CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12100	**Date: June 29, 2023**
	Change Request 13209

SUBJECT: Ninth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to clarify several provider enrollment topics, including end-stage renal disease (ESRD) facility enrollment and certified provider/supplier referrals to CMS.

EFFECTIVE DATE: July 31, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 31, 2023
Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/Table of Contents
R	10/10.2/10.2.1.3/End-Stage Renal Disease Facilities (ESRDs)
R	10/10.2/10.2.1.4/Federally Qualified Health Centers (FQHCs)
R	10/10.2/10.2.1.8.1/Rural Emergency Hospitals (REHs)
R	10/10.2/10.2.3.12/Physician Assistants
R	10/10.2/10.2.5.1/DMEPOS Supplier Accreditation
R	10/10.6/10.6.21/Miscellaneous Enrollment Topics
R	10/10.7/10.7.9/Revocation Letters
N	10/10.7/10.7.19/ESRD Approval Letters

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

directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 12100	Date: June 29, 2023	Change Request: 13209

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EFFECTIVE DATE: July 31, 2023
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IMPLEMENTATION DATE: July 31, 2023

I. GENERAL INFORMATION

A. Background: Chapter 10 of Pub. 100-08 outlines policies related to Medicare provider enrollment and instructs contractors on the processing of Form CMS-855 provider enrollment applications. This CR clarifies several provider enrollment topics, including ESRD facility enrollment and certified provider/supplier referrals to CMS.

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	
13209.1	The contractor shall adhere to the revised ESRD facility and certified provider/supplier instructions outlined in this CR.	X	X	X						

III. PROVIDER EDUCATION TABLE

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

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

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

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 10 – Medicare Enrollment
Table of Contents
(Rev. 12100; Issued: 06-29-23)

Transmittals for Chapter 10

10.2.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

(In this section 10.2.1.3, the terms "ESRD" and "ESRD facility" have the same meaning and will be used interchangeably).

A. General Background Information

ESRD facilities are entities that provide renal services and related care for patients with irreversible and permanent kidney failure.

The provider-based rules for ESRD facilities are outlined in 42 CFR § 413.174 and are slightly different than those in the main provider-based regulation (42 CFR § 413.65). (For instance, § 413.174 uses the term "hospital-based" as opposed to "provider-based.")

The ESRD Network is a group of organizations under contract with CMS that serve as liaisons between the agency and ESRD providers. The organizations oversee the care that ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

B. Types of ESRD Facilities

Pub. 100-07, State Operations Manual, lists several classifications of ESRD facilities. They are summarized as follows:

1. Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that (1) is an outpatient department of a hospital and (2) meets the ESRD conditions of coverage at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CCN and be separately enrolled.

A hospital-based ESRD facility is discussed at 42 CFR § 413.174(c) and must meet the criteria listed therein (e.g., ESRD facility and hospital have a common governing body and are financially integrated). Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

2. Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility: (1) is separately certified and surveyed; (2) must independently meet the ESRD conditions of coverage; (3) is assigned its own CCN; and (4) be separately enrolled. Satellite renal dialysis facilities (hospital-based) are assigned CCNs in the 3500-3699 series.

3. Independent Renal Dialysis Facility

An independent renal dialysis facility is any outpatient ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but it is not owned and/or administered by the hospital.

Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series and are individually enrolled.

4. Special Purpose Renal Dialysis Facility (SPRDF) (§ 494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e., up to 8 months in any 12-month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area. The SOG Location must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications. The special locations for SPRDF fall into two categories:

(A) Vacation Camps - Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding interruption of the camping experience. Vacation camps may be approved for the duration of the camp but up to a maximum of 8 months in any 12-month period.

(B) Emergency Circumstance SPRDFs - These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their geographical area as a result of a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location. The CMS SOG Location may extend the time period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

SPRDFs are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities. Although they are individually enrolled, they cannot convert to a permanent ESRD facility (i.e., to a non-SPRDF). They must instead reapply as a brand new ESRD facility and receive an initial certification survey.

C. Processing Instructions for ESRD Initial Form CMS-855A Applications

An ESRD facility is separately and individually certified and does not have any branch, multiple, or parent locations. As such, each type of ESRD facility/location must independently and separately enroll as such via the Form CMS-855A; multiple sites cannot be listed on a single application.

Note that the instructions in this section 10.2.1.3(C) apply to all ESRD facility types except for SPRDFs. This ESRD type is not "transitioning" as that term is described in this chapter. Accordingly, the contractor shall continue to process initial applications from SPRDFs consistent with longstanding instructions rather than those described in this section 10.2.1.3(C) (e.g., receiving the final approval from the SOG location rather than the state; no need to send the application to PEOG after final SOG location approval).

1. Receipt of Application

Upon receipt of an initial ESRD 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 section 10.2.1.3 and this chapter.

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

- Part I of the Form CMS-3427A (End Stage Renal Disease Application and Survey and Certification Report) (See Pub. 100-07, chapter 2, section 2247B for more information on this form.)

- A certificate of need (CON) if required by state law (though SPRDFs need not submit a CON)

(The ESRD must complete and submit Part I of the Form CMS-3427A, though the ESRD need not complete those sections of the form reserved for CMS. For organizational ESRDs, an authorized official (as defined in § 424.502) must sign the form; for sole proprietorships, the sole proprietor must sign. Note that there is no provider agreement for ESRD facilities; the Form CMS-3427A is a survey and certification document, not a provider/supplier agreement.)

Notwithstanding the foregoing, if Part I of the Form-CMS-3427A and/or CON evidence is missing, unsigned, undated, or otherwise incomplete, the contractor need not develop for the form(s) or the information thereon. (Nor need the contractor: (1) research individual state laws to ascertain whether the state requires a CON; or (2) review the data on the CON.) 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 10.2.1.3(C) prohibits the contractor from returning or rejecting the ESRD 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 10.2.1.3(C) 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 ESRD, 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----typically via the Form CMS-1539, although 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 10.2.1.3(C)(2)(B) above.

(B) Approval Recommended

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

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

- The Form CMS-855 application (or PECOS Application Data Report) and all application attachments
- A copy of the Form CMS-1539 from the state or similar documentation received from the AO
- 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.)

(As required per section 10.6.21 of this chapter, the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.))

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

D. Additional/Changed Stations

If an enrolled ESRD seeks to add/change services or stations (e.g., add ESRD services in SNFs, additional modalities), the ESRD need not submit a Form CMS-855A application to do so, for these services and stations do not constitute practice locations and cannot otherwise be reported on the application. Instead, the ESRD contacts the state or accreditation organization (AO) to request these changes. The ESRD must complete a Form CMS-3427 and submit it to the state or AO (as applicable). A survey may be performed, and the state will update the applicable national database with any administrative changes.

The state will also send a CMS-1539 or approval letter to the contractor as notification of the additional/change service(s) or station(s). *When the contractor receives such a notice, it shall abide by the following:*

- *As applicable, and consistent with longstanding practice, the contractor shall enter all relevant data into PECOS. No referral to or prior approval from PEOG is necessary. However, the contractor may contact its PEOG BFL if it has questions regarding the Form CMS-1539 or the supplier's PECOS record.*
- *For situations involving new/expanded/changed ESRD stations, the contractor shall send to the supplier the "ESRD Service Station/Modality Changes" letter identified in section 10.7.19 of this chapter. (The state and, as applicable, the AO shall be copied on said letter.)*

E. ESRD Location Changes

An ESRD facility that is changing its location must submit either a Form CMS-855A change of information application or an initial enrollment application. The specific transaction type involved (change request or initial) will depend on the particular situation. These situations include the following, and they will generally trigger the termination of the ESRD's existing CCN and the issuance of a new one.

