CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11432	**Date: May 26, 2022**
	Change Request 12749

SUBJECT: Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 10 of CMS Publication (Pub.) 100-08, Program Integrity Manual, with instructions regarding the processing of various certified provider and supplier enrollment transactions.

EFFECTIVE DATE: May 27, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 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/Table of Contents
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	10/10.2/10.2.1.4/Federally Qualified Health Centers (FQHCs)
R	10/10.2/10.2.1.6/Home Health Agencies (HHAs)
N	10/10.2/10.2.1.6.1/HHA Ownership Changes
N	10/10.2/10.2.1.6.2/HHA Capitalization
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	10/10.2/10.2.2.8/Portable X-Ray Suppliers (PXRSs)
R	10/10.6/10.6.1.1/Changes of Ownership (CHOWs) – Transitioned Certified Providers and Suppliers
R	10/10.6/10.6.1.1.3.1/Step 1 - Initial Review of the CHOW Application
R	10/10.6/10.6.1.1.3.3/Step 3 – Post-State Review Actions and Scenarios
R	10/10.6/10.6.1.2/Changes of Information – Transitioned Certified Providers and Suppliers
R	10/10.6/10.6.22/Non-Transitioned Certified Provider/Supplier Changes of Ownership
R	10/10.6/10.6.22.1/Non-Transitioned Certified Provider/Supplier Changes of Information

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: 11432	Date: May 26, 2022	Change Request: 12749

SUBJECT: Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions

EFFECTIVE DATE: May 27, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 27, 2022

I. GENERAL INFORMATION

A. Background: As stated in previous CMS sub-regulatory guidance, CMS is "transitioning" certain administrative functions involving certified provider/supplier enrollment transactions from the CMS Survey & Operations Group (SOG) Locations to the Medicare Administrative Contractors (hereafter "contractors") and CMS' Provider Enrollment & Oversight Group. To date, these transactions have included (but are not limited to) voluntary termination applications and federally qualified health center initial enrollment applications, changes of ownership, and changes of information. Effective May 27, 2022, the following enrollment transactions will "transition":

- Ambulatory surgical center (ASC) initial enrollment applications, changes of ownership, and changes of information
- Community mental health center (CMHC) initial enrollment applications, changes of ownership, and changes of information
- Comprehensive outpatient rehabilitation facility (CORF) initial enrollment applications, changes of ownership, and changes of information
- Home health agency (HHA) initial enrollment applications, changes of ownership under 42 CFR § 489.18 (as distinguished from changes in majority ownership under 42 CFR § 424.550(b)), and changes of information
- Outpatient physical therapy/outpatient speech pathology (OPT/OSP) provider initial enrollment applications, changes of ownership, and changes of information
- Portable x-ray supplier (PXRS) initial enrollment applications, changes of ownership, and changes of information

This CR will update Chapter 10 of CMS Pub. 100-08 with instructions regarding the processing of these transactions effective May 27, 2022.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12749.1	The contractor shall process CMHC, CORF, HHA,	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	OPT/OSP, ASC, and PXRS initial applications in accordance with the instructions in Chapter 10 of Pub. 100-08.									
12749.2	The contractor shall process CMHC, CORF, HHA, OPT/OSP, ASC, and PXRS change of ownership applications in accordance with Section 10.6.1.1 in Chapter 10 of Pub. 100-08.	X	X	X						
12749.3	The contractor shall process CMHC, CORF, HHA, OPT/OSP, ASC, and PXRS change of information applications in accordance with Section 10.6.1.2 in Chapter 10 of Pub. 100-08.	X	X	X						
12749.4	The contractor shall, as applicable, utilize the model letters in Section 10.7.5.1 in Chapter 10 of Pub.100-08 for CMHC, CORF, HHA, OPT/OSP, ASC, and PXRS enrollment	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	transactions.									
12749.5	The contractor shall observe that Business Requirements 12749.1 through 12749.4 apply to all applications other than those for which the contractor received a final decision (e.g., CMS-1539, CMS-2007 (tie-in notice)) from the state or SOG Location before May 30, 2022. (That is, they apply to all applications that -- (1) The contractor has not yet received from the provider/supplier or has not yet sent to the state; or (2) Are pending with the state or SOG Location).	X	X	X						
12749.5.1	The contractor shall observe that -- unless it is directed otherwise -- any information it needs regarding the status of an application it has already forwarded to the state shall be obtained from the state, rather than the SOG	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	Location.									
12749.6	The contractor shall abide by the site visit instructions in Section 10.2.1.4 in Chapter 10 of Pub. 100-08.	X								

III. PROVIDER EDUCATION TABLE

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

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC

Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Reminder and Assistance for Health Centers for CMS FQHC Site Enrollment

Health centers are reminded that whenever they receive approval from HRSA to add a new Permanent or Seasonal site to their scope of project and wish to receive FQHC designation and reimbursement from Medicare for this site, the specific Notice of Award (NoA) or Notice of Look-Alike Designation (NLD) which the health center received through the Electronic Handbooks (EHBs) which documents HRSA's approval of the new site, must be provided to CMS.

Specifically, to enroll new sites as FQHCs for Medicare reimbursement, a health center must--

- Submit a complete application package (Form CMS-855A and supporting documents) to the appropriate Medicare Administrative Contractor (MAC) for each new site;
- Receive from the appropriate CMS Regional Office a CMS Certification Number, a signed Medicare agreement, and an effective date ; and
- Along with a completed CMS-855A application, FQHCs should submit the following information:

    - Exhibit 177 (Attestation Statement for Federally Qualified Health Center)
    - **The specific HRSA NoA or NLD <u>which documented the approval of the site</u> the health center wishes to enroll.**
    - CMS-588 Electronic Funds Transfer Authorization Agreement
    - All licenses and certifications for the facility

For an overview of the NoA form, health center can review the following TA resource available at: https://help.hrsa.gov/pages/releaseview.action?pageId=112460729

Please direct CMS enrollment questions to providerenrollment@cms.hhs.gov

For specific steps on how to find your NoA, please see below.

1. Log into EHBs and Click the "Grants" tab

2. Click the dropdown arrow next to the Grant Folder you want to access.

3. Select Last NoA or the Award History Link

4. If you selected the Last NoA link, the View NoA page will display.

5. If you select the Award History Link, the Awards List page will display showing NoAs in the Options column.

    ++ Click the arrow next to the NoA link to View or Download the NoA

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents
(***Rev. 11432; Issued: 05-26-22)***

10.2.1.1 - Community Mental Health Centers (CMHCs)

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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).*

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

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

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. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

(A) Approval Not Recommended

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

b. 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.

c. 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

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

A. Statutory Background

Section 4161(a)(2) of OBRA '90 (P.L. 101-508) amended §1861(aa) of the Act and established FQHC services as a benefit under the Medicare program effective October 1, 1991. The statutory requirements that entities must meet to be considered an FQHC for Medicare purposes are at §1861(aa)(4) of the Act. Regulations establishing the FQHC benefit and outlining the Conditions for Coverage for FQHCs were published on June 12, 1992, in the Federal Register (57 FR 24961) and became effective on the date of publication. These regulations were amended on April 3, 1996 (61 FR 14640). Section 13556 of OBRA 1993 (P.L. 103-66) amended §1861(aa) of the Act by adding outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, as entities eligible to participate in Medicare as FQHCs.

B. Requirements

FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, certified nurse-midwives, and clinical social workers. This also includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See Pub. 100-02, chapter 13 for more information). To participate in the Medicare program, applicants seeking initial enrollment as an FQHC must submit a Form CMS-855A application to the appropriate Medicare Administrative Contractor (MAC). Even though they complete the Form CMS-855A application, FQHCs are considered Part B certified suppliers and are paid Part B benefits for FQHC services.

FQHCs are not required to obtain a state survey. However, FQHCs still must meet all applicable state and local requirements and submit all applicable licenses. Typically, the Health Resources and Services Administration (HRSA) will verify such state/local compliance by asking the FQHC to attest that it meets all state/local laws.

FQHCs can be located in a rural or urban area that is designated as either a health professional shortage area or an area that has a medically underserved population.

For purposes of Medicare enrollment, an FQHC is defined as an entity that has entered into an agreement with CMS to meet Medicare program requirements under 42 CFR § 405.2434(a), and (as outlined in Pub. 100-07, chapter 9, exhibit 179):

- Is receiving a grant under § 330 of the Public Health Service (PHS) Act;
- Is receiving funding under a contract with the recipient of a § 330 grant, and meets the requirements to receive a grant under § 330 of the PHS Act;
- Is an FQHC "Look-Alike" (i.e., HRSA), has notified it that it meets the requirements for receiving a § 330 grant, even though it is not actually receiving such a grant);
- Was treated by CMS as a comprehensive federally funded health center as of January 1, 1990; or
- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

C. Initial FQHC Applications

1. Contractor Review and Required Documents

In contrast to both past practice and the process that is normally followed with other certified provider/certified supplier types, the contractor does not make a recommendation for approval to the state/SOG Location for FQHC applications. Instead, the contractor will either approve or deny the application at the contractor level pursuant to the instructions in this section.

