.3(C)(6)(i)(C) below for additional instructions concerning cessations of business.)
- (2) The termination reason does not involve a cessation of business or non-operational status (e.g., the provider simply wishes to depart Medicare without closing its business; the provider elects not to renew its state license) The contractor shall include on the draft approval letter the termination effective date the provider/supplier furnished. However, the contractor shall include in its e-mail to PEOG (see section 10.6.1.3(B)(1)(ii) above) notification as to whether this effective date is less than 6 months from the date on which the contractor first received the provider/supplier's Form CMS-855/letter. If it is less than 6 months, PEOG will determine whether this termination effective date is acceptable.
- (B) If the provider/supplier's initial submission contains the termination effective date and reason, and no development on these issues is needed, the contractor shall proceed as instructed per, as applicable, sections 10.6.1.3(B)(1), (B)(2), and (C)(6)(i)(A) above.
- (C) In cases where a cessation of business (including non-operational status) is involved, a retroactive termination effective date is permissible if there were no Medicare beneficiaries receiving services from the facility on or after the requested termination date. The contractor shall confirm this via a claims review prior to forwarding the e-mail and approval letter to PEOG per section 10.6.1.3(B)(1)(ii). If claims were submitted, the contractor shall contact the provider/supplier via e-mail to confirm that services were indeed rendered and adjust the termination date with the provider/supplier; if no adjustment is made or contact cannot be made, an overpayment request must be issued.
- (ii) <u>The contractor is processing a Form CMS-1539 or other documentation received from the state/SOG Location other than the provider/supplier's voluntary termination letter The state/SOG Location other than the provider/supplier's voluntary termination letter The</u>

contractor shall use the termination date listed on the Form CMS-1539 or other documentation as the termination effective date, even if a subsequent submission from the provider/supplier (e.g., Form CMS-855) uses a different date. If no termination date is listed on the submission from the state/SOG Location, the contractor shall contact the state agency for guidance.

Except as otherwise stated in this section 10.6.1.3 or unless directed otherwise by PEOG, the contractor: (1) shall use/apply the termination effective date listed on whichever submission it is processing (e.g., the contractor is processing the provider's Form CMS-855 voluntary termination application before receiving any documentation from the state); and (2) need not alter this termination effective date based on a subsequent submission from provider/supplier or the state/SOG Location.

7. State Agency Performs Survey Based on Cessation of Business

(i) Solicitation of Information

Situations may arise where the state (i) performs a survey of a certified provider/supplier based on a compliant or a cessation of business and (ii) finds that the provider/supplier is no longer operational and/or has vacated the practice location. The state will notify the contractor of its findings via the Form CMS-1539 or other documentation. Upon receipt of this documentation, the contractor shall send to the provider/supplier the applicable notice in section 10.7.2 of this chapter requesting that the provider/supplier: (1) provide evidence to the contractor (with a copy to the state) that it is still operational; (2) submit a request to the contractor (either via letter or a Form CMS-855) to voluntarily terminate its enrollment; or (3) submit a Form CMS-855 change of information application to report a changed practice location address (and any other changed data). The contractor shall copy the state and SOG Location on the notice and give the provider/supplier 10 calendar days from the date the notice is sent to respond to the request.

(ii) Potential Outcomes

(A) The provider/supplier timely furnishes evidence to the contractor and the state that it is still operational at the same location – The contractor need take no additional action on the matter until it receives confirmation from the state concerning the latter's review. (If the contractor receives evidence from the provider/supplier more than 10 days after the request was made, it shall contact the state for guidance.)

While the contractor may forward the provider/supplier's evidence to the state to ensure that the latter received it, the contractor is not required to do so. It is ultimately (1) the provider/supplier's responsibility to copy the state on its submission to the contractor and (2) up to the state to determine whether the evidence of operational status the provider/supplier submitted is sufficient.

Upon receiving notice from the state as to the review's results, the contractor shall follow the applicable instructions in this section 10.6.1.3 if the provider/supplier is to be terminated (e.g., the state sends a Form CMS-1539 to the contractor). If the provider/supplier was indeed found operational, the contractor need take no further action.

(B) The provider/supplier submits a Form CMS-855 voluntary termination and/or a voluntary termination letter in response to the contractor's aforementioned solicitation - The contractor shall process the submission consistent with the instructions in section 10.6.1.3(B)(1) and/or (B)(2), as applicable. Notwithstanding any instruction to the contrary in this section 10.6.1.3, the contractor shall use the termination effective date listed on the

Form CMS-1539 or other documentation from the state (rather than the date on the Form CMS-855/letter) as the termination effective date.

- (C) The provider/supplier timely submits a Form CMS-855 to change its address The contractor shall process the change request to completion, notify the provider/supplier thereof via the applicable instructions in this chapter 10, and forward a copy of the change request via e-mail to the state and SOG Location via e-mail. In this e-mail, the contractor shall: (1) notify the state/SOG Location of the new address; (2) reference the Form CMS-1539 (or other documentation) that the state had sent to the contractor; and (3) notify the state if PECOS indicated any addresses other than the "old" or "new" address at which the provider/supplier might be located.
- (D) <u>The provider/supplier fails to respond to the contractor's solicitation</u> The contractor shall process the voluntary termination consistent with the instructions in section 10.6.1.3(B)(3) above.
- 8. <u>Clock Stoppages</u> In any circumstance where the contractor is <u>required</u> under section 10.6.1.3 to contact PEOG (including sending a termination to PEOG for approval) or the state/SOG Location for a determination, approval, or guidance of some type, the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG/state/SOG Location's decision, resolution, determination, or final guidance, as applicable. Interim communication between the contractor and PEOG/state/SOG Location during such "waiting periods" (e.g., PEOG request for additional information from the contractor) does not restart the clock. Optional communications—that is, communications with PEOG/state/SOG Location that are not specifically directed under this section 10.6.1.3—do not stop the processing clock.

9. PECOS Deactivation Date

- a. Matching Dates As indicated previously, the termination effective date will be entered into ASPEN. The date of deactivation in PECOS (and except if PEOG instructs otherwise) should match the termination effective date with the exception of certified suppliers paid via MCS, in which case the PECOS deactivation date shall be the day after the termination date.
- b. Already Deactivated If the provider/supplier is already deactivated in PECOS pursuant to 42 CFR § 424.540(a)(1) through (a)(6) (i.e., the provider/supplier's billing privileges are merely stopped) and the provider/supplier is now voluntarily terminating their enrollment, no change in the deactivation effective date in PECOS is needed (notwithstanding any contrary instruction in this chapter).
- c. Seller CHOW Notwithstanding paragraph (9)(b) above, the deactivation effective date in PECOS---as well as the voluntary termination date---is the day before the date of the sale. For certified suppliers paid via MCS, however, the deactivation effective date shall be the date of the sale. (Note that this paragraph (9)(c) does not apply to HHA changes in majority ownership for which no exception applies; see section 10.2.1.6.1(B) of this chapter for more information.)