(i) A hospital-based ESRD facility is relocating to an off-campus location in the same state.

In this situation, the ESRD's current CCN will be retired.

If the off-campus location will still function under a common governing body, operate under the hospital's policies and practices, continue to serve the same community, and utilize the same staff at this new location, the new CCN will be that of a renal satellite facility. The application can be processed as a change of information pursuant to the instructions in section 10.6.1.2(A).

If the off-campus location will no longer be operationally, administratively, or financially integrated with the hospital, the new CCN will be that of an independent dialysis facility. The hospital must voluntarily terminate this location from its enrollment, and the site must enroll as a new ESRD facility.

If the contractor has any questions as to whether the relocated location will still be sufficiently integrated with the hospital to permit a change of information application rather than an initial enrollment, the contractor may contact the state for guidance. The processing time clock stops while the contractor awaits the state's guidance.

(ii) An independent ESRD facility is relocating to become a hospital-based facility or a renal satellite facility of a hospital

Since the ESRD facility will be serving a different community under different policies, etc., the facility must terminate its existing enrollment and enroll as a new ESRD facility.

(iii) An independent ESRD facility is relocating to another location and will remain independent

If the ESRD facility will be serving a different community, the facility must terminate its existing enrollment and enroll as a new/initial ESRD facility. If it will serve the same community, the relocation can be processed as a change of information.

(iv) ESRD facility relocating out-of-state

If an ESRD facility of any type (e.g., independent, satellite) is relocating out-of-state --- and notwithstanding any other instruction to the contrary in this chapter ---- it must terminate its existing enrollment and enroll as an initial/new applicant.

F. CHOWs and Changes of Information

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

G. New ESRD Model Letters

Notwithstanding any other instruction to the contrary in this chapter, the contractor shall use the applicable ESRD letters in section 10.7.19 of this chapter for initial enrollments and state-approved changes of ownership.

H. Beds and Services

A CMS-3427 is often included with an initial or CHOW Form CMS-1539 that identifies, as applicable, the services or number of beds at issue. If, nonetheless, this data is not furnished by the state to the contractor for an initial or CHOW application, the contractor may secure it from the state (or, for CHOWs, and as applicable, the AO).

I. **ESRD Survey and Certification**

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. For more information on this form, see Pub. 100-07, chapter 2, section 2247B.

For further information on ESRD facilities, refer to:

- Section § 1881 of the Social Security Act
- 42 CFR Part 405, Subpart U
- Pub. 100-07, chapter 2, section 2270 – 2287B
- Pub. 100-02, chapter 11
- Pub. 100-04, Claims Processing Manual, chapter 8

10.2.1.4 - Federally Qualified Health Centers (FQHCs)

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

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. Supporting Documentation

1. Revalidations

Upon revalidation of an FQHC site, the FQHC must submit --- along with any other supporting documentation required per this chapter --- either an NOA (for awardees) or notice of look-alike designation (NLD, for look-alikes) approving the site. If an NOA or NLD is unavailable for the site, a copy of the FQHC's "Form 5B: Service Sites" list downloaded from HRSA's Electronic Handbooks documenting all of the provider's approved FQHC program sites is acceptable. However, any NOA, NLD, or Form 5B must include the physical address of the site in question that matches the physical address on file with CMS and the address submitted on the Form CMS-855A application. If the addresses do not match, the contractor shall develop for additional information.

2. Initial Applications, CHOWs, and Location Changes

The contractor cannot accept a copy of the Form 5B as supporting documentation for initial applications, CHOWs, and new/changed FQHC locations. As explained previously, only a valid, "in effect" NOA or NLD, as applicable, is acceptable.

***H*. 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

I. 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.

J. 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.

K. 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.

10.2.1.8.1 – Rural Emergency Hospitals (REHs)

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

Section 125 of Division CC of the Consolidated Appropriations Act, 2021 added a new section 1861(kkk) to the Social Security Act (the Act) to establish REHs as a new Medicare provider type to address the growing concern over closures of rural hospitals. In accordance with section 1861(kkk), a facility is eligible to convert to an REH if it was a CAH or rural hospital with not more than 50 beds as of December 27, 2020. REHs must provide emergency services and observation care and are prohibited by the statute from providing inpatient services.

The CY 2023 OPPS/ASC final rule (CMS-1772-F) established, among other things, requirements that REHs must meet in order to bill Medicare. These included enrollment

requirements, addressed in part in new 42 CFR § 424.575. In short, the rule specified the following:

- A CAH or rural hospital wishing to convert to an REH must submit a Form CMS-855A change of information application, rather than an initial application
- No application fee need be paid
- REHs will be in the "limited" screening category under 42 CFR § 424.518
- REHs fall within 42 CFR § 424.520(a) in terms of establishing an effective date of billing privileges.

This section 10.2.1.8.1 instructs contractors on the processing of REH enrollment applications. Note that REHs (like CAHs) are not "transitioning" as that term is used in this chapter with respect to the survey and certification process.

A. Initial Process

(CMS will notify the contractors and the public as to when prospective REHs may begin to submit applications.)

1. Submission

In submitting a Form CMS-855A change of information (COI) application to convert to an REH, the facility must:

(a) Check the "You are changing your Medicare information" box in Section 1(A)

(b) Check the "Other" box in Section 2(A)(2) and write "Rural emergency hospital" or "REH" in the line next thereto

(c) Complete Sections 2(B) (with REH information), 3, and 15 and/or 16 (as applicable)

(d) Report any additions/deletions/changes to its current enrollment information (that is, its current CAH or rural hospital enrollment) that will stem from its conversion to an REH (e.g., new billing agency, adding/deleting two managing employees, deleting a 10 percent owner)

(e) Submit all required state licenses/certifications for operation as an REH (if available to the provider at the time)

(CMS will conduct outreach to the prospective REH community regarding the above requirements.)

However, the facility need not submit with its application:

- An application fee

- Any documentation related to its existing enrollment as a CAH or rural hospital (e.g., CAH licensure) except if a new adverse legal action is also being reported, in which case the contractor shall follow the instructions in section 10.6.6 of this chapter concerning documentation acquisition.

- Any other documentation that: (1) is specific to the survey and certification process; and (2) a non-transitioned, certified provider/supplier typically submits directly to the state or SOG Location pursuant to this process (e.g., a signed provider agreement). The state or SOG Location will, as applicable, collect this information. If the provider nonetheless submits these materials with its application, the contractor shall include them in any recommendation

package it sends to the state; however, the contractor need not review them for compliance, signatures, etc.

2. Initial Contractor Review

In reviewing the application, the contractor shall adhere to the following:

(i) Eligibility - The contractor shall check PECOS to see whether the REH was enrolled as a CAH or a rural hospital as of December 27, 2020. (Facilities that were in a deactivated status in PECOS pursuant 42 CFR § 424.540(a)(2) or (3) as of that date still qualify as having been enrolled at that time.) If it was not, the contractor shall return the application pursuant to § 424.526(a)(7) on the basis that the application is inapplicable to the transaction in question. If it was, the contractor shall continue to process the application.