The following documents must be included with the FQHC's completed Form CMS-855A application:

- One signed and dated copy of the attestation statement (Exhibit 177). In order to attest to being in compliance, the facility must be open and operating when the attestation is signed. Since FQHCs must sign an agreement stipulating that they will comply with § 1861(aa)(4) of the Act and specific FQHC regulations, this statement serves as the Medicare FQHC benefit (or provider/supplier) agreement when it is also signed and dated by PEOG. (See Pub. 100-07, chapter 2, section 2826B.)
- HRSA Notice of Grant Award (NOA) or FQHC Look-Alike Designation that includes an address for the site of the applicant which matches the practice location reported on the Form CMS-855A. A Notice of Grant Award by HRSA verifies that the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies look-alike status.
- Form CMS-588; Electronic Funds Transfer (EFT) Authorization Agreement.
- Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable). Facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. One example would be facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostics test. Pub. 100-07, chapter 6, section 6002 provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the FQHC's responsibility to review the CLIA requirements and obtain a CLIA certificate if

needed. Neither the contractor nor CMS determines whether the FQHC needs to obtain and submit a CLIA certificate.

- Copy of state license (if applicable).

2. General Processing Concepts

(A) Practice Locations - An FQHC cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own CCN.

(B) Date on the NOA - The project period (Item 6 of the NOA) *must* be valid through the date on which the FQHC's application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if the project period and/or budget period do not meet the aforementioned requirement. *(In developing for this data, the contractor may (but is not required to) send the "Reminder and Assistance for Health Centers for CMS FQHC Site Enrollment" guidance to the FQHC.)*

(C) Name on Exhibit 177 - The contractor shall ensure that Exhibit 177 contains the same legal business name and address as that which the FQHC provided in Section 2 and Section 4, respectively, of the Form CMS-855A. If the attestation contains a different name, the contractor shall develop for the correct name.

(D) Date on Exhibit 177 - The contractor shall ensure that the date on which the Exhibit 177 was signed is on or after the date the FQHC listed as its effective date on the Form CMS-855A application. If the Exhibit 177 was signed prior to the listed effective date, the contractor shall (using the development procedures outlined in this chapter) develop for an Exhibit 177 signed on or after the FQHC's listed effective date; the FQHC should be providing services in order to meet the regulations noted in Exhibit 177.

(E) Date Application Complete - When reviewing an initial FQHC application, the contractor shall determine the date on which the FQHC's application was complete. To illustrate, assume that the FQHC submitted an initial application on March 1. Two data elements were missing, so the contractor requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its approval letter as the effective date of the FQHC.

(*F*) Contractor Jurisdiction - Except for tribal and Urban Indian FQHCs, a freestanding FQHC that is initially enrolling is assigned to the Medicare Administrative Contractor (MAC) that covers the state in which the FQHC is located. An initially enrolling tribal or Urban Indian FQHC is assigned to the Jurisdiction H MAC.

(*G*) Tribal/Urban Indian Organizations – Certain outpatient health programs or facilities may be operated by a tribe or tribal organization or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act. The contractor shall confirm the applicant's attestation and tribal/urban Indian status if the FQHC indicates on the application that it has such status; several means are available:

- The applicable Indian Health Service (IHS) web link at https://www.ihs.gov/locations/. The contractor can search for the facility by clicking on the "Find Health Care" sub-link https://www.ihs.gov/findhealthcare/?CFID=15011511&CFTOKEN=36378825 or downloading the Excel complete listing of HIS facilities. (These are the highly recommended means of verification.)

- Contacting (1) the IHS directly, (2) contacting the applicable SOG Location, or (3) the contractor's PEOG BFL.

(*H*) Potential RHC Relationship – On occasion, a rural health clinic (RHC) may seek to convert to an FQHC. (A facility cannot be both an RHC and an FQHC.) Accordingly, in its review of an initial FQHC application, the contractor shall check PECOS to determine whether an RHC is enrolled at the same location. If one is, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov. In doing so, the contractor shall furnish to PEOG (1) the names, NPIs, and shared address of the RHC and FQHC, and (2) a copy of all information submitted with the FQHC application; the e-mail's subject line shall state: "RHC & FQHC shared address".

3. Determination

a. Approval

The contractor shall contact PEOG via email at MedicareProviderEnrollment@cms.hhs.gov if it believes that the FQHC's initial application should be approved. The contractor shall provide to PEOG: (1) a copy of the draft approval letter (see section 10.7.5.1(N) of this chapter for a model FQHC approval letter); (2) the Form CMS-855A application or PECOS Application Data Report (ADR) and all supporting documentation; (3) a copy of the FQHC's HRSA documentation; and (4) Exhibit 177.

While awaiting PEOG's final determination---and beginning on the date following the sending of the aforementioned e-mail---the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

b. Denial

If the contractor believes that the FQHC's application should be denied, the contractor shall notify the applicant of the denial using the appropriate model letter guidance in section 10.7.8 of this chapter. If the contractor is uncertain as to whether a denial is warranted or what the appropriate denial ground under 42 CFR 424.530(a) should be, it may contact its PEOG BFL for guidance.

4. Post-PEOG Review and Response to Contractor

If PEOG determines (based on the information the contractor furnished) that the FQHC's application should be approved, PEOG will:

- Assign the CCN, which will be part of the 1800-1989 series
- Assign the effective date, which will be the date the FQHC application was considered complete by the contractor
- Make any necessary revisions to the draft approval letter
- Sign and date the attestation using the completion date, which is also the effective date (Exhibit 177)
- E-mail all of the foregoing documents and data to the contractor, at which point the aforementioned processing time clock resumes.

5. Post-Approval Contractor Action

If PEOG notifies the contractor that the FQHC's application should be approved, the contractor shall send the approval letter to the FQHC with a copy of the signed Exhibit 177.

D. Changes of Information

1. Location Changes

a. Verification

If an FQHC is changing the physical location of an existing site, the FQHC must submit the following documentation (as applicable to that FQHC) to the contractor:

- For §330 grantees, a Notice of Grant Award approving the physical location change and the new address; or
- For look-alikes, an updated letter from HRSA approving the physical location change and listing the new address.

(Consistent with the instructions in this chapter, the contractor shall develop for this documentation with the FQHC if the latter fails to submit it.)

For tribal/Urban Indian organizations, the contractor may confirm the new location via the IHS website or by contacting IHS. (See section 10.2.1.4(C)(2)(G) above for the web link.)

In all cases, the new address listed on the notice of grant award (NOA), IHS website, etc., must match that listed on the Form CMS-855A change request. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter. In addition, both the budget date and the project date on the NOA must be valid through the date on which the FQHC's change request application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if the project period and/or budget period do not meet the aforementioned requirement.

b. Approval

If approving the location change or updating the contact information (as described in section 10.6.1.2 of this chapter), the contractor does not issue a recommendation of approval to the SOG Location, notwithstanding any instruction to the contrary in this chapter; rather, the contractor shall approve the location change in PECOS and issue an approval letter to the FQHC (with an e-mailed copy to PEOG at MedicareProviderEnrollment@cms.hhs.gov (Subject line: FQHC COI—Address Change/Contact Change/Other). PEOG will update ASPEN accordingly.). Beginning on March 15, 2021, tie-in notices will not be issued for address changes.

c. Denial

If the contractor does not approve the location change (i.e., the FQHC is no longer located in a shortage area, the FQHC fails to submit the applicable HRSA supporting documentation after contractor development (discussed above), or another reason is implicated), the contractor shall refer the matter to PEOG at ProviderEnrollmentRevocations@cms.hhs.gov consistent with all applicable instructions in this chapter and other CMS directives. (The referral shall include, at a minimum, the FQHC's LBN and NPI as well as a brief explanation of the situation and the reason for referral.) PEOG will review the matter and instruct the contractor on how to proceed.

2. LBN, TIN, or DBA Name Changes Not Involving a CHOW

The contractor shall process LBN, TIN, or DBA name changes not involving a CHOW consistent with the instructions in sections 10.6.1.2(B)(1) and (3) of this chapter. No notification to the state or SOG Location regarding the change is needed.

3. All Other Change Requests

For all change requests not described in subsections (D)(1) and (2) above, the contractor shall follow the instructions in sections 10.6.1.2(C)(1) and (2) of this chapter.

E. Changes of Ownership (CHOWs)

This section 10.2.1.4(E) addresses procedures for processing FQHC CHOWs. Except as noted otherwise, these instructions take precedence over those in section 10.6.1.1.3 et seq. of this chapter.

