CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal-203 **Date: March 12, 2021**

SUBJECT: Revisions to the State Operations Manual (SOM), Chapter 2 for Federally Qualified Health Centers (FQHCs)

I. SUMMARY OF CHANGES: This Transmittal includes revisions based on the Medicare Administrative Contractor (MAC) transition work on processing certification enrollment actions for FQHCs.

NEW/REVISED MATERIAL - EFFECTIVE DATE: March 12, 2021
IMPLEMENTATION DATE: March 12, 2021

The revision date and transmittal number apply to the red italicized material only. 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 not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/2826A/General
R	2/2826B/Information to Be Provided to Potential Applicants
R	2/2826C/Request to Participate
R	2/2826D/Processing Requests
R	2/2826E/Assigning Applicants a FQHC CMS Certification Number (CCN)
R	2/2826F/Effective Date
D	2/2826G/RO Completion of Forms
R	2/2826H/Complaint Investigations

2826A - General

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

An FQHC *applicant* seeking to enroll as a Medicare-participating supplier is subject to a filing procedure instead of SA certification or recertification. Under this procedure, the FQHC *applicant* must attest that it is in compliance with all applicable Medicare regulations. *To attest to being in compliance, the facility must be open and operational when the attestation is signed.* The SA does not survey to confirm the FQHC *applicant's* compliance with Medicare's regulations.

FQHCs must remain in substantial compliance with all of the FQHC regulatory requirements specified in 42 CFR Part 405, Subpart X, and in 42 CFR Part 491, with the exception of Section 491.3.

CMS will enter into an agreement with an entity that qualifies to participate as an FQHC when:

- The applicant provides a copy of its Notice of Grant Award by HRSA that verifies the applicant qualifies as an FQHC; the applicant provides a copy of its FQHC Look-Alike Designation Memo from CMS; or the applicant is confirmed as a qualifying tribal or Urban Indian organization outpatient healthcare facility;

- The applicant assures CMS through a self-attestation that it satisfies the regulatory requirements in 42 CFR 405 Subpart X and 42 CFR Part 491, except for Section 491.3;

- The applicant submits a complete Form CMS-855A enrollment application (along with all supporting documentation) to its MAC, and the MAC recommends approval of said application; and

- The entity terminates other Medicare provider agreement(s) it has, unless it assures CMS that it is not using the same space, staff, and resources simultaneously as a physician's office or other type of provider or supplier. For example, an RHC cannot concurrently be approved for Medicare as both an RHC and FQHC.

In accordance with 42 CFR 491.5(a)(3)(iii), if an FQHC provides services in permanent units in more than one location, each such unit must be separately enrolled in the Medicare program. One FQHC permanent unit cannot be provider-based to another FQHC unit. However, mobile units operated by the FQHC do not require separate enrollment, but are considered part of the permanent FQHC unit that operates them.

In general, *CMS Provider Enrollment Oversight Group (PEOG) is* responsible for reviewing and approving or denying requests for Medicare participation as an FQHC. The *MAC* notifies the FQHC applicant and HRSA's Bureau of Primary Health Care or the Indian Health Service, as appropriate, of approvals or denials (The only exception to this involves situations where the MAC determines that the applicant does not comply with the enrollment requirements at 42 CFR 424.500-525, in which case the contractor itself will issue the denial per *the Program Integrity Manual*). For approvals:

- A freestanding FQHC undergoing initial enrollment, except for a tribal or Urban Indian FQHC, is to be assigned to the MAC that covers the State where the FQHC is located.

- A tribal or Urban Indian FQHC undergoing initial enrollment is to be assigned to the

Jurisdiction *H* MAC.

NOTE: For FQHCs already enrolled in Medicare:

- *All* freestanding FQHCs, except for tribal or Urban Indian FQHCs, *will remain with their originally assigned MAC, i.e., will not be moved to* the MAC that covers the State where the FQHC is located.

- *All* tribal *and* Urban Indian FQHC*s will continue* to be assigned to the Jurisdiction *H* MAC.