10.6.12 – Opting-Out of Medicare

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

Physicians and practitioners are typically required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. They are also not permitted to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not

required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare-covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to CMS Pub. 100-02, Chapter 15, sections 40 - 40.39 for more information regarding the maintenance of opt-out affidavits and the effects of improper billing of claims during an opt-out period.

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

A. Who May Opt-Out of Medicare

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

Physicians who are:

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

Non-physician practitioners who are

- Physician assistants,
- Nurse practitioners,
- Clinical nurse specialists,
- Certified registered nurse anesthetists,
- Certified nurse midwives,
- Clinical psychologists,
- Clinical social workers, or
- Registered dietitians or nutrition professionals who are legally authorized to practice by the state 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 practitioners who opt-out of Medicare are not the same as non-participating physicians/suppliers. The latter are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment-related basis as required by law (e.g., for drugs, ambulance services, etc.). Non-participating physicians/suppliers must therefore comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Opt-out eligible practitioners, on the other

hand, are excused from the mandatory claim submission, assignment, and limiting charge rules, though **only** when they maintain compliance with all of the requirements for opting out.

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

B. Requirements for an Opt-out Affidavit

1. Affidavit Contents

As stated in Pub. 100-02, chapter 15, section 40.9, the affidavit shall state that, upon signing the affidavit, the eligible practitioner agrees to the following requirements:

- Except for emergency or urgent care services, during the opt-out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;
- The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary;
- During the opt-out period, the eligible practitioner understands that he/she may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;
- An eligible practitioner who opts out of Medicare acknowledges that, during the opt-out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;
- On acknowledgment by the eligible practitioner to the effect that, during the opt- out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;
- Acknowledge that the eligible practitioner recognizes that the terms of the affidavit apply
 to all Medicare-covered items and services furnished to Medicare beneficiaries by the
 eligible practitioner during the opt-out period (except for emergency or urgent care
 services furnished to the beneficiaries with whom the eligible practitioner has not
 previously privately contracted) without regard to any payment arrangements the eligible
 practitioner may make;
- With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;
- Acknowledge that the eligible practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services;

- Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and
- Be filed with all MACs that have jurisdiction over claims the eligible practitioner would otherwise file with Medicare; the initial two-year opt-out period will begin the date on which the affidavit meeting the requirements of 42 C.F.R. § 405.420 is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs his or her first private contract with a Medicare beneficiary.

(See Pub. 100-02, chapter 15, section 40.9 for more information on the requirements of optout 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 needs to obtain data that is missing from an affidavit, it may (1) obtain this information from other sources (such as the state license board) or (2) contact the eligible practitioner only **one time** directly. The contractor shall **not** use Internet-based PECOS or the Form CMS-855 to secure the data from the eligible practitioner, for the eligible practitioner **is not** enrolling in Medicare. If the eligible practitioner is requested to submit missing information to permit the processing of the affidavit and fails to do so within 30 days, the contractor shall reject the opt-out affidavit.

2. Opting-Out and Ordering/Certifying/Referring

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

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

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

3. Adverse Actions

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

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

4. No Dual Status

- a. <u>Form CMS-855O</u> 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. <u>Form CMS-855I</u> A Form CMS-855I enrollment can simultaneously exist with a valid opt-out affidavit <u>only</u> if the Form CMS-855I is to bill for emergency services. If a Form CMS-855I is received <u>and</u> 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 optout 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, chapter 15, section 40.17, eligible practitioners receive effective dates based on their participation status.

1. Eligible Practitioners Who Have Never Enrolled In Medicare

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

2. Non-Participating Practitioners

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

3. Participating Practitioners

If an eligible practitioner who is a participating provider (one who accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. Per 42 CFR § 405.410(d), an eligible practitioner may opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in 42 CFR § 405.420 is submitted to the applicable contractor(s) at least 30 days before the beginning of the selected calendar quarter. (The contractor shall, however, add 5 calendar days to the 30day period to allow for mailing.) An opt-out affidavit must therefore be submitted at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as the effective date. If the opt-out affidavit is submitted within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10. The eligible practitioner's effective date could not be January 1, for the affidavit was not submitted at least 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

4. Opt-Out After Enrollment

(This section 10.6.12(C)(4) applies notwithstanding any instruction to the contrary in this chapter.)

If an enrolled physician or eligible practitioner is now opting-out, the existing PECOS enrollment record shall be end-dated *the same day as the affidavit effective date*.

D. Emergency and Urgent Care Services

If an eligible practitioner who has opted-out provides emergency or urgent care services, he/she must apply for enrollment via the Form CMS-855I. Once he/she receives his/her PTAN, he/she must submit the claim(s) for any emergency or urgent care service furnished. The contractor shall contact its PEOG BFL for additional guidance when this type of situation arises. (See Pub. 100-02, chapter 15, section 40.28 for more information on emergency and urgent care services.)

E. Termination of an Opt-Out Affidavit

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

- 1. Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of his/her opt-out);
- 2. Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;

- 3. Notify all beneficiaries (or their legal representation) with whom the eligible practitioner entered into private contracts of the eligible practitioner's decision to terminate his/her optout and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period and;
- 4. Refund to each beneficiary with whom the physician or practitioner has privately contracted all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.

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

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

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

1. General Policies

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

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

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

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

The contractor shall issue an Opt-Out Renewal Alert Letter (found in section 10.7.14(E) of this chapter) to any eligible practitioner whose opt-out period is set to auto-renew. For this purpose, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The contractor shall access the report monthly through the Share Point Ensemble site. The contractor shall also review the opt-out report for opted-out eligible practitioners that will auto-renew in the next three-and-a-half months. In addition, the contractor shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date; the eligible practitioner will thus have at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide (1) the date on which the current opt-out period will be auto renewed and (2) the date by which the eligible practitioner will need to

submit a cancellation request. The letter will also furnish the eligible practitioner appeal rights if he/she fails to submit a cancellation request and the opt-out renews.

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

If an opted-out eligible practitioner submits a Form CMS-855I 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, if the eligible practitioner submits a cancellation request more than 90 days prior to the auto-renewal date, the contractor shall return the cancellation request to the eligible practitioner using the Cancellation Request Received Too Early return letter.

G. Failure to Properly Cancel or Terminate Opt-Out

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

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

10.7 – Model Letters

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

The contractor shall use the following letters when rejecting, returning, approving or denying an application, or when revoking an entity's Medicare billing privileges. Any exceptions to this guidance shall be approved by the contractor's CMS Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL), unless specified otherwise. The contractor shall document approval received by its PEOG BFL for QASP purposes.

A. Issuing Letters - Model Letter Guidance

All letters sent by contractors to providers and suppliers shall contain and/or adhere to the formats/requirements addressed in sections 10.7(A) and (B). Note, however, the following:

- (i) For certified provider/supplier types and transactions that have formally "transitioned" as described in section 10.7.5.1, the requirements (e.g., data elements) of the model letters in section 10.7.5.1 take precedence over any contrary instruction in section 10.7. For example, if section 10.7 requires a data element that a specific letter in section 10.7.5.1 pertaining to the same enrollment transaction/situation does not, the section 10.7.5.1 letter requirements supersede the former. Likewise, if section 10.7 requires the removal/addition of language that is/is not in the applicable section 10.7.5.1 letter, the latter controls.
- (ii) For certified provider/supplier types and transactions that have not transitioned (and except as otherwise stated in section 10.7 (e.g., subsection (A)(2)(n)), the contractor shall

continue to follow the existing instructions in section 10.7 and utilize the letters in section 10.7.5.