For background information on CHOWs (which, for purposes of section 10.2.1.4(E), includes acquisitions/mergers and consolidations) and potential CHOW situations, see sections 10.6.1.1.1 and 10.6.1.1.2 of this chapter. The contractor shall, as needed, refer to these instructions in examining whether a CHOW has occurred. In reviewing said sections, the contractor shall note the following:

- The "provider agreement" for FQHCs is the Exhibit 177.
- No recommendations to the state or SOG Location are involved. The contractor and PEOG alone will handle the transaction. In particular, the contractor---in lieu of making a recommendation to the state/SOG Location---will send its "final analysis" to PEOG. PEOG will then: (i) review the transaction; (ii) determine whether the CHOW should be approved; (iii) as needed, update ASPEN and perform any other related tasks; and (iv) notify the contractor of the results of its review and provide any required direction. The aforementioned process, in effect, combines a recommendation to the state/SOG Location and the contractor's post-recommendation e-mail to PEOG (described in section 10.6.1.1.3.3(B)) into a single step. For purposes of this section 10.2.1.4(E), the term "final analysis" (in the context of FQHC CHOWs) is roughly the equivalent of a recommendation to the state. Accordingly, when sending its "final analysis" to PEOG as described above, the contractor may—but is not required to—change the application's status in PECOS to "approval recommended."

In addition---and except as otherwise stated---the contractor shall adhere to the following subsections and instructions in sections 10.6.1.1.3 et seq. and 10.6.1.1.4:

(i) Section 10.6.1.1.3.1(A) (This does not include the list of documents in section 10.6.1.1.3.1(A)(iii), although all other instructions in section 10.6.1.1.3.1(A)(iii) shall be followed (e.g., development for missing/deficient documents). The required FQHC CHOW documents are identified in this section 10.2.1.4(E).)

(ii) Section 10.6.1.1.3.1(B) (Regarding section 10.6.1.1.3.1(B)(4), the contractor shall make this referral to PEOG before (and separate from) sending its final analysis to PEOG.)

(iii) Sections 10.6.1.1.3.1.1(A)(1), (A)(2), (A)(3), (B)(1), (B)(2), (B)(3)(a) and (c), (F), and (G). (The contractor can disregard references to state recommendations in these sections.) The remaining topics/instructions in section 10.6.1.1.3.1.1 are either inapplicable to FQHC CHOWs or addressed in this section 10.2.1.4(E).

(iv) Sections 10.6.1.1.4(A), (B), (C), (D), (E), (F), (G), and (H) (With respect to the application of 10.6.1.1.4(C) to FQHC CHOWs, receipt of an approval recommendation from

the state (as described in 10.6.1.1.4(C)) is the equivalent of the contractor sending its final analysis to PEOG.)

The following instructions address FQHC-specific CHOW processing activities that the contractor shall follow in addition to the procedures contained in the section 10.6.1.1 et seq. subsections outlined in (i) through (iv) above. If any inconsistency exists between these two sets of instructions (i.e., recommending approval to the state as described in 10.6.1.1 et seq. versus making a final analysis to PEOG as described below), the latter takes precedence.

1. Special Processing Steps

a. Required Documents – The contractor shall ensure that the FQHC submits all documentation otherwise required per this chapter. For FQHC CHOW purposes, this also includes:

- 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(B) for more information on such documents.)

- Evidence of state licensure of the new entity, if applicable. (This can be furnished consistent with existing instructions in this chapter concerning submission of evidence of state licensure.)

- Exhibit 177 containing the new owner's information.

- HRSA NOA or FQHC Look-Alike Designation containing the new owner's information. (NOTE: Both the budget date and the project date on the NOA must be valid through the date on which the FQHC's CHOW application was complete (as determined by the contractor). The contractor shall develop for a correct NOA date(s) if the project period and/or budget period do not meet the aforementioned requirement.)

b. Old and New Owner Applications

i. Order of Receipt - To the maximum extent practicable, FQHC CHOW applications from the previous and new owners should be processed as they arrive.

ii. Non-Receipt of Previous Owner's Application – Although the contractor shall attempt to collect the old owner's application, it may make its final analysis without it.

c. Relocation of Entity - A new owner may seek to relocate the FQHC concurrent with a CHOW. In such cases, the contractor shall ensure that the FQHC submits (along with the documents in (E)(1)(a) above):

- For § 330 grantees, a Notice of Grant Award approving the physical location change and the new address; or
- For look-alikes, an updated letter from HRSA approving the physical location change and listing the new address.

For tribal/Urban Indian organizations, the contractor may confirm the new location via the IHS website or by contacting IHS. (See section 10.2.1.4(C)(2)(H) above for the web link.)

The new address listed on the notice of grant award, IHS website, etc., must match that on the Form CMS-855A CHOW application. If it does not, the contractor shall develop with the FQHC for clarification consistent with the instructions in this chapter.

Notwithstanding the foregoing, the entire transaction shall be processed as a CHOW rather than a COI.

d. Intervening Change of Ownership

In situations where the FQHC (1) submits a Form CMS-855 initial application or CHOW application and (2) subsequently submits a Form CMS-855 CHOW application, the contractor shall adhere to the following:

Situation 1 – The FQHC submitted an initial application followed by a CHOW application, and the contractor has not yet sent its final analysis to PEOG: The contractor shall return both applications and require the FQHC to re-submit an initial application with the new owner's information.

Situation 2 - The FQHC submitted a CHOW application followed by another CHOW application, and the contractor has not yet sent its final analysis to PEOG regarding the first application: The contractor shall process both applications, preferably in the order they were received. When sending its final analysis to PEOG, the contractor shall explain the dual CHOW application submission.

Situation 3 - The FQHC submitted an initial application followed by a CHOW application, and the contactor has sent its final analysis of the initial application to PEOG but before it has notified the FQHC of the approval of the initial application: The contractor shall:

- Return the CHOW application.

- Notify PEOG via e-mail that a change of ownership has occurred (the new owner should be identified) and that the contractor will require the FQHC to resubmit a new initial application containing the new owner's information.

- Request via letter that the FQHC submit a new initial Form CMS-855 application containing the new owner's information within 30 days of the date of the letter. If the FQHC fails to do so, the contractor shall return the originally submitted initial application and notify the FQHC accordingly. If the FQHC submits the requested application, the contractor shall process it consistent with the instructions in this chapter; the originally submitted initial application becomes moot. If the newly submitted/second initial application is denied, however, the first submitted application is denied as well; the contractor shall notify the FQHC accordingly.

Situation 4 - The FQHC submitted a CHOW application followed by another CHOW application, and the contactor has sent its final analysis of the first CHOW application to PEOG but before it has notified the FQHC of the approval thereof - The contractor shall:

- Notify PEOG via e-mail that (1) a subsequent change of ownership has occurred (the new owner should be identified) and (2) the contractor will require the FQHC to resubmit a new CHOW application containing the subsequent/second new owner's information.

- Process the new/second CHOW application as normal. If a final analysis to PEOG is made for this application, the contractor shall explain this situation in its e-mail; the first CHOW application becomes moot. If the newly submitted/second CHOW application is returned or rejected per the instructions in this chapter, the first application should, too, be returned or rejected (as applicable). The contractor shall notify the provider and PEOG accordingly.

2. Post-Initial Review Actions and Scenarios

After the contractor completes the tasks described in the above-referenced sections, several results are possible. These are discussed below. Should the contractor encounter a scenario not addressed herein, it may contact its PEOG BFL for guidance prior to its final analysis. As a reminder, nothing in this section 10.2.1.4(E)(2) prohibits the contractor from returning or rejecting the application if otherwise permitted to do so per this chapter.

a. The contractor ascertains that the transaction falls within the scope of § 489.18 and that the new owner has accepted assignment – If there are no apparent grounds for denying the CHOW application, the contractor shall send its final analysis to PEOG via e-mail at MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application or PECOS Application Data Report; (2) a copy of the final sales/transfer agreement; (3) a copy of the provider-signed Exhibit 177; and (4) NOA. PEOG will countersign the Exhibit 177 and assign an effective date of the CHOW based on the date the application was complete (as determined by the contractor). Within 5 business days of receiving from PEOG the signed Exhibit 177 and effective date, the contractor shall: (1) send the CHOW approval letter and a copy of the CMS-countersigned Exhibit 177 to the FQHC; and (2) switch the PECOS record to "approved" consistent with existing instructions.

If a denial ground exists, however, the contractor shall refer the matter to its PEOG BFL for guidance notwithstanding any other instruction in this chapter to the contrary. The contractor should include an explanation of the ground(s) it believes exists for the denial (including the regulatory citation); the e-mail referral shall state in the subject line "FQHC Guidance Required."

b. The contractor ascertains that the transaction falls within the scope of § 489.18 but the new owner has not accepted assignment – The contractor shall: (a) return the application; and (b) notify the new owner in the return letter that it must submit the following within 30 days from the date of the return letter: (1) an initial Form CMS-855 application to enroll as a new FQHC; and (2) a voluntary termination application for the existing FQHC. If the new owner fails to do so within 30 days of the request, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter. PEOG will review the matter and respond to the contractor.

c. The contractor ascertains that the transaction does not fall within the scope of § 489.18 (e.g., stock transfer), regardless of whether the new owner accepted assignment - This qualifies as an ownership change under 42 CFR § 424.516 rather than a CHOW under § 489.18. The contractor shall: (A) return the application; and (B) notify the FQHC in the return letter that it must submit a Form CMS-855 application to report the ownership change within 30 days of the return letter and provide all supporting documentation (including a revised NOA and agreement). If the provider fails to do so, the contractor shall contact its PEOG BFL via e-mail with this information notwithstanding any other instruction to the contrary in this chapter.