- The term "rural hospital" as used above means a hospital as defined in section 1886(d)(1)(B) of the Act "with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D)), or was a subsection (d) hospital (as so defined) with not more than 50 beds that was treated as being located in a rural area pursuant to section 1886(d)(8)(E)." (See section 1861(kkk)(3)(B) of the Act for this quoted language.) Unless the contractor has strong reason to believe that the hospital in question is not a rural hospital, it need not perform any research to determine whether it is. This determination can be made after the application is referred to the state per the below. If the contractor has doubts as to whether it is a rural hospital, it can contact its PEOG BFL or the state for guidance.

- If the facility was enrolled as of December 27, 2020 but was thereafter voluntarily or involuntarily terminated, the contractor shall contact its PEOG BFL for guidance.

(ii) Submission of New/Initial Enrollment – In the highly unlikely event that the facility submits a full, initial REH enrollment application rather than a COI, the contractor shall nonetheless process the application. No fee is required. (See subsection (A)(3) below for more information.)

(iii) Application Fee – If the facility submits an application fee and/or hardship waiver, the contractor shall refund/return it consistent with the instructions in this chapter. However, if the facility seeks to add a new location pursuant to its application, the contractor in all cases shall contact its PEOG BFL for guidance.

(iv) Returns – If the contractor determines that a basis exists for returning the application under 42 CFR § 424.526 and section 10.4.1.4.2 of this chapter, the contractor shall contact its PEOG BFL for guidance.

(v) Authorized/Delegated Officials – The facility is not required to assign and utilize new authorized and delegated officials pursuant to the conversion. It may continue to use the officials who are part of its existing CAH or rural hospital enrollment. However, as with any other change of information stemming from the conversion, the facility must report any changes to its current authorized/delegated officials; this could occur, for example, if the facility will be under new leadership or management.

(vi) Voluntary Termination – The facility is not required to submit a voluntary termination application to terminate its existing CAH or rural hospital enrollment. Any termination will be effectuated upon the approval of the REH's enrollment. (See subsection (B) below.)

3. Processing and PECOS

Subject to the provisions in subsections 10.2.1.8.1(A)(1) and (2) above, the contractor shall process the COI consistent with the COI processing instructions in this chapter. This includes, but is not limited to, performing all required verifications (e.g., a new managing employee and/or delegated official is reported), developing for any missing or incomplete data, etc. It does not include, however, making determinations normally reserved to the state or SOG Location. For REHs, this includes, but is not limited to: (1) the number of beds; (2) whether emergency services, observation care, and inpatient services will be performed; (3) whether the facility is indeed in a rural area; and (4) whether CoPs are met.

Absent clear evidence to the contrary, the contractor can assume that any Form CMS-855A data that is not reported as changing per subsection (A)(1)(d) above is remaining intact. For instance, suppose the provider does not report any changes in Section 4 of the COI. The contractor can assume that the provider's practice location data will remain as is.

During the aforementioned process, the contractor shall create a new enrollment record in PECOS for the REH. The record shall include: (1) the data submitted on the COI; and (2) data that is currently part of the CAH's or rural hospital's enrollment record but is not changing on the COI. To illustrate, assume a CAH submits a COI to convert to an REH. Sections 6, 7, and 8 are blank, but Section 2(B) contains new REH licensure data. The new REH enrollment record shall include the Section 2(B) REH licensure information as well as the Section 6, 7, and 8 data that is in the CAH's current enrollment record. The CAH's enrollment record shall remain active and intact at this point.

For submitted initial applications:

- The contractor shall process the application consistent with this chapter's instructions for processing initial applications involving non-transitioning certified providers/suppliers.

- While the contractor shall create a new PECOS enrollment record for the REH, it need not (unlike with a COI) populate it with data from the facility's existing CAH or rural hospital record. It can simply use the data on the initial application; the application shall be designated as an initial application in PECOS.)

4. Recommendation/Disposition

i. Approval Recommended – If the contractor believes that a recommendation for approval is warranted, it shall forward its recommendation to the state consistent with the instructions for processing non-transitioned certified provider/supplier applications. The state will *review the matter* and thereafter refer *it* to the SOG Location for final review.

ii. Rejection or Denial – If the contractor believes the application should be rejected or denied, it shall send an e-mail to its PEOG BFL that: (1) identifies the provider (e.g., LBN); (2) explains the basis for the contractor's position; and (3) if a potential denial is involved, includes a copy of the draft denial letter for non-transitioned certified providers/suppliers. PEOG will review the matter. If PEOG approves the rejection or denial, the contractor shall --- within 3 business days of receiving said approval --- follow existing procedures for rejecting or denying an application; the state and SOG shall be copied on any denial letter.

B. Post-SOG Location Procedures

1. Denial

If the SOG Location denies the REH's request for participation, it will notify the contractor thereof. The contractor shall accordingly follow the procedures in this chapter for denying

non-transitioned certified provider/supplier applications. (No prior PEOG approval of the denial is needed.) The facility's CAH or rural hospital enrollment, however, remains as is.

2. Approval

If the SOG Location notifies the contractor of its approval of the REH's request for participation, the contractor shall follow the procedures in this chapter for approving non-transitioned certified provider/supplier applications. As part of this, the contractor shall: (a) switch the REH's PECOS record to "Approved" (using the participation effective date on the SOG Location approval notice); and (b) deactivate the facility's CAH or rural hospital enrollment (with a status of "voluntary withdrawal"), as well as any CAH reassignments, effective the day before the REH's approval effective date

C. Additional Considerations

1. Letters

- Denial – Any denial letter sent pursuant to this section 10.2.1.8.1 shall include the following language: "Your existing enrollment as a [insert critical access hospital or other hospital type, as applicable] is not affected by this determination."

The contractor shall use the denial letter applicable to the type of application submitted (e.g., a COI denial letter for a COI application).

- Approval – The approval letter shall include the following language: "With your enrollment as a rural emergency hospital, your existing enrollment as a [insert critical access hospital or other hospital type, as applicable] has been deactivated effective [insert date]. You will no longer be able to bill for [insert critical access hospital or other hospital type, as applicable] services under this enrollment." (No separate voluntary termination letter is required.)

The contractor shall use the approval letter applicable to the type of application submitted (e.g., an initial approval letter for an initial application).

The exact placement of the aforementioned language in the letters lies within the contractor's discretion.

2. Processing Alternatives and Clock Stoppages – Except as otherwise indicated in this section 10.2.1.8.1, all processing alternatives and clock stoppages described in this chapter apply to REH enrollment applications.

D. Enrolled REHs

Once enrolled, the REH, like all providers and suppliers, must maintain compliance with the enrollment requirements in 42 CFR Part 424, subpart P. This includes, but is not limited to, reporting changes to its enrollment information, undergoing revalidation (and submitting the required fee with this application), etc. The contractor need not undertake any special actions unique to enrolled REHs that are different from those applicable to all other provider/supplier types.