It is unlikely that a new FQHC would qualify for provider-based, as opposed to freestanding, status, since HRSA's requirements for governance of an FQHC preclude the FQHC from satisfying CMS' requirements for clinical, financial and administrative integration with the main provider. However, 42 CFR 413.65(n) permits any FQHC or FQHC Look-Alike facility that, since April 7, 1995, furnished only services that were billed as if they were furnished by a department of a provider to continue to do so, regardless of satisfying the criteria for provider-based status, so long as it was qualified as an FQHC (not including tribal/Urban Indian facilities) or FQHC Look-Alike on or before April 7, 2000. A provider-based FQHC is assigned its own CMS Certification Number (CCN), but uses the same MAC as the main provider to which it is provider-based.

The *CMS Location* reviews FQHC complaints and either refers them to HRSA or the Indian Health Care Service (IHS), as applicable, for investigation or, in the case of credible allegations that allege an FQHC does not meet applicable Medicare requirements, to the SA for investigation. The CMS *Location* will conduct *an investigation of any complaint allegation* that a FQHC does not meet applicable Medicare requirements when the FQHC is located on reservation property. *Surveyors are to use the State Operations Manual (SOM), Chapter 5- Complaint Procedures and Appendix G Guidance for Surveyors: Rural Health Clinic (RHC) and Federal Qualified Health Centers (FQHCs) when conducting a FQHC complaint investigation.* (See §2826H.)

The *CMS Location* may terminate the agreement with an FQHC if it finds that the FQHC no longer meets the Medicare eligibility standards to participate as an FQHC and/or is not in substantial compliance with the Medicare requirements for FQHCs.

2826B - Information to Be Provided to Potential Applicants

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

The *MACs* are to provide potential applicants for enrollment as an FQHC a copy of the document entitled Information on Medicare Participation for FQHCs (*Exhibit 179*). This document includes information on:

- Obtaining a copy of Form CMS-855A enrollment application from CMS' Web site at http*s*://www.cms.gov/*Medicare*/*CMS-F*orms/*CMS-Forms*/*D*ownloads/cms855a.pdf; and

- Attestation Statement for FQHCs (Exhibit 177)

2826C - Request to Participate

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

To participate in the Medicare program, applicants seeking initial enrollment as an FQHC must submit a Form CMS-855A application:

- In the case of applicants that are operated by a tribe or tribal organization, to the jurisdiction H A/B MAC; and

- In the case of all other applicants, to the A/B MAC that covers the State where the applicant facility is located. (Previously all FQHC applications and claims were processed by one national fiscal intermediary. This system *was* phased out as CMS *has* implement*ed* the MAC contracts. *Therefore,* all new FQHC applications are to be assigned to the applicable MAC, as described above *in section 2826A*.

Information on enrollment procedures and a list of A/B MACs may be found at:

- http://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html?redirect=/center/fqhc.asp
  (Accessed November 17, 2020)

- http://www.cms.gov/medicare-coverage-database/indexes/contacts-part-a-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAA&
  (Accessed November 17, 2020)

- https://www.cms.gov/medicare-coverage-database/indexes/contacts-part-b-medicare-administrative-contractor-index.aspx?bc=AAAAAAAQAAAA&
  (Accessed November 17, 2020)

- https://www.cms.gov/medicare-coverage-database/indexes/contacts-part-ab-medicare-administrative-contractor-index.aspx?bc=AAAAAAAQAAAA&
  (Accessed November 17, 2020)

The following documents must be included in the application:

- A signed and completed application Form CMS-855A enrollment application;

- *S*igned and dated copies of the attestation statement (Exhibit 177). *To attest to being in compliance, the facility must be open and operational 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 agreement when it is also signed and dated by *CMS PEOG*.

- HRSA Notice of Grant Award or FQHC Look-Alike Designation that includes an address for the site of the applicant which matches the practice location reported on the Form 855A;

- 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. Chapter 6, Section 6002 of the *SOM* provides additional details regarding laboratories and laboratory tests NOT subject to CLIA requirements. It is the responsibility of the FQHC applicant to review the CLIA requirements and obtain a CLIA certificate if needed. Neither the MAC nor *CMS can* make a determination as to whether the FQHC applicant must obtain and submit a CLIA certificate; and

- Copy of State License (if applicable).