F. Timeframes and Alternatives

While awaiting PEOG's final determination (and beginning on the date following the sending of the aforementioned e-mail) for the applications described in subsections (C), (D), and (E), the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's decision. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock. In addition, nothing in this section 10.2.1.4 negates other processing alternatives outlined in this chapter that can apply to the processing of FQHC applications.

G. Revocations and Other Transactions

Except as otherwise stated or required by CMS, the contractor shall continue to adhere to the applicable instructions in this chapter and all other CMS directives regarding:

- Potential FQHC revocations and referrals (including sending the referral/information to the appropriate PEOG mailbox)
- Changes of ownership
- Changes of information
- Revalidations
- Reactivations

Upon revalidation or reactivation, an FQHC need not submit a new HRSA Notice of Award (NoA) (unless HRSA made an update and issued the FQHC a new one) or new Exhibit 177; new provider agreements are not required for either transaction.

H. Complaint Investigations

CMS SOG Locations investigate complaints that raise credible allegations of an FQHC's noncompliance with health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR 491 Subpart A (except for 42 CFR § 491.3). The contractor shall refer such complaints to the SOG Location that has jurisdiction over the FQHC.

I. FQHC DPV Errors

(This only applies to initial applications (subsection (C)(1) above) and location changes (subsection (D)(1).)

A site visit for FQHCs is generally not required. However, the contractor shall order a site visit if there is a DPV error. The site visit shall be ordered before the contractor sends the applicable e-mail described in subsections (C)(3)(a) and (D)(1)(b) above. If the site visit finds that the facility is not open and operational, the contractor shall deny the application. If the facility is open and operational, the contractor can proceed as normal.

J. Additional Data

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Act
- 42 CFR Part 491 and 42 CFR Part 405, subpart X
- Pub. 100-07, chapter 2, sections 2825 – 2826H
- Pub. 100-07, chapter 9, exhibits 177 and 179
- Admin Info 21 06-ALL – Transitioning FQHC Certification Enrollment Performed by the CMS SOG (Standard Operating Procedures attached)
- Pub. 100-04, chapter 9
- Pub. 100-02, chapter 13

For additional information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see Pub. 100-04, chapter 1, section 20 as well as Pub. 100-07, chapter 9, exhibit 179.

10.2.1.6 - Home Health Agencies (HHAs)

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) 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).)

If:

***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 "*Y*es" 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. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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, the contractor shall send a letter to the HHA notifying it 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.*

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. The effective date of the deactivation shall be the date the HHA is notified that it must enroll as an initial applicant. If the sale has not occurred, the contractor shall alert the HHA that it must 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).

10.2.1.6.2 – HHA Capitalization

(Rev. 11432; Issued:0 5-26-22; Effective: 05-27-22; Implementation: 05-27-22)

A. Background

Effective January 1, 2011, and pursuant to 42 CFR §§ 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program - including a new HHA resulting from a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds (known as initial reserve operating funds) at (1) the time of application submission and (2) all times during the enrollment process, to operate the HHA for the three-month period after the Medicare contractor conveys billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

B. Points of Review

At a minimum, the contractor shall verify that the HHA meets the required amount of capitalization:

- *1st Review - Prior to making its recommendation for approval to the state;*

- *2nd Review - After a recommendation for approval is made but before the contractor receives the state's recommendation;*

- *3rd Review - After the contractor receives the state recommendation but before it sends to PEOG the e-mail described in section 10.2.1.6(B)(3)(B); and*

- *4th Review - During the 3-month period after the contractor conveys Medicare billing privileges to the HHA*

For initial applications, the contractor shall verify that the HHA meets all of the capitalization requirements addressed in 42 CFR §489.28. (Note that capitalization need not be reviewed for revalidation, reactivation applications, and changes of ownership that do not require a new/initial enrollment under §424.550(b).) The contractor may request from the HHA any and all documentation deemed necessary to perform this task.

The HHA must submit proof of capitalization within 30 calendar days of the contractor's request to do so. Should the HHA fail to furnish said proof and billing privileges have not yet been conveyed, the contractor shall deny the HHA's application pursuant to §424.530(a)(8)(i) or (ii), as applicable. If billing privileges have been conveyed, the contractor shall revoke the HHA's billing privileges per §424.535(a)(11).

Should the contractor deem it necessary to verify the HHA's level of capitalization more than once within a given period (e.g., more than once between the time a recommendation is made and the completion of the state review process), the contractor shall seek approval from its PEOG BFL.

C. Determining Initial Reserve Operating Funds

Initial reserve operating funds are sufficient to meet the requirement of 42 CFR §489.28(a) if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of three or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first 3 months of operation--or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs--whichever is greater.

The contractor shall determine the amount of the initial reserve operating funds by using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the contractor serves that are comparable to the HHA seeking to enter the Medicare program. Factors to be used in making this determination shall include:

- *Geographic location and urban/rural status;*
- *Number of visits;*
- *Provider-based versus free-standing status; and*
- *Proprietary versus non-proprietary status.*

The adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first 3 months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a 3-month period for the HHAs used in determining the average cost per visit.

D. Proof of Operating Funds

As described further in section 10.2.1.6.2(E) and (G) below, the HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For purposes of the capitalization requirement, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify as meeting the initial reserve operating funds requirement. Examples of cash equivalents for purposes of the capitalization requirement are Treasury bills, commercial paper, and money market funds.

As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS may later require the HHA to furnish: (1) another attestation from the financial institution that the funds remain available; and/or (2) documentation from the HHA that any cash equivalents remain available until a

date when the HHA will have been surveyed by the state agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds constitutes non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

E. Borrowed Funds

1. General Information

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA. As part of this, and except as stated in section 10.2.1.6.2(E)(2) and (H) below, the HHA must (at a minimum) furnish: (1) a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds; and (2) an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds; this could include furnishing an attestation from a financial institution or other source (as may be appropriate) to establish that such funds will remain available until a date when the HHA will have been surveyed by the state agency or by an approved accrediting organization.

2. Inability to Obtain Attestation Statements

Several national bank chains are no longer providing the attestation statements referenced in 42 CFR § 489.28(d) and § 489.28(e) (e.g., to verify the existence of capitalization funds for HHAs). Accordingly, the contractor may accept a current bank statement unaccompanied by an attestation from an officer of the bank or other financial institution if the HHA cannot secure the attestation. (See the phrase "(if the financial institution offers such attestations)" in revised § 489.28(d) and (e).) All efforts must be exhausted, however, to obtain the attestation of funds statement before the contractor can forgo this requirement. In no circumstances shall the contractor instruct the HHA to obtain a different bank that will provide an attestation statement. All other documents listed in section 10.2.1.6(G) must be obtained if required.

F. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

G. Documents

As part of ensuring the prospective HHA's compliance with the capitalization requirements, the contractor shall obtain the following from the HHA:

- *A document outlining the HHA's projected budget – preferably, a full year's budget broken out by month*

- *A document outlining the number of anticipated visits - preferably a full year broken out*

by month

- *An attestation statement from an officer of the HHA defining the source of funds*

- *Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)*

- *Except as stated in section 10.2.1.6.2(E)(2) above, a letter from an officer of the bank attesting that funds are available*

- *If available, audited financial statements*

The contractor shall also ensure that the capitalization information in Section 12 of the Form CMS-855A is provided.

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

(Rev.1 1432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) 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. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

a. Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) 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. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) 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

10.2.2.8 – Portable X-Ray Suppliers (PXRSs)

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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 10.7.5.1 of this chapter; and (2) if required under section 10.6.6 (or another CMS directive) of this chapter, referring the matter to PEOG for review prior to denying the application.

3. Completion of State Review

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

(A) Approval Not Recommended

If the state does not recommend approval, it will notify the contractor thereof. (The contractor may accept any notification that is in writing (e-mail is fine).) 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 inside the vehicle. Examples of such vehicles include mobile homes and trailers. A portable unit involves a supplier transporting medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.

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

- All geographic locations at which services will be rendered.

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

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

10.6.1.1 – Changes of Ownership (CHOWs) – *Transitioned Certified Providers and Suppliers*

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

(Until further notice from CMS, the instructions in sections 10.6.1.1 through 10.6.1.1.4 apply only *to certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, Part A OPT/OSP, ASCs, and PXRSs. T*he contractor shall continue to use the existing CHOW instructions--now in section 10.6.22 of this chapter--for all non-*transitioned* certified provider/supplier types.