It is possible that an enrolled REH may seek to return to its former status as a CAH or rural hospital. To do so---and consistent with 42 CFR Part 424, subpart P and this chapter---it must submit an initial enrollment application and, for the REH enrollment, a voluntary termination application. It cannot do so via a change of information.

10.2.3.12 – Physician Assistants

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

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

A. PA Requirements Under § 410.74

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

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

(i) Meets the qualifications set forth in § 410.74(c);

(ii) Is legally authorized to perform the services in the state in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and PAs (including explicit supervisory or collaborative practice requirements) describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Social Security Act. For states with no explicit state law and scope of practice rules regarding physician supervision of a PA's services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physician(s) when furnishing professional services; and

(v) Performs the services: (A) in all settings in either rural and urban areas; or (B) as an assistant at surgery.

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

- *(1)* Have graduated from a PA educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; *OR (2) h*ave passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA);

  AND

- Be licensed by the state to practice as a PA. (The PA need not be currently NCCPA-certified.)

(In other words, either (1) or (2) in the first bullet must be met, and the licensure requirement in the second bullet must always be met.)

B. PA Employer

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

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

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

C. PA Enrollment Information

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

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

2. Transactions

a. Initial Enrollment - If a PA is initially enrolling in Medicare and does not intend to reassign his/her benefits, he/she need not complete Section 2(I) of the Form CMS-855I. (The PA's practice location information, however, shall be furnished.)

b. Initial Enrollment - If a PA is initially enrolling in Medicare and intends reassign his/her benefits, the PA shall complete Section 2(I) with the name, PTAN (if assigned), NPI, and EIN of the employer/entity/supplier to which benefits will be reassigned. With PECOS unable to accommodate Form CMS-855R PA reassignments at this time, Section 2(I) will effectively constitute a reassignment application in the interim. (For purposes of this section 10.2.3.12, such situations will be labeled "PA payment arrangements.") Reassigned payments can therefore be made to the employer/entity/supplier listed in Section 2(I), similar to how employers have previously been paid for PA services.

Regarding verification, the contractor:

- Shall follow this chapter's existing instructions for validating PA employer information rather than those for Form CMS-855R submissions

- Shall apply the Form CMS-855I's effective date to the PA payment arrangement

- Consistent with existing policy concerning PA employers, shall confirm that the employer/entity/supplier is enrolled in Medicare

- Need not secure the employer/entity/supplier's signature to effectuate the PA payment arrangement (as occurs with Form CMS-855R reassignees)

- If Section 2(I) is blank, the contractor can assume that the PA seeks direct payment. If there is evidence to the contrary, however, the contractor can (via any means) ask the PA whether reassignment is or is not desired. If it is, the contractor shall develop for the completion of Section 2(I).

c. Change Request Involving Section 2(I)

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

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

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

d. Form CMS-855B

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

e. Effective Date

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

10.2.5.1 – DMEPOS Supplier Accreditation

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

A. General Requirement

DMEPOS suppliers must be accredited prior to submitting an application to the contractor. The contractor shall deny any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt.

The contractor shall revoke an enrolled DMEPOS supplier's billing privileges if the supplier fails to: (1) obtain and submit supporting documentation that it has been accredited; or (2) maintain its required accreditation.

In the future, Medicare will deny claims for DMEPOS suppliers that fail to maintain accreditation information on file with the contractor.

B. Exemptions

Individual medical practitioners, inclusive of group practices of same, do not require accreditation as a condition of enrollment. The practitioner types are those specifically stated in Sections 1848(K)(3)(B) and 1842(b)(18)(C) of the Social Security Act. In addition, the practitioner categories of physicians, orthotists, prosthetists, optometrists, opticians, audiologists, occupational therapists, physical therapists, and suppliers who provide drugs and pharmaceuticals (only) do not require accreditation as a condition of enrollment.

Although suppliers that provide only drugs and pharmaceuticals are exempt from the accreditation requirement, suppliers that provide equipment to administer drugs or pharmaceuticals must be accredited.

C. Changes of Ownership

A DMEPOS supplier undergoing a change of ownership for an existing supplier location with a new tax identification number (TIN) *must submit an initial Form CMS-855S enrollment application to enroll as a new supplier. The supplier's application* shall be denied (consistent with 42 CFR § 424.57) if the new owner does not have an accreditation that covers all of its locations. If the old owner has such an accreditation, the new owner can be enrolled as of the date of sale if the accreditor determines that the accreditation should remain in effect as of the date of sale. (This, however, is only applicable when the new owner also meets all other enrollment criteria found at 42 CFR § 424.57).

Some ownership changes do not result in a complete change of ownership, since the business entity remains the same with no change in TIN. However, in cases where more than 5 percent of the ownership has changed, the following principles apply:

(i) If the change in ownership has not been reported to the contractor within the required 30-day period, the contractor shall proceed with revocation action.

(ii) If the change has been received within the required 30-day period and the supplier has been accredited, the contractor shall immediately notify the accreditor of the ownership change and request that the latter advise the contractor if the accreditation should still remain in effect.

D. Accreditation and Deactivation/Revocation

A non-exempt DMEPOS supplier requesting reactivation after a deactivation (regardless of the deactivation reason) is required to be accredited.

A revoked DMEPOS supplier that has submitted an acceptable corrective action plan can be reinstated without accreditation unless the accreditation was already required prior to revocation.

10.6.21 – Miscellaneous Enrollment Topics

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

This section 10.6.21 addresses additional provider enrollment policies. Except as otherwise stated, the instructions in this section supersede any other instructions to the contrary in this chapter. It is anticipated that the provisions in this section 10.6.21 will eventually be moved to those sections of this chapter most applicable to their respective subject matter. For organizational reasons, section 10.6.21 is merely a placeholder section of chapter 10.

A. Group and Reassignment Reactivation

If a group practice submits a reactivation application after being deactivated for non-response to a revalidation request, the contractor shall reactivate the group's reassignments when the group's reactivation application has been approved; Form CMS-855I and/or CMS-855R applications for the reassignments are not required. The effective dates assigned to the reassigned providers shall align with the group's effective date per existing reactivation instructions.
This section 10.6.21(A) only applies to deactivations based on a non-response to a revalidation request.

B. Specialty Changes

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

C. Reassignments Related to Revoked or Deactivated Reassignee

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

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

D. Interstate License Compacts

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

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

At present, there are interstate compacts involving physicians, physical therapists, occupational therapists, speech language pathologists, and psychologists (though none for nurse practitioners). More are possible.

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

E. Provisions in CMS-1770-F

The CMS Calendar Year 2023 Physician Fee Schedule Final Rule (CMS-1770-F) included a number of revisions to our provider enrollment regulations. This subsection 10.6.21(E) addresses these matters. Effective January 1, 2023, the contractor shall apply and execute the policies in this subsection 10.6.21(E) notwithstanding any other instruction to the contrary in this chapter.

1. Managing Organizations, Officers, and Directors

a. Definitions

CMS-1770-F finalized definitions of managing organization, officer, and director in 42 CFR § 424.502. These definitions are consistent with those commonly understood in the provider enrollment arena and are as follows:

- Managing organization - An entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.
- Officer - An officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.
- Director - A director of a corporation, regardless of whether the provider or supplier is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member; said body could be a board of directors, board of trustees, or similar body.