1. General Guidance

- (a) The CMS logo (2012 version) displayed per previous CMS instructions.
- (b) The contractor's logo shall be displayed however the contractor deems appropriate. There are no restrictions on font, size, or location. The only restriction is that the contractor's logo must not conflict with the CMS logo.
- (c) Excluding items in the header or footer, all text shall be written in Times New Roman 12-point font (with the exception of name and address information per USPS requirements).
- (d) All dates in letters, except otherwise specified, shall be in the following format: month/dd/YYYY (e.g., January 26, 2012).
- (e) Letters shall contain fill-in sections as well as static, or "boilerplate" sections. The fill-in sections are delineated by words in brackets in italic font in the model letters.
- (f) The static sections shall be left as-is unless there is specific guidance for removing a section (e.g., removing a CAP section for certain denial and revocation reasons; removing state survey language for certain provider/supplier types that do not require a survey). If there is no guidance for removing a static section, the contractor must obtain approval from its PEOG BFL to modify or remove such a section.

2. Approval Letters

- (a) Part A/B certified provider and supplier paper/web COI and revalidation approval recommended letters shall detail the recommended changes (e.g. practice location changed to 123 Main Street, Baltimore MD 21244).
- (b) For COI and revalidation applications that do not require a tie-in or recommendation but require notification to the SOG Location as a cc, the contractor shall add the additional fields applicable to the letter (e.g., cc the state/SOG Location). The contractor should itemize the changes if it is beneficial to the SOG Location.
- (c) Part A/B and DME provider and supplier paper/web COI and revalidation letters shall only list the section title (at the sub-section level) from the paper/web Form CMS-855 and Form CMS-20134 application (e.g., Correspondence Mailing Address, Final Adverse Legal Actions, Remittance Notices/Special Payments Mailing Address, etc.).
- (d) If, as part of a revalidation, the provider/supplier only partially revalidates (i.e., a provider has multiple PTANs, and one PTAN is revalidated with the others end-dated), the contractor shall notate the reassignments that were terminated due to non-response and the effective date of termination (i.e., the revalidation due date or the development due date).
- (e) If the provider is submitting a change as part of a voluntary termination application (e.g. special payment address, EFT, authorized official), the contractor shall enter the applicable fields into the Medicare Enrollment information table.
- (f) Approval letters may include a generic provider enrollment signature and contact information (e.g. customer service line). However, all development letters shall include a provider enrollment analyst's name and phone number for provider/supplier contacts.

- (g) Participation status shall only be included in initial and reactivation letters for Part B sole proprietors, Part B sole owners, any Part B organizations and DME suppliers. Change of information approval letters shall only include the participation status if it was changed as part of the application submission.
- (h) The contractor shall add lines to the enrollment information tables on any reactivation letter if the provider/supplier has reactivated following non-response to a revalidation and enrollment information was changed on the application.
- (i) The contractor shall enter an effective date on all change of information approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality).
- (j) The contractor shall add appeal rights to all change of information and revalidation approval letters if a new PTAN is issued based on the changes (e.g., a new location is added to a new payment locality; a new reassignment is created).
- (k) If the provider/supplier is revalidating multiple reassignments to different groups, the contractor shall add additional lines to the grid to identify the separate groups and PTANs.
- (1) If the provider/supplier revalidates both reassignments and one or more sole proprietorship locations, the contractor shall indicate on the appropriate letter that the approval covers the reassignments and sole proprietorship locations.
- (m) In the Part B non-certified supplier letters, the contractor shall populate 42 CFR§ 424.205 for MDPP suppliers or § 424.516 for all other providers/suppliers with the following paragraph: "Submit updates and changes to your enrollment information within the timeframes specified at [42 CFR § 424.516 or 42 CFR§ 424.205]. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617."
- (n) For all pre-transition and post-transition seller CHOWs (both HHA and non-HHA), the contractor shall use the "M. Approval Seller CHOW (Part A/B Certified Org") letter in section 10.7.5.1 when voluntarily terminating the seller's enrollment in a 42 CFR § 489.18 CHOW (which includes mergers, acquisitions, and consolidations). The contractor shall use the effective date of the CHOW as the "Effective Date of Enrollment Termination" in the letter.
- (o) The contractor shall remove the following language when issuing the Approval Voluntary Termination (Part B Non-Certified Org or Part B Sole Owner) letter in section 10.7.6(V) for a Part B non-certified supplier: "Reassignments and any physician assistant employment arrangements are also deactivated", unless other active reassignments/employment arrangements exist on the enrollment.

3. Denial/Revocation Letters

- (a) The contractor shall populate the fill-in sections with the appropriate information, such as primary regulatory citation, specific denial and revocation reasons, names/addresses, etc.
- (b) The fill-in sections shall be indented ½ inch from the normal text of the letter.
- (c) All specific or explanatory reasons shall appear in bold type and shall match the federal registry heading. This applies to headings. For example, if the revocation letter contains the following specific explanatory language, the heading should be in bold type and the explanation should be in normal type as shown in the excerpt below:

42 CFR § 424.535(a)(8)(i) – Abuse of Billing Privileges

Data analysis conducted on claims billed by [Dr. Ambassador], for dates of service [Month XX, XXXX], to [Month XX, XXXX], revealed that [Dr. Ambassador] billed for services provided to [XX] Medicare beneficiaries who were deceased on the purported date of service.

- (d) There may be more than one primary reason listed.
- (e) This subsection (A)(3)(e) applies to certified provider and certified supplier denial or revocation letters that meet both of the following requirements:
- The provider enrollment denial or revocation also requires the denial or termination of the corresponding provider or supplier agreement (e.g., Form CMS-1561, Form CMS-370, etc.)
- The SOG Location is responsible for handling the reconsideration/appeal of the provider/supplier agreement denial or termination.

If these requirements are met -- and notwithstanding any instruction to the contrary in this chapter -- the contractor shall insert the following language into the provider enrollment denial or revocation letter (preferably at the conclusion of the letter's discussion/outline of appeal rights):

"Note that the provider enrollment appeal rights addressed in this letter are unrelated to any appeal rights concerning the [denial or termination, as applicable] of your [provider or supplier, as applicable] agreement. The two processes are separate and distinct, and a successful appeal of your enrollment [denial or revocation, as applicable] does not automatically restore your [provider or supplier] agreement. Any such restoration of the latter is handled by the Survey Operations Group Location and not by CMS' Provider Enrollment & Oversight Group."

4. Voluntary Terminations

If a provider/supplier (certified or non-certified) is voluntarily terminating their enrollment, the contractor shall use the applicable voluntary termination letter.

5. No PEOG Approval

The following letter revisions do not require prior PEOG BFL approval. (Notwithstanding the language in subsection 10.7(A)(i), this includes the letters in section 10.7.5.1 et seq.)