When executing the instructions in sections 10.6.1.1 through 10.6.1.1.4, the contractor can disregard directives that obviously do not apply to *the provider/supplier type in question* (e.g., references to home health agencies *do not apply to SNFs).*

Except as otherwise noted, the term "CHOW" as used in section 10.6.1.1 et seq. includes CHOWs, acquisitions/mergers, and consolidations. Though the Change of Ownership (CHOW) Information section of the Form CMS-855A separates the applicable transactions into CHOWs, acquisition/mergers, and consolidations for ease of disclosure and reporting, they fall within the general CHOW category under 42 CFR § 489.18 (e.g., an acquisition/merger is a type of CHOW under § 489.18).

Note that the CHOW instructions in 10.6.1.1 through 10.6.1.1.4 apply to HHA CHOWs taking place under 42 CFR § 489.18. For changes in majority ownership under 42 CFR § 424.550(b), see section 10.2.1.6.1 of this chapter.

10.6.1.1.3.1 – Step 1 - Initial Review of the CHOW Application

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

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-Certification/SurveyCertEmergPrep/Downloads/Facility-Transfer-Agreement-Example.pdf for an example.)

(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 rej*ected 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. TIN Change - 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 should review the sales/lease agreement closely, for this will help indicate whether a CHOW has occurred.

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. Acceptance of Assignment – 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. Situations Requiring Referral to PEOG – 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).

10.6.1.1.3.3 – Step 3 – Post-State Review Actions and Scenarios

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

The state will notify the contractor once it has completed the tasks identified in section 10.6.1.1.3.2(B) above (normally within 90 days of receiving the package from the contractor). In general, 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 the notification so long as it is in writing (e-mail is fine). No later than 5 business days after receiving this notification, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application or PECOS Application Data Report; (2) a copy of the final sales/transfer agreement; and (3) a copy of the Form CMS-1539 or similar documentation received from the state. PEOG will review the matter, perform any administrative functions, and respond to the contractor with applicable direction.

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 tie-in or tie-out notice, neither of which are issued any longer for CHOWs.)

No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov with the following information and documents: (1) the Form CMS-855 application (or PECOS Application Data Report) and all application attachments; (2) a copy of the final sales/transfer agreement; (3) a copy of the Form CMS-1539 or similar documentation received from the state; (4) a copy of the provider-signed Form CMS-1561/1561A/370 (as applicable); (5) a copy of the Form HHS-690; and (6) 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. PEOG will countersign the provider agreement, assign an effective date of the CHOW based on the information received from the contractor, and approve the draft letter (with possible edits).

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

10.6.1.2 – Changes of Information – *Transitioned Certified Providers and Suppliers*

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

(Until further notice from CMS, the instructions in this section 10.6.1.2 apply only to *certified provider and certified supplier types that have officially "transitioned" as part of the transition of various certification activities from the SOG Location to the states, the contractors, and PEOG. These provider/supplier types include SNFs, HHAs, CMHCs, CORFs, Part A OPT/OSP providers, ASCs, and PXRSs;* said instructions will eventually apply to *most other* certified provider and certified supplier types, and the instructions are written with this in mind. In the interim, the contractor shall continue to use the existing change of information instructions--now in section 10.6.22.1 of this chapter--for all *non-transitioned* certified provider/supplier types.

When executing the instructions in this section 10.6.1.2, the contractor can disregard directives that obviously do not apply *to the transitioned provider/supplier type* in question (e.g., references to *hospitals*).

All references to the SOG Location (formerly the "RO") in this section 10.6.1.2 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

The instructions in this section 10.6.1.2 address the handling of changes of information involving certified providers and certified suppliers. With the transition of certain functions from the SOG Locations to the contractors and the Provider Enrollment & Oversight Group (PEOG), the processing instructions for these changes of information are slightly different from previous guidance. In particular: (1) the SOG Locations will be much less involved in the process; (2) tie-in and tie-out notices will no longer be issued; (3) the contractor will be responsible for finalizing changes previously requiring SOG Location approval; and (4) recommendations of approval will be made to (and reviewed by) the state agency (hereafter occasionally referenced simply as "state") only and not the SOG Location.

Except as stated otherwise:

(1) Any provider-specific instructions in section 10.2.1 et seq. of this chapter pertaining to changes of information (e.g., relocation of a federally qualified health clinic site) take precedence over those in this section 10.6.1.2.

(2) Any instructions pertaining to ownership changes in section 10.6.1.1 et seq. of this chapter take precedence over those in this section 10.6.1.2.

(3) Any instructions pertaining to voluntary terminations of entire enrollments and/or provider agreements in section 10.6.1.3 of this chapter take precedence over those in this section 10.6.1.2.

(4) Any instructions in this section 10.6.1.2 concerning the voluntary termination of a branch, sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section 10.6.1.2 when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Changes of Information Requiring Recommendation to the State

1. Types

The following Form CMS-855 transactions require an approval recommendation to (and review by) the state prior to approval:

- Addition of outpatient physical therapy/outpatient speech pathology extension site
- Addition of hospice satellite
- Addition of HHA branch
- Addition or deletion of a prospective payment system (PPS)-excluded psychiatric unit or rehabilitation unit
- Addition or deletion of swing-bed approval (see Section 2A2 of the Form CMS-855A)
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- *Addition of hospital physician/practitioner group practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)*
- *Excluding hospital physician/practitioner group practice locations,* change and/or relocation of a practice location *regardless of whether* a survey of the new site may be required.
- Addition of PXRS practice location

2. Initial Contractor Review and Recommendation

The contractor shall process the change request consistent with the instructions in this chapter (e.g., verification of data, developing for missing or conflicting data). If the contractor determines that the change/addition should be approved, it shall send the appropriate recommendation letter (see section 10.7 et seq.) to the state with all applicable documentation that the contractor currently sends in such situations. The SOG Location need not be copied on the letter.

Nothing in this section 10.6.1.2(A)(2):

- Prohibits the contractor from returning or rejecting the application if grounds for doing so exist.
- Supersedes any applicable requirement for performing a site visit (including the timing of such visits).

3. State Review and Contractor Receipt of Recommendation

The state will review the recommendation of approval, the application, and any other pertinent information. If the state decides to perform a survey, it will do so and notify the contractor thereof.

a. State Recommends Approval

If the state concludes that the change/addition should be approved, it will make a recommendation to this effect to the contractor, typically via a Form CMS-1539 and/or similar confirming documentation. No later than 5 business days after receipt of the recommendation, the contractor shall send an e-mail to MedicareProviderEnrollment@cms.hhs.gov containing general identifying data about the provider (including LBN, NPI, CCN, specialty, facility name and address), a copy of the Form CMS-1539 (or other similar documentation evidencing the state's approval recommendation, if available), the draft provider approval letter, and a description of the change to be made. If, to the contractor's knowledge, a new CCN is required, the name and address of the new entity requiring the CCN should be furnished along with the effective date. If a termination is involved (e.g., HHA branch), the contractor shall include the old CCN and the termination date in the e-mail.

Once PEOG responds to the contractor, the latter may finalize its processing of the application (e.g., sending copies of the provider notification of approval to the state and, if applicable, accrediting organization; switching the PECOS record from "approval recommended" to "approved").

b. State Does Not Recommend Approval

If the state does not recommend approval, the contractor shall refer the matter to MedicareProviderEnrollment@cms.hhs.gov for guidance. The e-mail to him/her shall contain (1) the identifying data described in (3)(a) above; (2) a copy of the notification from the state declining to recommend approval; and (3) any other information the contractor deems pertinent. PEOG will review the matter and furnish the contractor additional instructions, which the contractor shall follow.

4. Additional Policies

a. Post-Recommendation Inquiries - Once the contractor has made its recommendation for approval to the state, any inquiry the contractor receives from the provider regarding the status of its change request shall be referred to the state.

b. Pending State Recommendation - So as not to keep the PECOS record in "approval recommended" status interminably, if the contractor does not receive the state's recommendation after 120 days, it may contact the state to see if its recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to ascertain the recommendation's status.

c. State Practice - The PECOS record should not be switched to "Approved" until the contractor receives the state's approval recommendation. However, if the contractor knows that the state in question generally does not review this type of transaction, the contractor need not send the transaction to the state and shall instead follow the instructions in section 10.6.1.2(B) below.

B. Post-Approval State Notification Required

Form CMS-855 changes that do not mandate a recommendation to the state but do require post-approval correspondence with PEOG and the state (and, if applicable, the accrediting organization) include:

- Deletions/voluntary terminations of practice locations or hospital subunits. (Note that this scenario is different from cases where the provider is voluntary terminating its enrollment

as a whole (per section 10.6.1.3 of this chapter) rather than simply terminating a single location or subunit within its enrollment.)

- LBN, TIN, or "doing business as name" changes that do not involve a CHOW
- *Except as described in section 10.6.1.2(A), a*ddress changes that generally do not require a survey of the new location
- *Except as described in section 10.6.1.2(A), addition of hospital practice location*
- Ownership changes that involve neither a 42 CFR § 489.18 CHOW nor a § 424.550(b) exempt or non-exempt change in HHA majority ownership (e.g., a 15 percent owner of a hospice sells her ownership stake).