Officers and directors can also include persons who serve in a voluntary or ceremonial capacity. CMS re-emphasizes, however, that officers and directors apply only to corporations.

Managing organizations, officers, and directors have long been reported in Section 5 or 6 (as applicable) of the Form CMS-855 and on the Form CMS-20134. The contractor shall continue to follow existing instructions in this chapter for: (1) ensuring that these parties and all required data pertaining thereto are disclosed, such as EINs/SSNs and any adverse legal history; and (2) performing all required verifications (e.g., reviewing against the OIG excluded parties list).

b. Expansion of § 424.530(a)(2)/(3) and § 424.535(a)(2)/(3)

Managing organizations, officers, and directors have been added to the scope of the denial/revocation reasons at §§ 424.530(a)(2), 424.530(a)(3), 424.535(a)(2), and 424.535(a)(3). This means that a felony conviction within the past 10 years, an OIG exclusion, or a SAM debarment against an officer, director, or managing organization can

serve as the basis for the provider/supplier's denial/revocation. The contractor shall continue to follow existing instructions in this chapter for handling potential denial and revocation situations with the understanding that officers, directors, and managing organizations now fall within the aforementioned denial and revocation reasons. Thus, for example, if an officer of the provider has a current OIG exclusion, the contractor shall handle the matter in the same fashion it would if a supervising physician were excluded.

Note that CMS-1770-F also formally incorporated into § 424.530(a)(2)/(3) and § 424.535(a)(2)/(3) the policy that the individuals and entities listed within these regulatory provisions include W-2 employees and contracted individuals and organizations of the provider/supplier.

c. Expansion of § 424.530(c) and § 424.535(e)

As mentioned in sections 10.4.2.3(B) and 10.6.18(C)(7) of this chapter, §§ 424.530(c) and 424.535(e) state that if a denial or revocation, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider/supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, the denial or revocation may be reversed if the provider/supplier terminates (and submits proof that it has terminated) its business relationship with that party within 30 days of the denial/revocation notification. CMS-1770-F added officers, directors, and managing organizations to §§ 424.530(c) and 424.535(e).

2. Clarification of § 424.535(a)(12)

As stated in § 424.535(a)(12) and in section 10.4.7.3(L) of this chapter, CMS may revoke a provider or supplier that is terminated, revoked, or otherwise barred from participation in a state Medicaid program or any other federal health care program. Under § 424.535(a)(12)(ii), CMS cannot revoke unless and until the provider or supplier "has exhausted all applicable appeal rights." However, CMS-1770 added the following to the end of this quoted language in § 424.535(a)(12)(ii): "or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal." This merely incorporated into regulation CMS' existing policy that § 424.535(a)(12) can be applied if the provider or supplier fails to file an appeal within the prescribed timeframe.

3. Expansion of Providers and Suppliers Undergoing High-Risk Screening

CMS-1770-F also expanded the number and types of providers and suppliers that are subject to high-risk level screening under § 424.518. This generally involves, but is not limited to: (1) moving skilled nursing facilities (SNFs) from the "limited" screening category to the "high" screening category; and (2) including certain changes in ownership as among the types of enrollment transactions subject to the "high" screening category under § 424.518. These regulatory changes and the associated contractor instructions for effectuating them are described in (a) through (c) below.

a. Changes in Ownership

i. General Policy

As stated in § 424.518 and as described in section 10.6.15 of this chapter, the following three application types are subject to § 424.518's screening requirements: (1) initial applications; (2) revalidations; and (3) applications to add a new practice location. CMS-1770-F added the following two transaction types to the purview of § 424.518:

(i) Change of ownership applications pursuant to 42 CFR § 489.18
(ii) Applications to report any new owner (regardless of ownership percentage, though consistent with the definition of owner in section 10.1.1 of this chapter) pursuant to a change of information or other enrollment transaction under title 42.

The foregoing means that an application under (i) or (ii) must be processed at the high screening level if it is submitted by:

- An enrolled OTP that has not been fully and continuously certified by SAMHSA since October 24, 2018
- A DMEPOS supplier
- An MDPP supplier
- An HHA
- A SNF (described further below)

(For purposes of this subsection (E)(3)(a), these five provider/supplier types will be collectively referred to as the "affected providers.")

Categories (i) and (ii) above would include, for instance:

- A SNF CMS-855A CHOW, acquisition, merger, and consolidation application (as those terms are described on the CMS-855A and in section 10.6.1.1 of this chapter).

- An HHA CHOW under 42 CFR § 489.18. (See section 10.2.1.6.1 of this chapter for information on these types of CHOWs.) Note that a change in majority ownership under 42 CFR § 424.550(b) that requires a new enrollment would not fall under (i) or (ii) above because it would generate an initial enrollment, though, for this latter reason, it would still be processed at the high screening level (as all HHA initials are).)

- A DMEPOS supplier reporting a 15 percent new owner.

In sum, any change of/in ownership that meets all the following criteria would fall under (i) and (ii) above:

- Does not involve the triggering of an initial enrollment (e.g., an HHA change in majority ownership and no exception applies, thus warranting a new enrollment); and
- The change reports either:

    - For partnerships: A new partner (general or limited) that owns any percentage (even 1 percent) of the affected provider; or
    - Excluding partnerships: A new direct or indirect owner of at least 5 percent of the affected provider.

Changes of ownership involving providers/suppliers other than the five aforementioned affected provider categories (e.g., ambulance suppliers, CORFs) shall continue to be processed consistent with existing instructions.

ii. Processing Instructions

Upon receipt of an application described in subsection (E)(3)(a)(i) above, the contractor shall process it consistent with the instructions in this chapter and, in particular, with section 10.6.15. This includes requesting fingerprints from any new direct or indirect owner of 5 percent or more of the provider, though the contractor need not also solicit them from the provider/supplier's existing owners; only the new owner(s) need be fingerprinted.

The contractor shall also order a site visit of the affected provider consistent with existing instructions. In terms of the timing of the HHA or SNF site visit, however, the contractor shall also adhere to the following:

- No State/SOG Location Approval Required – If the ownership change does not require state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1 of this chapter for more information), the site visit shall be ordered and performed prior to the contractor's final decision regarding the application.
- State/SOG Location Approval Required - If the ownership change requires state or SOG Location approval under existing CMS instructions (see sections 10.6.1.1, 10.6.1.2, 10.6.22, and 10.6.22.1), the site visit shall be ordered and performed no later than 5 business days after the contractor receives notice of approval from the state or SOG Location but before the contractor switches the provider/supplier's enrollment record to an "Approved" status.

All clock stoppages permitted under this chapter (e.g., fingerprinting per section 10.5(C)(1)) apply to the situations described in this subsection (E)(3)(a). In addition, since a site visit and fingerprinting are required, the contractor shall adhere to the timeliness standards in section 10.5(A)(1)(a) for paper applications and those in section 10.5(A)(3)(a) for web-based applications.

b. SNFs

As already mentioned, SNFs are now in the "high" screening category under § 424.518(c). Accordingly, SNF initial applications require a site visit as well as the fingerprinting of the SNF's 5 percent or greater owners. In executing this policy, the contractor shall follow existing instructions in this chapter regarding the collection and processing of fingerprints, including those in subsection (E)(3)(a) above for SNF ownership changes. As for site visits, the contractor shall follow the instructions in section 10.2.1.14 for initial and revalidation applications and subsection (E)(3)(a) above for change in ownership applications.

c. "Bump-Ups"

Effective January 1, 2023 (and pursuant to CMS-1770-F), any screening level adjustment under § 424.518(c)(3) also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under § 424.518(c)(3) of this section was originally raised. See section 10.6.15(A)(4) of this chapter for more information.