- (a) If the contractor cannot format the enrollment information table as provided in these model letters, the contractor may provide the information in a similar non-table format.
- (b) Placing a reference n umber or numbers between the provider/supplier address and the salutation. (For Internet-based PECOS applications, the contractor can include its document control number and the Web Tracking ID in this field.)
- (c) The contractor shall enter "N/A" or leave blank a data element in an enrollment information table if said field is inapplicable (e.g., doing business as (DBA), effective date for changes).
- (d) The contractor shall include the applicable PTAN and NPI for the application submission on the letter. If multiple PTANs or NPIs apply, the contractor should: (1) enter "multiple" in the PTAN and NPI fields; (2) copy and add additional PTAN/NPI rows to the enrollment

information tables; or (3) attach a list of any and all PTAN and NPI combinations that apply in the letter.

- (e) For individual revalidations in which multiple PTANs may be revalidating from multiple reassignments or individual associations, the contractor may also list the group's LBN and PTAN effective date in connection with the appropriate individual NPI-PTAN combinations. The contractor has flexibility in relaying these fields when multiplicities exist, ensuring they meet the template's reporting requirements.
- (f) Appropriate documents attached to specific letters as needed.
- (g) Placing language in any letter regarding self-service functions, such as the Provider Contact Center Interactive Voice Response (IVR) system and Electronic Data Interchange (EDI) enrollment process.

B. Sending Letters

The contractor shall note the following:

- 1. Except as stated otherwise in this chapter (e.g., certain applications from already-transitioned certified provider/supplier types), the contractor shall issue approval letters within 5 business days of approving the application in PECOS.
- 2. For all applications other than the Form CMS-855S, the contractor shall send development/approval letters, etc., to the contact person if one is listed. Otherwise, the contractor may send the letter to the provider/supplier at the e-mail, mailing address, or fax provided in the correspondence address or special payments address sections.
- 3. The contractor may insert an attention field with the contact's name as part of the mailing address, but the letter should still be addressed to the provider/supplier. The National Supplier Clearinghouse shall continue to send letters to the supplier's correspondence address until their automated process can be updated to include the contact person as a recipient of the letters.
- 4. If the provider/supplier submits two Form CMS-855Rs concurrently, two separate approval letters shall be issued (one for each group reassignments).
- 5. For initial, change of information, revalidation, and voluntary termination applications submitted by sole owners, the contractor should issue one approval letter. However, the Medicare enrollment information table shall distinctly list the individual and sole owner information.
- 6. If, as part of revalidation, a physician assistant is adding and terminating an employment relationship, one letter shall be issued (approving the revalidation). However, the termination and additional employment relationship shall be noted in the approval letter.
- 7. The contractor shall issue all denial and revocation letters via certified mail.

10.7.4 – DME Approval Letter Templates

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Approval – Change of Information (DME)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your Change of Information (COI) application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Location Address	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Filing claims electronically? Contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B CGS, www.cgsmedicare.com
- Jurisdiction C CGS, <u>www.cgsmedicare.com</u>
- Jurisdiction D Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

B. Approval – Initial (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your initial enrollment application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Filing claims electronically? Contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listsery messages regarding Medicare billing policies at:

- Jurisdiction A Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B CGS, www.cgsmedicare.com
- Jurisdiction C CGS, www.cgsmedicare.com
- Jurisdiction D Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and

include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC] [Centers for Medicare & Medicaid Services]
[Address] or [Provider Enrollment & Oversight Group]
[City], ST [Zip] [ATTN: Division of Compliance & Appeals]
[7500 Security Blvd.]
[Mailstop: AR-19-51]
[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Con	ntractor] at [contact information].
Sincerely,	
[Name] [Title] [Company]	
C. Approval – Reactivation (DME)	
[Month, Day, Year]	
[Provider/Supplier Name] [Address] [City, State, Zip]	
Reference # (Application Tracking Number)	
Dear [Provider/Supplier],	
[Insert Contractor] approved your reactivation applicat	ion.
Medicare Enrollment Information	
Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

To file claims electronically, please contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B CGS, www.cgsmedicare.com
- Jurisdiction C CGS, www.cgsmedicare.com
- Jurisdiction D Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov...

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the
 decision. However, if you have additional information that you would like a Hearing
 Officer to consider during the reconsideration or, if necessary, an Administrative Law
 Judge (ALJ) to consider during a hearing, you must submit that information with your
 request for reconsideration. This is your only opportunity to submit information during
 the administrative appeals process unless an ALJ allows additional information to be
 submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC]		[Centers for Medicare & Medicaid Services]
[Address]	or	[Provider Enrollment & Oversight Group]

[City], ST [Zip] [ATTN: Division of Compliance & Appeals] [7500 Security Blvd.] [Mailstop: AR-19-51] [Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

D. Approval – Revalidation (DME)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your revalidation application.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section
	titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

To file claims electronically, please contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B CGS, www.cgsmedicare.com
- Jurisdiction C CGS, www.cgsmedicare.com
- Jurisdiction D Noridian Healthcare Solutions, med.noridianmedicare.com/web/jddme

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for handling the reconsideration.

[Name of MAC] [Centers for Medicare & Medicaid Services]
[Address] or [Provider Enrollment & Oversight Group]
[City], ST [Zip] [ATTN: Division of Compliance & Appeals]

[7500 Security Blvd.] [Mailstop: AR-19-51]

[Baltimore, MD 21244-1850]

Or emailed to:

[Insert MAC email address] or [ProviderEnrollmentAppeals@cms.hhs.gov]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

[Title]
[Company]

E. Approval – Voluntary Termination (DME)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] completed your application to *voluntarily* disenroll from the Medicare program.

Medicare Enrollment Information

Supplier Legal Business Name (LBN)	
Doing Business As (DBA)	
Physical Address Location	
Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Termination and Deactivation	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

With this voluntary termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to $42 \text{ C.F.R.} \ \S \ 424.540(a)(7)$.

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following: [Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name] [Title] [Company]

10.7.5 – Part A/B Certified Provider and Supplier Approval Letter Templates

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

A. Approval – Change of Information (Part A/B Certified Org, No Recommendation Required)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has approved your Change of Information (COI) application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or section
	titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title]

[Company]

[CC: **SOG Location** and State]

B. Approval - Post Tie-In Change of Information (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your change of information application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Changed Information	Include detailed changes or section titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

[Title]

[Company]

C. Approval - Post Tie-In Change of Ownership (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name] [Address]

[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your change of ownership application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
CHOW Effective Date	
Medicare Year-End Cost Report Date (Part A CHOWs	
only)	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

D. Approval - Post Tie-In/Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has processed the Medicare Tie in Notice approving your initial enrollment application.

Medicare Enrollment Information

	Legal Business Name (LBN)	
--	---------------------------	--

Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Medicare Year-End Cost Report Date (Part A	
only)	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the
 decision. However, if you have additional information that you would like a Hearing
 Officer to consider during the reconsideration or, if necessary, an Administrative Law
 Judge (ALJ) to consider during a hearing, you must submit that information with your
 request for reconsideration. This is your only opportunity to submit information during
 the administrative appeals process unless an ALJ allows additional information to be
 submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

E. Approval Recommended - Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] assessed your initial Medicare enrollment application and forwarded it to the Centers for Medicare & Medicaid Services (CMS) [City] Regional Office for a final review.