The contractor shall:

(1) Inform PEOG, the state, and the AO (if appropriate) of the changed information (via any mechanism it chooses, including copying PEOG/state/AO on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction. Such notice to the PEOG/state/AO shall specify the type of information that is changing. (Prior PEOG approval of the change is not required, though PEOG will update ASPEN as needed.)

(2) Switch the PECOS record to "Approved."

C. All Other Changes of Information

1. General Principle

For all Form CMS-855 change requests not identified in section 10.6.1.2(A)(1) and (B) above (and except as stated in subsection (C)(2) below), the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made; and (2) switch the PECOS record to "Approved." The contractor need not notify the state, SOG Location, or PEOG of the change.

2. FQHCs

If an FQHC is adding, deleting, or changing a Section 13 contact person , the contractor shall send an approval letter via e-mail and copy the MedicareProviderEnrollment@cms.hhs.gov mailbox (with "FQHC COI" in the subject line) thereon. (Aside from this exception, all other instructions in subsection (C)(1) apply to this scenario.) See section 10.2.1.4(D) of this chapter for more information on FQHC changes of information.

D. Revalidations, Reactivations, and Complete Form CMS-855 Applications

1. When Referral Required - In situations where the provider submits a (1) Form CMS-855 reactivation, (2) Form CMS-855 revalidation, or (3) full Form CMS-855 as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in section 10.6.1.2(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855, the contractor shall make a recommendation to the state and await the state's approval recommendation before switching the record to "Approved." In this situation, the contractor

should forward the application to the state with a note explaining that the only matter the state needs to consider is the new hospital unit.

2. No Referral Required - If the application contains new/changed data falling within one of the categories in section 10.6.1.2(B), the contractor can switch the PECOS record to "Approved." It shall also inform the state of the changed information (via any mechanism it chooses, including copying the state on the notification letter or e-mail to the provider) no later than 10 calendar days after it has completed processing the transaction.

E. Unsolicited Notifications from State

If the contractor receives notice of a provider's change of information from the state but the provider never submitted the required Form CMS-855 change request to the contractor, the contractor shall: (1) alert the state of the situation; and (2) contact the provider and have it complete and submit the change request. However, if the data in question is not collected on the Form CMS-855, the contractor need not make this request.

F. Clock Stoppages and Processing Alternatives - While awaiting PEOG's reply on any matter in this section 10.6.1.2 in which the contractor is required to refer a matter to PEOG - and beginning on the date following the sending of the e-mail referenced therein - the application processing time clock is stopped. It resumes on the date on which the contractor receives PEOG's final response. Communication between the contractor and PEOG during this "waiting period" (e.g., PEOG request for additional information from the contractor) does not restart the clock.

In addition, nothing in this section 10.6.1.3 negates other permissible clock stoppages and processing alternatives outlined in this chapter that can apply to the applications addressed in this section 10.6.1.3.

10.6.22 - Non-*Transitioned Certified Provider/Supplier* Changes of Ownership

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

(Until further notice, the contractor shall continue to follow these instructions for CHOWs involving *those* certified provider and *certified supplier types that have not "transitioned" as described in section 10.6.1.1 of this chapter.)*

All references to the SOG Location (formerly the "RO") in this section 10.6.22 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

Changes of ownership (CHOWs) are officially defined in and governed by 42 CFR § 489.18 and Publication 100-07, chapter 3, sections 3210 through 3210.5(C). The SOG Location – not the contractor – makes the determination as to whether a CHOW has occurred (unless this function has been delegated).

Except as otherwise specified, the term "CHOW" - as used in this section 10.6.22 - includes CHOWs, acquisitions/mergers, and consolidations.

Though the Change of Ownership (CHOW) Information section of the Form CMS-855A separates the applicable transactions into CHOWs, acquisition/mergers and consolidations for ease of disclosing and reporting, they fall within the general CHOW category under 42 CFR § 489.18 (e.g., an acquisition/merger is a type of CHOW under § 489.18).

A. Definitions for CHOWs

For purposes of provider enrollment only, there are three main categories of CHOWs captured on the Form CMS-855A application:

1. "Standard" CHOW

This occurs when a provider's CMS Certification Number (CCN) and provider agreement are transferred to another entity as a result of the latter's purchase of the provider. To illustrate, suppose Entity A is enrolled in Medicare, but Entity B is not. B acquires A. Assuming all regulatory requirements are met, A's provider agreement and CCN number will transfer to B.

This is the most frequently encountered change of ownership scenario. As explained in this section 10.6.22, even though it is technically an acquisition (i.e., B bought/acquired A) under § 489.18, this situation falls under the "CHOW" category – as opposed to the "Acquisition/Merger" category – on the Form CMS-855A.

2. Acquisition/Merger

In general, this occurs when two or more Medicare-enrolled entities combine, leaving only one remaining CCN number and provider agreement. For instance, Entity A and Entity B are both enrolled in Medicare, each with its own CCN number and provider agreement. The two entities decide to merge. Entity B's CCN number and provider agreement will be eliminated (leaving only Entity A's CCN number and provider agreement).

If the acquisition results in an existing provider having new owners but keeping its existing provider number, the applicant should check the CHOW box in the Basic Information section of the Form CMS-855A.

Unlike the new owner in a CHOW or consolidation, the new owner in an acquisition/merger need not complete the entire Form CMS-855A. This is because the new owner is already enrolled in Medicare. As such, the provider being acquired should be reported as a practice location in the Practice Location Information section of the new owner's Form CMS-855A.

3. Consolidations

This occurs when the merger of two or more Medicare-enrolled entities results in the creation of a brand new entity. To illustrate, if Entities A and B decide to combine and, in the process, create a new entity (Entity C), the CCN numbers and provider agreements of both A and B will be eliminated. Entity C will have its own CCN number and provider agreement.

Note the difference between acquisitions/mergers and consolidations. In an acquisition/merger, when A and B combine there is one surviving entity. In a consolidation, when A and B combine there are no surviving entities. Rather, a new entity is created – Entity C.

Under 42 CFR § 489.18(a)(4), the lease of all or part of a provider facility constitutes a change of ownership of the leased portion. If only part of the provider is leased, the original provider agreement remains in effect only with respect to the un-leased portion. (See Pub. 100-07, chapter 3, section 3210.1D (4) for more information.)

Note that a provider may undergo a financial or administrative change that it considers to be a CHOW, but does not meet the regulatory definition identified in §489.18.

B. Examining Whether a CHOW May Have Occurred

As stressed previously, the SOG Location – not the contractor – determines whether a CHOW has occurred (unless this function has been delegated). However, in processing the application, the contractor shall perform all necessary background research regarding whether: (1) a CHOW may have occurred, and/or (2) the new owner is accepting assignment of the Medicare assets and liabilities of the old owner. Such research may include reviewing the sales agreement or lease agreement, contacting the provider(s) to request clarification of the sales agreement, etc. (A CHOW determination by the SOG Location is usually not required prior to the contractor making its recommendation.)

While a CHOW is usually accompanied by a tax identification number (TIN) change, this is not always the case. There may be isolated instances where the TIN remains the same. Conversely, there may be cases where a 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. Hence, the contractor should review the sales/lease agreement closely, as this will help indicate whether a CHOW may or may not have occurred.

In addition:

(a) If the provider claims that the transaction in question is a stock transfer and not a CHOW, the contractor reserves the right to request any information from the provider to verify this (e.g., copy of the stock transfer agreement).

If – after performing the necessary research – the contractor remains unsure as to whether a CHOW has occurred and/or whether the new owner is accepting assignment, the contractor may refer the matter to the SOG Location for guidance. Such referrals to the SOG Location should only be made if the contractor is truly uncertain as to whether a CHOW and/or acceptance of assignment may have taken place and should not be made as a matter of course. A SOG Location CHOW determination is usually not required prior to the contractor making its recommendation.

(b) There may be instances where the contractor enters a particular transaction into PECOS as a CHOW, but it turns out that the transaction was not a CHOW (e.g., was a stock transfer; was an initial enrollment because the new owner refused to accept the Medicare liabilities). If the contractor cannot change the transaction type in PECOS, it can leave the record in a CHOW status; however, it should note in the provider's file that the transaction was not a CHOW.

C. Processing CHOW Applications

Unless stated otherwise in this chapter, the contractor shall ensure that all applicable sections of the Form CMS-855A for both the old and new owners are completed in accordance with the instructions on the Form CMS-855A.

1. Previous Owner(s)

The previous owner's Form CMS-855A CHOW application does not require a recommendation for approval. Any recommendations will be based on the CHOW application received from the new owner.

If the previous owner's Form CMS-855A is available at the time of review, the contractor shall examine the information therein against the new owner's Form CMS-855A to ensure consistency (e.g., same names). If the previous owner's Form CMS-855A has not been

received, the contractor shall contact the previous owner and request it. However, the contractor may begin processing the new owner's application without waiting for the arrival of the previous owner's application. It may also make its recommendation to the state agency without having received the previous owner's Form CMS-855A. The contractor, of course, shall not make a recommendation for approval unless the new owner has checked on the form that it will assume the provider agreement and the terms of the sales agreement indicate as such.