F. Special Form CMS-855S Instructions

1. Addresses

If an address (e.g., correspondence address, practice location) on the Form CMS-855S lacks a city, state, or zip + four, the contractor can verify the missing data in any manner it chooses. In addition, the contractor can obtain the zip + four from either the U.S. Postal Service or the Delivery Point Validation in PECOS.

2. Insurance

With respect to the comprehensive liability insurance supplier standard in 42 CFR § 424.57(a)(10), the contractor shall: (1) verify with the insurance agent that the insurance policy is active and current; and (2) ensure that the contractor (i.e., the NPE contractor) is listed as the policy holder on the certificate. The contractor may contact the insurance agent

via any manner it chooses; however, verification shall be documented consistent with section 10.6.19 of this chapter (e.g., documenting telephonic communications).

G. Transitioned Certified Providers and Suppliers – E-Mails to PEOG for Final Application Review and/or Approval

As described in this chapter, the contractor must refer various matters involving transitioned certified provider/supplier enrollment applications to PEOG for final application review and approval (e.g., system updates, assignment of CCN, etc.) When making such referrals---and notwithstanding any other instruction to the contrary in this chapter---the e-mail subject line shall include the following: SUBJECT LINE: S&C: Facility Type; Application Type; Facility Name; National Provider Identifier; CCN; Application Receipt Date (MMDDYY*) (*Date the Contractor Received the Application from the Provider/Supplier). (Note, however, that this data need not be duplicated in the e-mail's body.) This instruction, to reiterate, only applies to e-mails to PEOG involving: (1) transitioned certified providers/suppliers; and (2) instances where the contractor is explicitly required per this chapter to send the matter PEOG for final review, approval, and/or denial of an application (e.g., initial application, CHOW, certain COIs) and to wait for PEOG's determination. (See, for example, section 10.6.1.2(A)(3)(a) of this chapter.)

H. Contacting State or SOG Location for Updates

1. "Transitioned" Certified Providers/Suppliers - In situations where the contractor recommends approval to the state (initial applications, CHOWs, certain changes of information, etc.), the contractor---if it has not received the state's recommendation within 120 days after the contractor sent its recommendation---may contact the state to ascertain whether said recommendation is forthcoming. The contractor may contact the state every 30 days thereafter to determine the recommendation's status.

2. "Non-Transitioned" Certified Providers/Suppliers – If, as described in subsection (H)(1) above, the contractor recommends approval to the state, the contractor may contact the state for an update on the recommendation's status beginning 120 days after the recommendation was sent and every 30 days thereafter. If the state informs the contractor (via any means) that the application has been forwarded to the SOG Location, the contractor may contact the SOG Location for a status update every 30 days beginning on the date the contractor received this notice from the state.

I. Survey and Certification Documents – All Certified Providers and Certified Suppliers

1. Documents from the State/AO

As applicable to the provider/supplier type in question, the state or accrediting organization (AO) must provide the signed CMS-1561 (or other/similar contract) and copy of the HHS-690 to the contractor with its approval recommendation. (Note that the contractor can accept a CMS-1561 or HHS-690 from either the state or AO.)

*If the state/AO neither furnished said documents **nor** otherwise indicated that they were uploaded into the Automated Survey Process Environment (ASPEN)/Internet Quality Improvement and Evaluation System (IQIES), the contractor shall contact the state/AO via any means for the applicable document(s). If the state/AO responds within 10 days of the contractor's request by either (a) sending the document(s) to the contractor or (b) stating that it has uploaded the document(s) into ASPEN/IQIES, the contractor can continue processing the application consistent with applicable instructions. (If the state/AO indicated (b) above, the contractor shall note this in its referral to PEOG.) If the state/AO does neither (a) nor (b) within this 10-day period, the contractor shall: (1) proceed with sending the*

referral to PEOG consistent with existing instructions; and (2) include evidence of the state/AO's lack of responsiveness (e.g., e-mail evidence of the contractor's request).

2. AO Documents to PEOG

As applicable to the situation and provider/supplier type, the contractor shall include the AO deeming letter in referrals to PEOG that are required under this chapter (e.g., initial approvals).

10.7.9 – Revocation Letters

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

A. Revocation Letter Guidance

The contractor--

- Must submit one or more of the Primary Revocation Reasons as found in section 10.4.7.3 into the appropriate section on the specific Revocation Letter. Only the CFR citation and a short heading shall be cited for the primary revocation reason.

- Shall include sufficient details to support the reason for the provider or supplier's revocation;

- Shall issue all revocation letters via certified letter, per regulations found in 42 CFR 405.800(b)(1), and;

- Shall issue two revocation letters to any solely owned organizations, one for the individual and the other for the organization.

B. Model Revocation Letters

1. Revocation Example - Letter for DMEPOS Suppliers

[month] [day], [year]

[Supplier Name]
[Address]
[City] ST [Zip]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Certified mail number: [number]
Returned receipt requested

Dear [Supplier Name]:

The purpose of this letter is to inform you that pursuant to 42 CFR §§ 405.800, 424.57(x), 424.535(g), and 424.535(a)[(x)], your Medicare supplier number [xxxxxxxxxx] for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

[will be revoked effective 30 days from the postmarked date of this letter]

[is revoked. The effective date of this revocation has been made retroactive to [month] [day], [year], which is the date [revocation reason]]

Pursuant to 42 CFR §424.535(c), the supplier is barred from re-enrolling for a period of [number of years] year(s) in the Medicare program from the effective date of the revocation. In order to re-enroll, you must meet all requirements for your supplier type.

[The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [date]. This letter allowed you to demonstrate your full compliance with the DMEPOS supplier standards and/or to correct the deficient compliance requirement(s).]

[The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [date]. This letter allowed you to demonstrate your full compliance with the DMEPOS supplier standards and/or to correct the deficient compliance requirement(s)]

[[Contractor Name] has not received a response to the developmental letter sent to you on [date] informing you that the request for a hardship exception for the required application fee was denied. The notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application and an appeal period which you did not select.]

[[Contractor Name] has not received a response to the developmental letter sent to you on [date] informing you that the application fee was not paid at the time you filed the Form CMS-855S enrollment application. The 30day notification afforded you the opportunity to pay the mandatory application fee for processing your enrollment application]

We have determined that you are not in compliance with the supplier standards noted below:

42 CFR §424.57(c) [1-30] [Insert the specific performance standard not met]

Section 1834(j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834 (a)(A)(ii) of the Social Security Act and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under 1834 (j) (4) and 1879(h) of the Social Security Act, you may be liable for Civil Monetary penalties.