A survey may be conducted by a State Survey Agency or deemed accrediting organization approved by CMS to ensure compliance.

We will contact you when we have a decision.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Medicare Year-End Cost Report Date (Part A	
only)	

For questions concerning the application, contact [Insert State] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

[CC: **SOG Location** and State]

F. Approval Recommended – Change of Information or Change of Ownership (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] assessed your [Change of Information or Change of Ownership] Medicare enrollment application and forwarded it to the Centers for Medicare & Medicaid Services (CMS) [City] Regional Office for a final review.

A survey may be conducted by a State Survey Agency or deemed accrediting organization approved by CMS to ensure compliance.

We will contact you when we have a decision.

Medicare Enrollment Information

Legal Business Name (LBN)		
Doing Business As (DBA)		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number (PTAN)		
Medicare Year-End Cost Report Date (Part A		
only)		
Recommended Changes (applicable to COI	Existing	
and CHOW, remove if doesn't apply)	New	
	Effective Date	

For questions concerning th	e recommended a	application, cor	ntact [Insert State	e] at [contact
information].				

Sincerely,

[Name]

[Title] [Company]

[CC: **SOG Location** and State]

G. Approval – Revalidation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] has [approved your revalidation application/assessed your revalidation application and forwarded it to the Centers for Medicare & Medicaid Services (CMS) [City] Regional Office for a final review].

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
Provider/Supplier National Provider Identifier	
(NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or section
_	titles, as applicable.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the
 decision. However, if you have additional information that you would like a Hearing
 Officer to consider during the reconsideration or, if necessary, an Administrative Law
 Judge (ALJ) to consider during a hearing, you must submit that information with your
 request for reconsideration. This is your only opportunity to submit information during
 the administrative appeals process unless an ALJ allows additional information to be
 submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

H. Approval – Voluntary Termination (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[City] ST [Zip]

[Insert Contractor] completed your application to *voluntarily* disenroll from the Medicare program.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As (DBA)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
Effective Date of Termination and	
Deactivation	

Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this voluntary termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned

provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:
[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

[CC: **SOG Location** and State for Certified Providers/**Suppliers**]

I. Approval – Reactivation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor] approved your reactivation enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number (PTAN)	
PTAN Effective Date	
Participation Status	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR §424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

10.7.5.1 – Part A/B Certified Provider and Supplier Letter Templates – Post-Transition

(Rev. 11574; Issued: 08-25-22; Effective: 06-24-22; Implementation: 09-27-22)

The model letters in this section 10.7.5.1 pertain to certain enrollment transactions involving certified providers and certified suppliers. Except as otherwise stated, the contractor shall begin utilizing these letters (instead of those in section 10.7.5) upon completion of the transition of the applicable CMS Survey & Operations Group (SOG) function to the contractor and the CMS Provider Enrollment & Oversight Group (PEOG). In other words, once a provider specialty, provider agreement, or provider enrollment transaction type (for example, voluntary terminations) has been transitioned, the contractor shall commence using the section 10.7.5.1 letter(s) pertaining to said transaction. CMS will notify contractors once a particular transition has occurred.

For certified provider/supplier transactions (and transaction outcomes) not specifically addressed in this section 10.7.5.1, the contractor shall continue to use the existing model letters in section 10.7 et seq. (even after the aforementioned transition).

In addition:

- (i) Most of the documents in this section 10.7.5.1 identify parties that must receive a copy of the letter in question. If an inconsistency exists between said copied parties and those listed elsewhere in this chapter concerning a particular letter, the parties identified in this section 10.7.5.1 take precedence. To illustrate, suppose another section of this chapter requires X, Y, and Z to be copied on a certain letter while section 10.7.5.1 only requires X to be copied. The contractor in this situation need only copy X.
- (ii) The contractor need only copy an accrediting organization (AO) on a particular letter if the provider/supplier has an AO for the identified provider/supplier specialty. The contractor can typically ascertain this by checking PECOS (for currently enrolled providers/suppliers) or reviewing the application (for initial enrollments) to see if an AO is disclosed. Also, PEOG will often identify an AO (if one exists) in cases where it must review the transaction before notifying the contractor of its final approval (e.g., CHOWs, certain changes of information, voluntary termination).
- (iii) See section 10.7.5.1(P) below for the applicable e-mail addresses of the SOG Locations. The contractor shall insert the relevant e-mail address into any letter in section 10.7.5.1 that addresses the provider/supplier's right to a reconsideration of a provider agreement determination.
- (iv) Any data element boxes that the contractor cannot complete because the information is unavailable or inapplicable (e.g., CMS Certification Number (CCN) in certain instances) can be: (1) left blank; (2) denoted with "N/A," "Not applicable," or any similar term; or (3) removed altogether.
- (v) The Provider Transaction Access Number (PTAN) box should contain the CCN for all provider/supplier types other than ASCs and PXRSs; the PTAN for the latter two supplier types will be that which the contractor assigns or has assigned.
- (vi) The Primary Practice Location Address box shall include the suite number if one was/is listed on the application.
- (vii) For the Denial letter in section 15.7.5.1(H), the contractor shall indicate (in any manner it chooses) whether the denial pertains to the buyer's or the seller's application if a prospective CHOW was involved.
- (viii) In cases where provider/supplier data has changed and the contractor must list "detailed information or application section titles (as applicable)", the contractor has the discretion to list either (i.e., the info or the section titles).

A. Approval – Change of Information (Part A/B Certified Org; No Recommendation to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has approved your Change of Information (COI) application.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Changed Information	Include detailed changes or application	
	section titles, as applicable.	

Provider/Supplier Agreement-Specific Information	
CMS Certification Number (CCN)	
CCN Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title]

[Company]

CC: State Agency [& Accrediting Organization (AO), if applicable]

B. Approval - State Agency Approved Change of Information (Part A/B Certified; Recommendation to State Was Required)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the Medicare State Agency. Your change of information application is now approved.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Changed Information	Include detailed changes or application	
	section titles, as applicable	

Provider/Supplier Agreement Specific Information		
CMS Certification Number (CCN)		
CCN Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title]

[Company]

CC: State Agency [& AO, if applicable]

C. Approval - State Agency Approved Change of Ownership (Part A/B Certified Excluding FQHCs)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]
Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received a response from the State Agency. Your change of ownership application is now approved. The corresponding executed [insert provider/supplier agreement type] is enclosed/attached. Your enrollment and [provider/supplier agreement-specific] information is outlined below:

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	

Provider/Supplier Agreement Specific Information		
CMS Certification Number (CCN)		
CCN Effective Date (use effective date		
of seller's CCN)		
CHOW Effective Date		

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

And

If you are also requesting a reconsideration of the provider/supplier agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to: [Insert: Name and e-mail address of CMS Location Office]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

D. Approval - State Agency Approved Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency. Your initial enrollment application and [provider/supplier agreement] is approved. Your executed [insert provider/supplier agreement name] is enclosed/attached. The effective date is the date you met all federal requirements.