If a certification statement is not on file for the previous owner, the contractor shall request that the Individual Ownership and/or Managing Control section be completed for the individual who is signing the certification statement.

Note that a previous owner's Form CMS-855A CHOW application is essentially the equivalent of a Form CMS-855 voluntary termination submission, as the seller is voluntarily leaving the Medicare program. As such, the contractor shall not require the seller to submit a separate Form CMS-855 voluntary termination along with its Form CMS-855A CHOW application.

2. New Owner(s)

If a Form CMS-855A is not received from the new owner within 14 calendar days of receipt of the previous owner's Form CMS-855A, the contractor shall contact the new owner. If the new owner fails to: (1) submit a Form CMS-855A and (2) indicate that it accepts assignment of the provider agreement within 30 calendar days after the contractor contacted it, the contractor shall stop payments unless the sale has not yet taken place per the terms of the sales agreement. Payments to the provider can resume once this information is received and the contractor ascertains that the provider accepts assignment.

3. Order of Processing

To the maximum extent practicable, Form CMS-855A applications from the previous and new owners in a CHOW should be processed as they come in. The contractor should not wait for applications from both the previous and new owner to arrive before processing them. However, unless the instructions in this chapter indicate otherwise, the contractor should attempt to send the previous and new owners' applications to the state simultaneously, rather than as soon as they are processed. For instance, suppose the previous owner submits an application on March 1. The contractor should begin processing the application immediately, without waiting for the arrival of the new owner's application. Yet it should avoid sending the previous owner's application to the state until the new owner's application is processed. (For acquisition/mergers and consolidations, the contractor may send the applications to the SOG Location separately, since one number is going away.)

4. Sales and Lease Agreements

The contractor shall abide by the following:

(i) Verification of Terms - The contractor shall determine whether: (1) the sales/lease agreement includes the signatures of the buyer and seller and the information contained within is consistent with that reported on the new owner's Form CMS-855A (e.g., same names, effective date), and (2) the terms of the contract indicate that the new owner will assume the provider agreement. In many cases, the sales/lease agreement will not specifically refer to the Medicare provider agreement. Clearly, if the box in the Change of Ownership (CHOW) Information section is checked "Yes" and the sales/lease agreement either confirms that the new owner will assume the agreement or is relatively silent on the

matter, the contractor can proceed as normal. Conversely, if the agreement indicates that the assets and liabilities will not be accepted, the contractor should deny the application.

(ii) Form of Sales/Lease Agreement - There may be instances where the parties in a CHOW did not sign a "sales" or "lease" agreement in the conventional sense of the term; the parties, for example, may have documented their agreement via a "bill of sale." The contractor may accept this documentation in lieu of a sales/lease agreement so long as the document furnishes clear verification of the terms of the transaction and the information is consistent with that contained in the Form CMS-855A as discussed above.

(iii) Submission of Final Sales/Lease Agreement - The contractor shall not forward a copy of the application to the state until it has received and reviewed the final sales/lease agreement. It need not revalidate the information on the Form CMS-855A, even if the data therein may be somewhat outdated by the time the final agreement is received.

If a final sales/lease agreement is not submitted within 30 days after the contractor's receipt of the new owner's application, the contractor shall reject the application. Though the contractor must wait until the 30th day to reject the application, the contractor may do so regardless of how many times it contacted the new owner or what types of responses (short of the actual receipt of the agreement) were obtained.

Unless specified otherwise in this chapter, both the previous and new owners must submit separate Form CMS-855A applications, as well as copies of the interim and final sales/lease agreements.

5. CHOWs Involving Subtypes

On occasion, a CHOW may occur in conjunction with a change in the facility's provider subtype. This frequently happens when a hospital undergoes a CHOW and changes from a general hospital to another type of hospital, such as a psychiatric hospital. Although a change in hospital type is considered a change of information (COI), it is not necessary for the provider to submit separate applications – one for the COI and one for the CHOW. Instead, all information (including the change in hospital type) should be reported on the CHOW application; the entire application should then be processed as a CHOW. However, if the facility is changing from one main provider type to another (e.g., hospital converting to a skilled nursing facility) and also undergoing a CHOW, the provider must submit its application as an initial enrollment.

NOTE: For Medicare purposes, a critical access hospital (CAH) is a separately-recognized provider type. Thus, a general hospital that undergoes a CHOW while converting to a CAH must submit its Form CMS-855A as an initial enrollment, not as a CHOW.

6. Unreported CHOW

If the contractor learns via any means (including receipt of a tie-in notice or other SOG Location or state notice) that an enrolled provider (1) has been purchased by another entity or has purchased another Medicare enrolled provider, the contractor shall immediately request Form CMS-855A applications from both the previous and new owners. If the new owner fails to submit a Form CMS-855A within the latter of (1) the date of acquisition or (2) 30 days after the request, the contractor shall stop payments to the provider. Payments may be resumed upon receipt of the completed Form CMS-855A.

7. Relocation of Entity

A new owner may propose to relocate the provider concurrent with the CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the SOG Location immediately. Unless the SOG Location dictates otherwise, the provider shall - per CMS Publication 100-07, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the provider as a new applicant), rather than as an address change of the existing provider.

8. Transitioning to Provider-Based Status

Consistent with existing CMS policy, a provider undergoing a CHOW pursuant to 42 CFR § 489.18 may be assigned to a new contractor jurisdiction only if the provider is transitioning from freestanding to provider-based status. In such cases, the contractor for the new jurisdiction (the "new contractor") shall process both the buyer's and seller's Form CMS-855A applications. Should the "old/previous" (or current) contractor receive the buyer's and/or seller's Form CMS-855A application, it shall: (a) forward the application to the new contractor within 5 business days of receipt, and (b) notify the new contractor within that same timeframe that the application was sent.

9. Intervening Change of Ownership (CHOW)

(This section does not apply to home health agencies.)

In situations where (1) the provider submits a Form CMS-855A initial application or CHOW application and (2) a Form CMS-855A CHOW application is subsequently submitted but before the contractor has received the tie-in notice from the SOG Location, the contractor shall abide by the following:

Situation 1 – The provider submitted an initial application followed by a CHOW application, and a recommendation for approval has not yet been made with respect to the initial application – The contractor shall return both applications and require the provider to re-submit an initial application with the new owner's information.

Situation 2 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval has not been made for the first application - The contractor shall process both applications – preferably in the order in which they were received – and shall, if recommendations for approval are warranted, refer both applications to the state/SOG Location in the same package. The accompanying notice/letter to the state/SOG Location shall explain the situation.

Situation 3 - The provider submitted an initial application followed by a CHOW application, and a recommendation for approval of the initial application has been made – The contractor shall:

(i) Return the CHOW application.

(ii) Notify the state/SOG Location via letter (sent via mail or e-mail) that there has been a change of ownership (the new owner should be identified) and that the contractor will be requiring the provider to resubmit a new initial application containing the new owner's information.

(iii) Request via letter that the provider submit a new initial Form CMS-855A application containing the new owner's information within 30 days of the date of the letter. If the provider fails to do so, the contractor shall return the initial application and notify the provider and the state/SOG Location of this via letter. If the provider submits the application,

the contractor shall process it as normal and, if a recommendation for approval is made, send the revised application package to the state/SOG Location with an explanation of the situation; the initially submitted application becomes moot. If the newly submitted application is denied, however, the initially submitted application is denied as well; the contractor shall notify the provider and the state/SOG Location accordingly.

Situation 4 - The provider submitted a CHOW application followed by another CHOW application, and a recommendation for approval has been made for the first application - The contractor shall:

(i) Notify the state/SOG Location via e-mailed letter that there has been a change of ownership (the new owner should be identified) and that the contractor will be requiring the provider to resubmit a new initial application containing the new owner's information.

(ii) Process the new CHOW application as normal. If a recommendation for approval is made, the contractor shall send the revised CHOW package to the state/SOG Location with an explanation of the situation; the first CHOW application becomes moot. If the newly submitted CHOW application is denied, the first application is denied as well; the contractor shall notify the provider and the state/SOG Location accordingly.

10. CHOWs and Address Changes

A new owner may propose to relocate the supplier concurrent with a CHOW. If the relocation is to a site in a different geographic area serving different clients than previously served and employing different personnel to serve those clients, the contractor shall notify the SOG Location immediately. Unless the SOG Location dictates otherwise, the supplier shall - per Pub. 100-07, chapter 3, section 3210.1(B)(5) - treat the transaction as an initial enrollment (and the supplier as a new applicant), rather than as an address change of the existing supplier.

D. Form CMS-855A - Entry into PECOS

If the new owner will or will not be accepting assignment as well as the assets and liabilities of the old owner, the contractor shall enter the CHOW information into the new enrollment record that shall be created for the CHOW buyer. If the SOG Location approves the CHOW and sends the tie-in/approval notice to the contractor, the supplier's CCN will be maintained in the new owner's enrollment record once the record is switched to an approved status.