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to an enrollment revocation under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your enrollment was revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those denial bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to enroll in the Medicare program. (Optional Coversheet sentence: [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed to the address below or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

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

- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

Please note that CAPs may not be appealed further to the Departmental Appeals Board. Further appeal rights do exist for reconsideration requests (described below). CAP requests should be sent to:

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

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

Reconsideration Request:

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

Reconsideration requests must--

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

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

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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

The reconsideration request should be sent to:

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

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

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

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

Sincerely,

[Name]
[Title]
[Company]

2. Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers

[Month] [day], [year]

[Provider/Supplier Name]
[Address]
[City] ST [Zip]

Reference # (Contractor Control Number or NPI)

Dear [Provider/Supplier Name]:

Your Medicare privileges are being revoked effective [Date of revocation] for the following reasons:

xx CFR §xxx.(x) [heading]
[Specific reason]

xx CFR §xxx.(x) [heading]
[Specific reason]

(For certified providers and certified suppliers only: Pursuant to 42 CFR §424.535(b), this action will also terminate your corresponding (provider or supplier) agreement.)

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re-enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to the revocation of Medicare billing privileges under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your Medicare billing privileges were revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those revocation bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to maintain enrollment in the Medicare program. (Optional Coversheet sentence [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]). The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed or emailed to the address below;

- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.

    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.

    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.

- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

The CAP should be sent to:

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

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

Reconsideration Request:

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

Reconsideration requests must--

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

    - If the authorized representative is an attorney, the attorney's statement that he or

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

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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

The reconsideration request should be sent to:

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

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

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

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

Sincerely,

[Name]
[Title]

[Company]

C. Revocation Letter Examples

Note that each example contains instructions to send appeals to both CMS and the contractor, regardless of the example reason, so that the contractors may include the appropriate appeal address based on the provider or supplier type that has been revoked. In addition, note that the section advising the provider/supplier of their right to submit a CAP are only included in the examples of revocations based on 42 C.F.R. § 424.535(a)(1).

1. Abuse of Billing Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City, State & ZIP Code]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [Provider/Supplier Name]:

Your Medicare privileges are being revoked effective June 16, 2012 for the following reasons:

Revocation reason: 42 CFR § 424.535(a)(8)

Specifically, you submitted 186 claims to Medicare for services provided after the date of death of 15 beneficiaries.

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re-enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Reconsideration Request:

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

Reconsideration requests must--

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

    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept

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

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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

The reconsideration request should be sent to:

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

[Name of MAC]
[Address]
[City], [ST] [Zip]

or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51
Baltimore, MD 21244-1850

Or emailed to:

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

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

Sincerely,

[Name]
[Title]
[Company]

2. DMEPOS Supplier Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City], [ST] [Zip]

Reference #: [PTAN #, Enrollment #, Case #, etc.]
NPI: [xxxxxxxxxx]

Dear [Supplier Name]:

The purpose of this letter is to inform you that pursuant to 42 C.F.R. § 405.800, 42 C.F.R. §424.57(e), and 42 C.F.R. § 424.535(a)(5), your Medicare supplier number [xxxxxxxxxxx] for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) issued by [Contractor name) is revoked. The effective date of this revocation has been made retroactive to April 26, 2012, which is the date the Centers for Medicare & Medicaid Services (CMS) determined that your practice location is not operational.

We have determined that you are not in compliance with the supplier standards noted below:

42 C.F.R. § 424.57(c)(7) Maintain a physical facility on an appropriate site, accessible to the public and staffed during posted hours of business with visible signage.

Recently a representative of [Contractor name] attempted to conduct a visit of your facility on April 26, 2012. However, the visit was unsuccessful because your facility was closed, locked, and vacant. There was a "For Rent" sign on the window along with a sign directing customers to a nearby Rite Aid Pharmacy. Because we could not complete an inspection of your facility, we could not verify your compliance with the supplier standards. Based on a review of the facts, we have determined that your facility is not operational to furnish Medicare covered items and services. Thus, you are in violation of 42 CFR § 424.535(a)(5).

42 C.F.R. § 424.57(c)(26) must meet the surety bond requirements specified in 42 C.F.R. § 424.57(d).

We received a cancellation notice from Cook, Books & Hyde Surety indicating that the surety bond on file with the billing number 99999999 has been cancelled effective January 19, 2012. You failed to maintain a valid surety bond as required by law.

Section 1834 (j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834(a)(18)(ii) of the Social Security Act and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under sections 1834(j)(4) and 1879(h) of the Social Security Act, you may be liable for Civil Monetary penalties.

(Delete the following paragraph if no re-enrollment bar established.)[Pursuant to 42 C.F.R. § 424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re-enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.]

In addition, if submitting a Form CMS-855S application after the re-enrollment bar has expired, 42 C.F.R. § 424.57(d)(3)(ii) states suppliers will be required to maintain an elevated surety bond amount of $50,000 for each final adverse action imposed. Therefore, if you do not request a reconsideration of this decision or receive an unfavorable decision through the administrative review process, you must submit an elevated surety bond. Please note this amount is in addition to, and not in lieu of, the base $50,000 amount that must be maintained.

Right to Submit a Reconsideration Request:

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

Reconsideration requests must--

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

Providers and suppliers may--

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

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

The reconsideration request should be sent to:

[Contractor name]
[Address]
[City], [ST] [Zip]

If you choose not to request a reconsideration of this decision, or you do not receive a favorable decision through the administrative review process, you must wait [insert number] years before resubmitting your CMS-855S application, per the re-enrollment bar cited above. Applications received by [Contractor name] prior to this timeframe will be returned.

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

Sincerely,

[Name]
[Title]
[Company]

3. MDPP Supplier Use of an Ineligible Coach Revocation Letter Example

[month] [day], [year]

[Entity name]
[Address]
[City, State & ZIP Code]

Reference # (PTAN #, Enrollment #, Case #, etc.)

Dear [MDPP Supplier Name]:

Your Medicare privileges are being revoked effective June 16, 2018 for the following reasons:

Revocation reason: 42 CFR §424.535(a)(1) – Not in Compliance with Medicare Requirements

Per 42 CFR §424.205(d)(3), MDPP suppliers must only use eligible coaches.

Revocation reason: 42 CFR §424.205(h)(v) – Use of an Ineligible coach

Specifically, you were notified on April 1, 2018 that John Doe was ineligible to serve as an MDPP coach due to an assault conviction in June 2015. On April 15, 2018, you submitted a corrective action plan (CAP), which removed John Doe from Section 7 of your Form CMS-20134. On June 1, 2018, you submitted a claim with the NPI of John Doe for services rendered May 1st, after he was removed from your coach roster. This indicates knowingly use of an ineligible MDPP coach.

Revocations under 42 CFR §424.205(h)(v) are not eligible for CAP submission. The revocation becomes effective 30 days after the date of this notice.

Pursuant to 42 CFR §424.535(c), CMS is establishing a re-enrollment bar for a period of [Insert amount of time] that shall begin 30 days after the postmark date of this letter. This re-enrollment bar only applies to your ability to submit a new enrollment application to the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

Right to Submit a Corrective Action Plan (CAP) and Reconsideration Request:

Corrective Action Plan: (Only if revoked under 42 C.F.R. § 424.535(a)(1))

You may submit a corrective action plan (CAP) in response to the revocation of Medicare billing privileges under 42 C.F.R. § 424.535(a)(1). You may also request a reconsideration (described below). If your Medicare billing privileges were revoked under authorities other than 42 C.F.R. § 424.535(a)(1), you may **only** submit a reconsideration request in response to those revocation bases.