Medicare Enrollment and Provider/Supplier Specific Participation Agreement Information

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Enrollment Effective Date		

Provider/Supplier Agreement Specific Information	
CMS Certification Number (CCN)	
CCN Effective Date	
Medicare Year-End Cost Report Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to: ProviderEnrollmentAppeals@cms.hhs.gov

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name] [Title]

[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

E. Approval Recommended - Initial (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] assessed your initial Medicare enrollment application and your request for participation in the Medicare program as a [insert provider/supplier type] provider/supplier. A recommendation for approval has been forwarded to the [enter name of State Agency], which will review this application for further compliance. A survey may be conducted by a State Survey Agency or deemed accrediting organization approved by CMS.

We will contact you when we have a decision.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Medicare Year-End Cost Report Date	Date that the provider/supplier requested	
	(delete if not applicable)	

For questions concerning the application, contact [Insert State] at [contact information].

Sincerely,		
[Name] [Title] [Company]		

CC: State Agency [and AO, if applicable]

F. Approval Recommended – Change of Information, Change of Ownership, Revalidation, or Reactivation Containing Changed New/Changed Data that the State Must Review (if applicable) (Part A/B Certified)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] assessed your [change of information, change of ownership, revalidation, or reactivation] Medicare enrollment application. A recommendation of approval has been sent to [name of State Agency], which will conduct a review for further compliance.

A survey may be conducted by a State Survey Agency or deemed accrediting organization approved by CMS to ensure compliance.

We will contact you when we have a decision.

Medicare Enrollment Information		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number (PTAN)		

Provider/Supplier Agreement Information		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or	Existing	Seller
Revalidation; remove if inapplicable)	New	Buyer
	Effective Date	

For questions concerning the recommended application, contact [Insert State Agency name] at [contact information].

Sincerely,

[Name] [Title] CC: State Agency [and AO, if applicable]

G. Approval Revalidation (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your revalidation application [include if the application was sent to the state: "and forwarded it to the State Agency. The State Agency review has also been completed"]. Your Medicare enrollment information is provided below.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
PTAN Effective Date	
Changed Information	Include detailed changes or application
	section titles, as applicable.

Provider/Supplier Agreement Information		
CMS Certification Number (CCN)		
Requested Changes (applicable to COI, CHOW, or	Existing	Seller
Revalidation; remove if inapplicable)	New	Buyer
	Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Enroll, make changes or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

And

If you are also requesting a provider/supplier agreement reconsideration, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

H. Denial Letter – Post-1539 (Or Other Similar Notice) Received from State Agency for the following application types—Initials, COIs, CHOWs, revalidations, and reactivations

(This letter only applies in cases where:

(1) A recommendation to the state was required per the instructions in this chapter (e.g., the particular revalidation application contained information/changes requiring state review), and (2) The state sends notification to the contractor (e.g., via the 1539 or other notice) that the application should be denied and/or, if applicable, the provider/supplier agreement should be terminated.

As explained in this chapter, certain changes of information and revalidation applications can result in an enrollment revocation and provider agreement termination, though most do not. Accordingly, the contractor shall insert the applicable review result language (e.g., see bracketed options below) in the first paragraph of the letter.)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[The [insert name of State Agency] completed its evaluation of your [initial application] or [change of information] or [change of ownership] or [revalidation] or [reactivation]. [Insert the following language based on the situation involved and the specific result of the state's review:

[INITIAL ENROLLMENT: Your participation in the Medicare Program and your enrollment in the Medicare Program is [denied] for the following reasons]:

[NO REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION INVOLVED: Your application for [insert] is denied for the following reasons]:

[REVOCATION AND/OR PROVIDER AGREEMENT TERMINATION RESULTING FROM THE APPLICATION SUBMISSION. As a result of the state's review, your provider/supplier agreement for participation in the Medicare program is terminated and your enrollment in the Medicare program is revoked for the following reason(s]:

[INSERT DENIAL OR TERMINATION REASON GIVEN BY THE STATE AGENCY]

Information about your provider/supplier agreement and your Medicare enrollment are outlined in the text box below.

Medicare Administrative Contractor Name Contractor Number	&	
Contractor (varioe)		
Medicare Enrollme	nt Determination	
tatus DENIED [OR REVOKED]		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
National Provider Identifier (NPI)		
Provider Transaction Access Number (PTAN)		
Provider/Supplier Agree	ement Determination	
Provider/Supplier Agreement	Agreement DENIED [OR TERMINATED]	
CMS Certification Number (CCN)		

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

 Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

RECONSIDERATIONS REQUEST—MAILING ADDRESSES:

<u>Requests for Reconsideration: Medicare Provider Enrollment</u>: The reconsideration request regarding your Medicare enrollment may be submitted electronically via e-mail to: <u>ProviderEnrollmentAppeals@cms.hhs.gov</u> or addressed as follows:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

And

<u>Requests for Reconsideration: Medicare Provider/Supplier Agreement</u>: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"

[If a failed survey was involved, the contractor shall include the following language here: "Note that any survey deficiencies may only be addressed as part of the provider/supplier agreement reconsideration process."]

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

CC: State Agency [and AO, if applicable]

I. Approval – Voluntary Termination (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are voluntarily terminating your provider/supplier agreement **or** [Insert Contractor name [and Contractor number]] has completed processing your application [or letter] to voluntarily disenroll from the Medicare program. Therefore, your provider agreement has been terminated and your enrollment in the Medicare program has been voluntarily terminated effective on the dates shown below.

Medicare Enrollment and Provider Agreement Information

Medicare Enrollment Termination and Deactivation of Billing Privileges		
Legal Business Name (LBN)		
Doing Business As Name		
Primary Practice Location Address		
Provider/Supplier Type		
National Provider Identifier (NPI)		
Provider Transaction Access Number		
(PTAN)		
Effective Date of Enrollment		
Termination and Deactivation		

Provider/Supplier Agreement Termination	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the

decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following: [Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

J. Approval – Reactivation (Part A/B Certified Org)

(This letter should be used for reactivation approvals regardless of whether the application was referred to the state agency for review.)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and add Contractor number]] has approved your reactivation enrollment application.

Medicare Enrollment Information

Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
PTAN Effective Date	

Provider/Supplier Agreement Specific Information	
CMS Certification Number (CCN)	
CCN Effective Date	

Include if applicable: [While your PTAN(s) and effective date(s) remain the same, you will have a gap in billing privileges from [deactivation date] through [reactivation date] for failing to fully revalidate during a previous revalidation cycle. You will not be reimbursed for services provided to Medicare beneficiaries during this time period since you were not in compliance with Medicare requirements.]

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.

- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
 - Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the
 decision. However, if you have additional information that you would like a Hearing
 Officer to consider during the reconsideration or, if necessary, an Administrative Law
 Judge (ALJ) to consider during a hearing, you must submit that information with your
 request for reconsideration. This is your only opportunity to submit information during
 the administrative appeals process unless an ALJ allows additional information to be
 submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

And

<u>Requests for Reconsideration: Medicare Provider/Supplier Agreement</u>: For reconsideration of the Provider/Supplier Agreement determination, you must submit a separate Reconsideration Request. Your requests must be e-mailed to:

[Insert: Name and e-mail address of CMS Location Office]

Your e-mail must include the following in the subject line: "Subject: Medicare Provider/Supplier Agreement Reconsideration Request"

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

[Title]

[Company]

(Note: No CC: to State Agency/AO required. Deactivations do not impact certified provider CCN participation status.)

K. Voluntary Termination: Failure to Respond to Request for Information

Month, Day, Year

PROVIDER/SUPPLIER NAME ADDRESS CITY, STATE, ZIP

Reference # Application ID

Dear Provider Name (LBN),

[Insert Contractor name [and Contractor number]] has received notification from the State Agency that you are no longer operational. We have not received a response to the request sent on Month DD, YYYY to update your enrollment information. Therefore, we have disenrolled you from the Medicare program. Your [provider/supplier agreement] has also been terminated.

Medicare Enrollment and Provider Agreement Information

Medicare Enrollment Termination and Deactivation of Billing Privileges	
Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type/Specialty	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Deactivation	

Provider/Supplier Agreement Termination Information	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination. With this termination, your billing privileges are also being deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following:
[Contractor Rebuttal Receipt Address]
[Contractor Rebuttal Receipt Email Address]
[Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

L. Voluntary Termination Cessation of Business

[Month, Day, Year]

PROVIDER/SUPPLIER NAME ADDRESS CITY, STATE, ZIP

Reference Number:

Dear Provider/Supplier Name:

[Insert Contractor name [and Contractor number]] was notified by State Agency Name that on MONTH DD, YYYY, the State Agency attempted to verify if your Type of Provider is operational. The State Agency has reported that your facility was closed, not operational, and/or ceased business at your address of record.

Pursuant to 42 CFR § 489.52(b)(3), CMS considers a cessation of business and providing services to the community to constitute a voluntary withdrawal from the Medicare program.

If you believe that our determination is incorrect and your Type of Provider facility remains operational, you must notify the State Agency and copy this office within 10 days from your receipt of this notice that your facility is still operational and participating in the Medicare program. You must provide the State Agency and this office with information to clarify why your facility was not functional at the address of record at the time the State Agency performed the site survey.

STATE AGENCY NAME ADDRESS CITY, STATE, ZIP

We request that you complete and submit a CMS-855 or an application via the Internet-Based Provider Enrollment Chain and Ownership System (PECOS) for a change of information to indicate that your facility/practice location remains open and operational or to request a voluntary termination of your enrollment.

If we do not hear from you, your Medicare enrollment and corresponding Provider Agreement will be terminated pursuant to 42 CFR § 489.52(b)(3). With this termination, your billing privileges will also be deactivated effective on the aforementioned date of the termination pursuant to 42 C.F.R. § 424.540(a)(7).

If you have any questions, please contact our office at:

Sincerely,

[Name]
[Title]
[Company]

M. Approval – Seller CHOW (Part A/B Certified Org)

[Month, Day, Year]

[Provider/Supplier Name] [Address] [City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] has received notification from the [use "State Agency" or "CMS Survey & Operations Group Location", as appropriate] that the

change of ownership involving [insert seller name] is now approved. Therefore, you have been disenrolled from the Medicare program effective on the date shown below.

Medicare Enrollment Termination Information

Medicare Enrollment Termination	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Termination	

Provider/Supplier Agreement Information	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]

[Title]

[Company]

CC: State Agency [and AO, if applicable]

N. Federally Qualified Health Centers (FQHCs) – Initial Enrollment Approval Letter

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use this letter (which was formerly in section 10.7.19 of this chapter) for all FQHC initial enrollment approvals. For all other FQHC transactions (e.g., revalidations), the contractor may use the applicable letters in either 10.7.5 or 10.7.5.1.

[Month, Day, Year]

[FQHC Name]

[Address]

[City, State, Zip]

Reference # (Application Tracking Number)

Dear [FQHC],

[Insert Contractor] has approved your enrollment as a federally qualified health center (FQHC).

Medicare Enrollment Information

Legal Business Name (LBN)	

Doing Business As (DBA)	
Physical Location Address	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)/CMS Certification Number	
(CCN)	
PTAN/CCN Effective Date	
Medicare Year-End Cost Report Date	

Provider/Supplier Agreement Information	
CMS Certification Number (CCN)	
Effective Date of CCN	

Included with this letter is a copy of your "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes to, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
 - o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
 - o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

 Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

Providers and suppliers may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Compliance & Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

O. Approval – FQHC Change of Ownership

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City, State, Zip]
Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your change of ownership application is now approved. The corresponding executed "Attestation Statement for Federal Qualified Health Center" (Exhibit 177), which CMS has signed, is enclosed/attached. Your enrollment and Exhibit 177 information is outlined below:

Medicare Enrollment Information	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	

Provider Agreement Specific Information	
CMS Certification Number (CCN)	
CCN Effective Date (use effective date	
of seller's CCN)	
CHOW Effective Date	

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

Enroll, make changes, or view your existing enrollment information by logging into PECOS at https://pecos.cms.hhs.gov.

Submit updates and changes to your enrollment information within the timeframes specified at 42 CFR § 424.516. For more information on the reporting requirements, go to Medicare Learning Network Article SE1617.

Find additional Medicare program information, including billing, fee schedules, and Medicare policies and regulations, at [insert contractor's web address] or https://www.cms.gov.

Right to Submit a Reconsideration Request:

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. (Optional Coversheet sentence [To facilitate the processing of your reconsideration request, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.])

Reconsideration requests must:

- Be received in writing within 65 calendar days of the date of this letter and mailed or emailed to the address below.
- State the issues or findings of fact with which you disagree and the reasons for disagreement.
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

- o If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
- o If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
- Authorized or delegated officials for groups cannot sign and submit a reconsideration request on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

You may:

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 CFR Part 498.

The reconsideration request should be sent to:

Centers for Medicare & Medicaid Services Provider Enrollment & Oversight Group ATTN: Division of Provider Enrollment Appeals 7500 Security Blvd. Mailstop: AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

ProviderEnrollmentAppeals@cms.hhs.gov

For questions concerning this letter, contact [Insert Contractor] at [contact information].

Sincerely,

[Name]
[Title]
[Company]

CC: State Agency [and AO, if applicable]

Attachments: [Include any attachments that the contractor must send to the provider/supplier, the state agency, and/or the AO per the instructions in this chapter 10.]

P. 36-Month Rule Voluntary Termination Letter

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [HHA Seller],

[Insert Contractor name] has [Insert appropriate situation (e.g., reviewed [insert HHA's current name] change of ownership application; learned that [insert HHA's current name] may have undergone a change in majority ownership pursuant to 42 C.F.R. § 424.550(b)(1); etc.]. After our review, [Insert Contractor name] has determined that [insert HHA's current name] has undergone a change in majority ownership under 42 C.F.R. § 424.550(b)(1) and that none of the exceptions described in 42 C.F.R. § 424.550(b)(2) apply to this situation. Pursuant to 42 C.F.R. § 424.550(b)(1), therefore, [insert HHA's current name] provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of [insert HHA's current name] must instead:

- Enroll in the Medicare program as a new (initial) home health agency under the provisions of 42 C.F.R § 424.510; and
- Obtain a state survey or an accreditation from an approved accreditation organization.