If the CHOW is for a Part B certified supplier, a new enrollment record must be created if a new TIN is created in the CHOW.

E. Form CMS-855A - Electronic Funds Transfer (EFT) Payments and CHOWs

In a CHOW, the contractor shall continue to pay the old owner until it receives the tie-in/approval notice from the SOG Location. Hence, any application from the old or new owner to change the EFT account or special payment address to that of the new owner shall be rejected. It is the responsibility of the old and new owners to work out any payment arrangements between themselves while the contractor and SOG Location are processing the CHOW. It is advisable that the contractor notify the new owner of this while the application is being processed.

In a CHOW, the existing provider agreement is automatically assigned to the buyer/transferee. If the buyer/transferee does not explicitly reject automatic assignment before the transfer date, the provider agreement is automatically assigned, along with the CCN, effective on the transfer date. The assigned agreement is subject to all applicable

statutes and regulations and to the terms and conditions under which it was originally issued. Among other things, this means that the contractor will continue to adjust payments to the provider to account for prior overpayments and underpayments, even if they relate to services provided before the sale/transfer. If the buyer rejects assignment of the provider agreement, the buyer must file an initial application to participate in the Medicare program. In this situation, Medicare will **never** pay the applicant for services the prospective provides before the date on which the provider qualifies for Medicare participation as an initial applicant.

Depending on the terms of the sale, the buyer/transferee may obtain a new NPI or maintain the existing NPI. After CHOW processing is complete, the seller/transferor will no longer be allowed to bill for services (i.e., services furnished after CHOW processing is complete) and only the buyer is permitted to submit claims using the existing CCN. It is ultimately the responsibility of the old and new owners to work out between themselves any payment arrangements for claims for services furnished during the CHOW processing period.

F. Form CMS-855A CHOW: Pre-Approval Changes of Information

1. CHOW: Regarding Seller

If – prior to the issuance of the tie-in notice – the contractor receives from the seller a Form CMS-855 request to change any of the provider's enrollment data, the contractor shall reject the change request if the information in question involves changing the provider's:

i. EFT or special payment address information to that of the buyer

ii. Practice location or base of operations to that of the buyer

iii. Ownership or managing control to that of the buyer

iv. Legal business name, TIN, or "doing business as" name to that of the buyer

All other "pre-tie-in notice" Form CMS-855 change requests from the seller can be processed normally.

2. CHOW: Regarding Buyer

If – prior to the issuance of the tie-in notice – the contractor receives from the buyer a Form CMS-855 request to change any of the provider's existing enrollment information, the contractor shall reject the change request. Until the tie-in notice is issued, the seller remains the owner of record. Hence, the buyer has no standing to submit Form CMS-855 changes on behalf of the provider.

10.6.22.1 - Non-*Transitioned Certified Provider/Supplier* Changes of Information

(Rev. 11432; Issued: 05-26-22; Effective: 05-27-22; Implementation: 05-27-22)

(Until further notice, the contractor shall continue to follow these instructions for changes of information involving all certified provider and certified supplier types *that have not "transitioned."*)

All references to the SOG Location (formerly the "RO") in this section 10.6.22.1 refer to the applicable CMS Regional Office's Survey & Operations Group (SOG) Location. Also, and except as otherwise indicated, all references to "provider" include certified suppliers (e.g., ambulatory surgical centers, portable x-ray suppliers).

Any instructions in this section 10.6.22.1 concerning the voluntary termination of a sub-unit, or other practice location that does not involve the termination of the entire enrollment and/or provider agreement take precedence over those in section 10.6.1.3. For instance, suppose a certified provider's Form CMS-855A enrollment has three practice locations and/or sub-units. The provider is voluntarily terminating one of them. Here, the contractor shall use the instructions in section *10.6.22.1 (or, for transitioned providers/suppliers, section 10.6.1.2)* when processing this transaction. Now assume that a provider is of a type that must individually and separately enroll each location. The provider has three separately enrolled locations with three separate provider agreements. The provider seeks to terminate one of these locations. Since this will involve the termination of an individual/entire enrollment and corresponding provider agreement, the instructions in section 10.6.1.3 apply.

A. Form CMS-855A - Referrals to State/SOG Location

1. Transactions

The following is a list of Form CMS-855A transactions that generally require a recommendation and referral to the state/SOG Location:

- Addition of hospice satellite
- Change in type of Prospective Payment System (PPS)-exempt unit
- Conversion of a hospital from one type to another (e.g., acute care to psychiatric)
- *Addition of hospital physician/practitioner group practice location when a survey of the new site may be required. (If the contractor is uncertain as to whether the state will perform a survey, it may (1) contact the state for guidance or (2) make the referral based on the contractor's experience with these types of changes and with the practices of the state in question. Note that a survey often may be required if the location is shifting outside of the existing geographic area.)*
- *Excluding hospital physician/practitioner group practice locations,* change and/or relocation of a practice location *regardless of whether* a survey of the new site may be required.
- Stock transfer (except as stated below in subsection (A)(2) below)

In these situations, the Provider Enrollment, Chain and Ownership System (PECOS) record should not be switched to "approved" until the contractor receives notice from the SOG Location that the latter has authorized the transaction. However, if the contractor knows that the particular state/SOG Location in question typically does not review, approve, or deny this type of transaction, the contractor need not send the transaction to the state/SOG Location for approval and shall instead follow the instructions in section 10.6.22.1(B) below.

2. Stock Transfers

If the transaction is a stock transfer, the contractor need not send the transaction to the state/SOG Location for approval (and shall instead follow the instructions in section 10.6.22.1(B) below) if the following three conditions are met:

(i) The contractor is confident that the transaction is merely a transfer of stock and not a CHOW,

(ii) The SOG Location in question (based on the contractor's past experience with this SOG Location) does not treat stock transfers as potential CHOWs, and

(iii) The contractor knows that the particular state/SOG Location in question does not review, approve, or deny this type of transaction.

If any of these three conditions are not met, the contractor shall send the transaction to the state/SOG Location for approval.

3. Additional Instructions

SOG Location approval for the transactions listed above in section 10.6.22.1(A)(1) may be furnished to the contractor via tie-in notice, letter, e-mail, fax, or even telephone; the contractor may accept any of these formats.

If the SOG Location (after receiving the transaction from the contractor for review) notifies the contractor that it does not normally review/approve/deny such transactions, the contractor may finalize the transaction (e.g., switch the PECOS record to "approved).

B. Form CMS-855A - Post-Approval SOG Location Contact Required

Form CMS-855A changes that do not mandate a recommendation to the state/SOG Location but do require post-approval correspondence with the SOG Location include:

- Deletions/voluntary terminations of practice locations or hospital subunits

- Legal business name, tax identification number, or "doing business as name" changes that do not involve a CHOW

- *Except as described in section 10.6.22.1(A)(1), a*ddress changes that do not require a survey of the new location

- The transactions (excluding stock transfers) described in section 10.6.22.1(A)(1) for which the contractor knows that the state/SOG Location does not issue approvals/denials

- Stock transfers for which all three conditions mentioned in section 10.6.22.1(A)(2) are met

- Voluntary terminations of PTANs (except as otherwise stated in this section 10.6.22.1 and in section 10.6.1.3 of this chapter)

For these transactions, the contractor shall: (1) notify the provider via letter, fax, e-mail, or telephone that the change has been made, and (2) switch the PECOS record to "approved." The contractor shall also notify the state and SOG Location of the changed information (via any mechanism it chooses, including copying the state/SOG Location on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction. Such notice to the State/SOG Location shall specify the type of information that is changing.

C. Form CMS-855A - All Other Changes of Information

For all Form CMS-855A change requests not identified in section 10.6.22.1(A) or (B), the contractor shall notify the provider via letter, fax, e-mail, or telephone that the change has been made and shall switch the PECOS record to "approved." The state and SOG Location need not be notified of the change.

D. Form CMS-855A Revalidations, Form CMS-855A Reactivations and Complete Form CMS-855A Applications

In situations where the provider submits a: (1) Form CMS-855A reactivation, (2) Form CMS-855A revalidation, or (3) full Form CMS-855A as part of a change of information (i.e., the provider has no enrollment record in PECOS), the contractor shall make a recommendation to the state/SOG Location and switch the PECOS record to "approval recommended" only if the application contains new/changed data falling within one of the categories in 10.6.22.1(A)(1). For instance, if a revalidation application reveals a new hospital psychiatric unit that was never reported to CMS via the Form CMS-855A, the contractor shall make a recommendation to the state/SOG Location and await the SOG Location's approval before switching the record to "approved." In this situation, the contractor should forward the application to the state with a note explaining that the only matter the state/SOG Location needs to consider is the new hospital unit.

If the application contains new/changed data falling within one of the categories in section 10.6.22.1(B), the contractor can switch the PECOS record to "approved." It shall also notify the state and SOG Location of the changed information (via any mechanism it chooses, including copying the state/SOG Location on the notification letter or e-mail) no later than 10 calendar days after it has completed processing the transaction.