2826D - Processing Requests

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

The MAC will review the completed Form CMS-855A and other documents submitted by the applicant to ensure all required information and documentation has been provided, and thus is complete. *A complete FQHC application consists of: the Form CMS-855A, two signed original Attestation Statement for Qualified Health Centers (Exhibit 177), a copy of the HRSA Notice of Grant Award, a copy of the applicant's State license if applicable, and a copy of its CLIA certificate, if applicable.* Upon completion of its review, the MAC will either: (1) forward its recommendation for approval *of the application to CMS PEOG*; or (2) deny the *enrollment* application *based on enrollment criteria.*

If the MAC recommends approval, CMS PEOG will sign the approval letter, and countersign and date both of the applicant's Attestation Statement for Federally Qualified Health Centers (Exhibit 177). CMS PEOG will use the date the FQHC application was considered complete by the MAC (i.e., the date of the approval recommendation to CMS PEOG) as the effective date. In addition, CMS PEOG will update the national database system and issue the FQHC's CCN, and will send the countersigned attestation to the MAC contractor. Following receipt of this information from CMS PEOG, the MAC will provide the approval letter to the FQHC and include the countersigned attestation, with a carbon copy of the approval letter to the applicable CMS Location.

In the event the enrollment application is denied on the basis of enrollment criteria, the MAC will process the denial and will provide the denial letter to the FQHC applicant, with a carbon copy to the CMS Location. MACs are not required to forward denials to CMS PEOG.

For outpatient health programs or facilities 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 *MAC* confirms the applicant's attestation by using the IHS lists of facilities or organizations provided by *the CMS Location,* or by contacting *the CMS Location* or the IHS for applicants not on the list.

Each *MAC* should designate a primary point-of-contact (POC) for coordination with HRSA, IHS, and CMS.

2826E - Assigning Applicants a FQHC CMS Certification Number (CCN)

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

The *PEOG* assigns each FQHC permanent site that it approves, a CCN using the 1800-1989 series. This includes RHCs converting to FQHCs. The *CMS PEOG* retires the CCN of the RHC and notifies the FQHC replacing the RHC of its new CCN.

2826F - Effective Date

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

If the *MAC* determines that the FQHC application *is complete and recommends approval to CMS PEOG, CMS PEOG then* signs and dates the applicant's Attestation Statement for Federally Qualified Health Centers (Exhibit 177). *CMS PEOG follows the CMS enrollment guidelines for FQHCs in establishing the effective date (see Program Integrity Manual) and in accordance with 42 CFR 489.13. CMS PEOG will use the date the FQHC application was considered complete by the MAC (i.e., the date of the approval recommendation to CMS PEOG) as the effective date. The MAC will send the approval letter and countersigned attestation to the FQHC after it receives it from CMS PEOG*.

2826H - Complaint Investigations

(Rev. 203, Issued: 03-12-21, Effective: 03-12-21, Implementation: 03-12-21)

CMS investigates complaints which raise *substantial* allegation of noncompliance by an FQHC with Medicare requirements and health and safety standards found at 42 CFR 405 Subpart X, and 42 CFR 491 Subpart A, except for 42 CFR 491.3. In conducting complaint investigations, SAs (or *CMS Location* in the case of tribal FQHCs) use the instructions in Chapter 5, particularly §§5200 through 5240, and Appendix G of the *SOM* to determine whether the FQHC is in substantial compliance with Medicare requirements.

If the FQHC is found not to be in substantial compliance with Medicare requirements, then the *CMS Location* may initiate termination of the CMS agreement with the FQHC, in accordance with the provisions at 42 CFR 405.2436. The *CMS Location* will follow the appropriate termination procedures and document and report as required. (See SOM Chapter 3, §§3010-3028 for termination procedures.) If a determination is made to terminate the FQHC's provider agreement, the *CMS Location* will notify the FQHC in writing of its intention to terminate the agreement at least 15 days before the termination date stated in the notice. An FQHC may appeal CMS' decision to terminate its agreement in accordance with the provisions at 42 CFR Part 498.

CMS refers complaints about FQHCs that do not involve Medicare health and safety standards found at 42 CFR Part 491 Subpart A, to HRSA or the IHS, as applicable.

The IHS investigation referrals are coordinated with *CMS* Native American Contacts (NAC). The HRSA investigation referrals are coordinated with HRSA's Bureau of Primary Care, Division of Policy and Development, Policy Branch.