The CAP is an opportunity to demonstrate that you have corrected the deficiencies identified above and thereby, establish your eligibility to maintain enrollment in the Medicare program. (Optional Coversheet sentence [To facilitate the processing of your CAP, please utilize and include the [attached] coversheet [also found at [[insert web address for coversheet]] with your submission.]) The CAP must--

- Be received in writing within 35 calendar days of the date of this letter and mailed or emailed to the address below;
- Be signed by the provider or supplier, an authorized or delegated official that has been reported within your Medicare enrollment record, or an authorized representative.
    - If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.
    - If the authorized representative is not an attorney, the individual provider, supplier, or authorized or delegated official must file written notice of the appointment of its representative with the submission of the reconsideration request.
    - Authorized or delegated officials for groups cannot sign and submit a CAP on behalf of a reassigned provider/supplier without the provider/supplier submitting a signed statement authorizing that individual from the group to act on his/her behalf.
- Provide evidence to demonstrate that you are in compliance with Medicare requirements.

(Insert correct address based on whether the MAC or CMS is responsible for reviewing the CAP)

[Name of MAC]
[Address]
[City], [ST] [Zip]

Or

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
Attn: Division of Provider Enrollment Appeals
7500 Security Boulevard
Mailstop AR-19-51

Baltimore, MD 21244-1850

Or emailed to:

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

Reconsideration Request:

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

Reconsideration requests must--

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

Providers and suppliers may--

- Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.
- Include an email address if you want to receive correspondence regarding your appeal via email.
- (If revoked under 42 C.F.R. § 424.535(a)(2)) Please note that you may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.

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

The reconsideration request should be sent to:

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

[Name of MAC] [Address] [City], [ST] [Zip]	or	Centers for Medicare & Medicaid Services Center for Program Integrity Provider Enrollment & Oversight Group Attn: Division of Provider Enrollment Appeals 7500 Security Boulevard Mailstop AR-19-51 Baltimore, MD 21244-1850

Or emailed to:

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

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

Sincerely,

[Name]
[Title]
[Company]

10.7.19 – ESRD Approval Letters

(Rev. 12100; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)

In the ESRD situations described in this section 10.7.19, the letters below shall be used as directed in section 10.2.1.3 notwithstanding any other instruction to the contrary in this chapter.

A. ESRD Service Station/Modality Changes

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

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

Your State Agency has notified [insert contractor name] [insert contractor number] that your end-stage renal disease (ESRD) facility changed [your approved service modalities and/or number of stations.] Therefore, your facility is now approved for a total of [number of in-center hemodialysis stations] maintenance stations and the services outlined below:

Medicare Enrollment Information

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

CMS Certification Information

CCN
Effective Date
Changed Information
Effective Date of Change(s) (Include detailed changes or section. Select from list below.)

__In Center Hemodialysis
__In Center Peritoneal Dialysis
__In Center Nocturnal Hemodialysis
__Patient Training and Support for Home Hemodialysis
__Patient Training and Support for Continuous Ambulatory Peritoneal Dialysis (CAPD)
__Patient Training and Support for Continuous Cycling Peritoneal Dialysis (CCPD)

You should report to the [State Agency ([SA])] any changes in location, services, or organization which might affect your certification status or the status of your ESRD facility. In addition, providers must notify CMS when there is a change of ownership. Therefore, you must notify your Medicare Administrative Contractor (MAC) and the [SA] promptly if there is a change in the legal status of the ownership of this facility.

We look forward to continuing to work with you in the administration of the Medicare program. If you have any questions regarding this, please contact [STATE AGENCY NAME], [STATE AGENCY EMAIL ADDRESS].

[Include appropriate MAC signature]

Cc: State Agency
Accrediting Organization (if appropriate)

B. State Agency Approved Initial

[Month, Day, Year]
[Provider/Supplier Name]
[Address]
[City, State, Zip]

Reference # (Application Tracking Number)

Dear [Provider/Supplier],

[Insert Contractor name [and Contractor number]] received a response from the Medicare State Agency [and Accrediting Organization}]. Your initial enrollment application is approved.

Your unit has been approved as a renal dialysis [facility/center]. This approval is for a total of [number] maintenance stations. Your [facility/center] is approved to provide the following services:

[List all that apply--]

-In Center Hemodialysis
-In Center Peritoneal Dialysis
-In Center Nocturnal Hemodialysis
-Patient Training and Support for Home Hemodialysis

-Patient Training and Support for Continuous Ambulatory Peritoneal Dialysis (CAPD)
-Patient Training and Support for Continuous Cycling Peritoneal Dialysis (CCPD)

Medicare Enrollment and Provider/Supplier Information

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

Please inform the [State Survey Agency/AO] if you wish to relocate your [facility/center], change the services that you are currently providing, change the number of approved stations, or undergo a change in ownership.

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.
Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

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

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

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

<u>Right to Submit a Reconsideration Request</u>:

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

Reconsideration requests must:

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

- *If the authorized representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the representative.*

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

Providers and suppliers may:

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

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

The reconsideration request should be sent to:

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

Or emailed to: ProviderEnrollmentAppeals@cms.hhs.gov

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

Sincerely,

[Name]
[Title]
[Company]
CC: State Agency [and AO, if applicable]

C. Change of Ownership

[Month, Day, Year]

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

Subject: *ESRD Medicare Change of Ownership*

Dear Administrator:

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

[INSERT or CHECK THE APPLICABLE PARAGRAPH]:

__ [Facility status is not changing]
When an ESRD facility undergoes a change of ownership, the new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from free-standing to hospital-based]
When an ESRD facility undergoes a change of ownership and changes its status from a free-standing ESRD facility to a hospital-based ESRD center, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD center is issued a new CCN number that links it to the provider with which it is associated. The new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner.

___ [Changing from hospital-based to free-standing]
When an ESRD center undergoes a change of ownership and changes its status from a hospital-based ESRD center to a free-standing ESRD facility, the existing CCN, formerly known as the Medicare Provider/Supplier Number, is automatically terminated and the ESRD facility is issued a new CCN to indicate the free-standing designation. The new owner is subject to all of the Medicare program terms and conditions that applied to the prior owner. Therefore, the CCN of [old CCN] is hereby terminated effective [Date of CHOW]. Your facility's approved CCN is provided below.

Your facility has been approved for a total of [number of in-center hemodialysis stations] maintenance stations. Also, your facility is approved to provide the following services:

[CHECK OR INSERT ALL APPLICABLE]

-In Center Hemodialysis
-In Center Peritoneal Dialysis
-In Center Nocturnal Hemodialysis
-Patient Training and Support for Home Hemodialysis
-Patient Training and Support for Continuous Ambulatory Peritoneal Dialysis (CAPD)
-Patient Training and Support for Continuous Cycling Peritoneal Dialysis (CCPD)

Medicare Enrollment Information

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

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system. Contact our electronic data interchange (EDI) department for enrollment and further instructions on electronic claims filing at [phone number].

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

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

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

Right to Submit a Reconsideration Request

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

Reconsideration requests must:

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

Providers and suppliers may:

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

Sincerely,

[Name]
[Title]

[Company]
CC: State Agency [and AO, if applicable]