Consistent with the foregoing, [insert HHA's current name] provider agreement [will be/has been] voluntarily terminated and its Medicare billing privileges [will be/have been] deactivated pursuant to 42 C.F.R § 424.540(a)(8) effective [Insert date(s)].

Medicare Enrollment and Provider Agreement Information

Medicare Enrollment Deactivation	
Legal Business Name (LBN)	
Doing Business As Name	
Primary Practice Location Address	
Provider/Supplier Type	
National Provider Identifier (NPI)	
Provider Transaction Access Number	
(PTAN)	
Effective Date of Enrollment	
Deactivation	

Provider/Supplier Agreement Termination	
CMS Certification Number (CCN)	
Effective Date of CCN Termination	
Reason for Termination	

In accordance with 42 CFR § 489.52, Medicare will not reimburse you for any claims with dates of service on or after your effective date of termination.

REBUTTAL RIGHTS:

If you believe that this deactivation determination is not correct, you may rebut the deactivation as indicated in 42 C.F.R. § 424.545(b). The rebuttal must be received by this office in writing within 15 calendar days of the date of this letter. The rebuttal must state the

issues or findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the rebuttal that you believe may have a bearing on the decision. You must submit all information that you would like to be considered in conjunction with the rebuttal. This includes any application(s) to update your enrollment, if necessary. You may only submit one rebuttal in response to this deactivation of your Medicare enrollment.

The rebuttal must be signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative. Please be advised that authorized or delegated officials for groups cannot sign and submit a rebuttal on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her/their behalf.

If the provider/supplier wishes to appoint a legal representative that is not an attorney to sign the rebuttal, the provider/supplier must include with the rebuttal a written notice authorizing the legal representative to act on the provider/supplier's behalf. The notice should be signed by the provider/supplier.

If the provider/supplier has an attorney sign the rebuttal, the rebuttal must include a statement from the attorney that he/she/they have the authority to represent the provider/supplier.

If you wish to receive communication regarding your rebuttal via email, please include a valid email address in your rebuttal submission.

The rebuttal should be sent to the following: [Contractor Rebuttal Receipt Address] [Contractor Rebuttal Receipt Email Address] [Contractor Rebuttal Receipt Fax Number]

If you have any questions, please contact our office at [phone number] between the hours of [x:00 AM/PM ET/CT/MT/PT] and [x:00 AM/PM ET/CT/MT/PT].

Sincerely,

[Name] [Title] [Company]

CC: State Agency [and AO, if applicable]

Q. Applicable SOG Location E-mail Boxes

CMS Locations Corporate Email Addresses CMS LOCATION BRANCH EMAIL Address CMS Boston CMS Boston ACC & LTC DSC@cms.hhs.gov Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

CMS Philadelphia ACC & LTC ROPHIDSC@cms.hhs.gov

Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

CMS New York	ACC & LTC	RONYdsc@cms.hhs.gov
New Jersey, New York, Puerto Rico, Virgin Islands		
CMS Atlanta	ACC & LTC	ROATLHSQ@cms.hhs.gov
Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee		
CMS Chicago	ACC & LTC	ROCHISC@cms.hhs.gov
Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin		
CMS Kansas City	ACC & LTC	ROkemSCB@cms.hhs.gov
Iowa, Kansas, Missouri, Nebraska		
CMS Denver	ACC & LTC	DenverMAC@cms.hhs.gov
Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming		
CMS Dallas	ACC & LTC	RODALDSC@cms.hhs.gov
Arkansas, Louisiana, New Mexico, Oklahoma, Texas		
CMS San Francisco	ACC & LTC	ROSFOSO@cms.hhs.gov
Arizona, California, Hawaii, Nevada, Pacific Territories		
CMS Seattle	A CCD	CMC DOIO CEDO 11
Alaska, Idaho, Oregon, Washington	ACCB	CMS RO10 CEB@cms.hhs.gov
Alaska, Idalio, Olegoli, washington	LTC	Seattle_LTC@cms.hhs.gov

Alaska, Idaho, Oregon, Washington ACCB CMS_RO10_CEB@cms.hhs.gov LTC Seattle LTC@cms.hhs.gov

10.7.5.1.1 – Additional Certified Provider and Certified Supplier Letters (Rev. 11574; Issued: 08-25-22; Effective: 6-24-22; Implementation: 09-27-22)

This section 10.7.5.1.1 contains additional letters that contractors shall use in certain special situations involving certified providers and suppliers. They take precedence over all other letters in this chapter potentially pertaining to the situations described in this section

A. Denials Based on Survey Failure for Transitioned Certified Providers/suppliers

(This letter does not apply to non-transitioned certified providers/suppliers.)

[Month, Day, Year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier]:

We regret to inform you that (Provider/Supplier] does not meet the requirements for participation in the Medicare program (Title XVIII of the Social Security Act).

In order to participate in the Health Insurance for the Aged and Disabled Program, a [list the provider/supplier type] must be in compliance with all applicable Conditions of [Participation or Coverage, as applicable] established by the Secretary of Health and Human Services. Based on the [list date survey occurred] survey conducted by [list the state agency or accrediting organization name], CMS has determined that your facility does not qualify. The deficiencies that the [list the state agency or accrediting organization name] found are listed on the Survey Report. Your facility is not in compliance with the following Conditions of [Participation or Coverage]:

§ [List regulatory cite (e.g., 42 CFR § 418.56) and the specific provision in question (e.g.,: Interdisciplinary Group, Care Planning, and Coordination of Services]

You may take steps to correct the deficiencies and reapply to establish eligibility. However, current survey funding levels (as appropriated by Congress) may not allow for a resurvey. CMS' priority for use of the limited funds available are to ensure the health and safety of Medicare beneficiaries at currently participating facilities. Contact [list the state survey agency or accrediting organization that performed the initial survey] for the status of initial surveys of non-participating facilities.

Please note that you may submit no more than two reapplications for certification in connection with one enrollment application, and no more than six months may elapse between the date of the first survey denial notification and the CMS Survey & Certification Group's receipt of the second reapplication for certification. Applicants who reapply for certification must undergo and pass a subsequent survey. (Note that a reapplication for certification is different from the submission of a [Form CMS-855A or Form CMS-855B, as applicable to the provider/supplier type] Medicare enrollment application. At this time, you need not submit a [Form CMS-855A or Form CMS-855B, as applicable] to request another survey per the previous paragraph.)

If you believe that this decision is not correct, you may request that this decision be reconsidered. The request must be submitted in writing to [list applicable SOG Location] within 60 days of the date you receive this notice. You may submit with your request any additional information which you feel may have a bearing on this decision. If you have any questions, please contact [list appropriate SOG Location contact person] at xxxxxx@cms.hhs.gov.

Sincerely,

[Name] [Title] [Company] CC: State Agency [and AO, if applicable]