DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Admin Info: 21-06-ALL

DATE: **February 10, 2021**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Transitioning Federally Qualified Health Center (FQHC) Certification Enrollment Performed by the CMS Survey and Operations Group (SOG)

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) will be transitioning certain certification enrollment functions performed by the CMS Locations (formerly CMS Regional Offices) to CMS' Center for Program Integrity (CPI) Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MACs).
- The first transition of certification enrollment work commenced with voluntary terminations.
- The next transition of certification enrollment work is Federally Qualified Health Centers (FQHCs) on March 15, 2021.
- The State Operations Manual (SOM) and Program Integrity Manual (PIM) will be updated accordingly to reflect these changes.
- Attached is a standard operating procedure for the processing of FQHC certification enrollment work.

Background:

To streamline the enrollment process for certified providers/suppliers, CMS is transitioning certain certification enrollment functions performed by the Survey & Operations Group (CMS locations) to CMS' CPI/PEOG and the MACs. The transition of certification enrollment work commenced with voluntary terminations on July 27, 2020. The transition of workload will continue to occur with implementation rollouts projected throughout CY2021. CMS will implement these rollouts via updated instructions to the appropriate CMS manuals and training. Please see memorandum Admin Info 20-08-ALL REVISED for additional information on the transition of certification enrollment work effort and the process for voluntary terminations.

This transition of certification enrollment work for Federally Qualified Health Centers (FQHCs) will commence on March 15, 2021.

General Overview

A FQHC applicant seeking to enroll as a Medicare-participating supplier is subject to a filing procedure instead of a SA initial certification survey. Under this procedure, the FQHC applicant must attest that it is and will remain 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'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, except for Section 491.3. CMS will enter into an agreement with an entity that qualifies to participate as a FQHC based on certain criteria. For additional information, please see the State Operations Manual (SOM) Chapter 2, Section 2826A – General.

Discussion

The enrollment process for FQHCs is defined in SOM Chapter 2, Section 2826. With the transition of certification enrollment from the CMS Locations to the CPI/PEOG and the MACs, CMS has revised the SOM and provided a Standard Operating Procedure (SOP) for use.

The intent behind the SOP is to provide direction to the CMS Locations on the process going forward for FQHCs. Corresponding guidance has been issued to the MAC by CPI/PEOG as it relates to the processing of FQHCs.

Abbreviated Process for Certification

In short, when an application is received by the FQHC, CMS 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 MAC will review the completed Form CMS-855A and other documents submitted by the applicant to ensure that 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 the applicant's Attestation Statement for FQHCs (Exhibit 177). CMS PEOG will set the effective date (the date the application was considered complete by the MAC) and update the national database. CMS PEOG will issue the CMS Certification Number (CCN) to the FQHC and submit the attestation to the MAC. Once all steps are completed, the MAC will issue the approval letter to the FQHC and copy the CMS Location.

In the event the enrollment application is denied based on 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. The MACs are not required to forward denials to CMS PEOG.

Complaints/Enforcement

The CMS Locations remain responsible for processing enforcement actions and reviewing FQHC complaints. Refer to SOM Chapter 2, Section 2826H for additional information.

Resources

SOM Chapter 2 sections for FQHCs are revised and an advance copy is attached. The PIM instructions to the MACs will be updated in accordance with the SOM and implementation rollout. Training on the transition of FQHC work for CMS and the MACs will be hosted before implementation and details are forthcoming.

Contact: For questions or concerns relating to this memorandum, please contact ProviderEnrollment@cms.hhs.gov.

Effective Date: Immediately. This information should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachments –
CMS Standard Operating Procedures for Medicare Enrollment of FQHCs

CMS State Operations Manual FQHC Chapter 2 Revisions – Advance Copy

CMS
Standard Operating Procedure (SOP) for Medicare Enrollment of Federally Qualified Health Centers (Certification Enrollment Transition Work)

Purpose: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the Survey & Operations Group (SOG) locations, State Survey Agencies (SAs), the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG), and the Medicare Administrative Contractors (MAC) as it relates to processing initial Medicare enrollment of Federally Qualified Health Center (FQHC) applicants. This includes responsibilities for updating the Survey and Certification national database system (e.g. ASPEN).

Scope: This SOP pertains to FQHC enrollment and includes a **pilot** standardized process for issuance of CMS Certification Numbers (CCNs) by PEOG.

Background: Over the next year, CMS will continue to conduct activities related to the transition of certification work. Specifically, CMS will transfer some survey and certification enrollment functions for certified providers/suppliers to CPI/ PEOG and the MAC. The processing of Medicare enrollment of FQHCs is scheduled to commence on March 15, 2021. FQHC enrollment actions will follow the existing process prior to March 15, 2021, by the SOG Locations.

Section 1861(aa)(4) of the Social Security Act provides the statutory requirements that entities must meet to be considered a FQHC for Medicare purposes. FQHCs are "suppliers" under Part B of Medicare and are paid Part B benefits for FQHC services. For 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, and:

- Is receiving a grant under Section 330 of the Public Health Service (PHS) Act; or
- Is receiving funding under a contract with the recipient of a Section 330 grant, and meets the requirements to receive a grant under §330 of the PHS Act; or
- Is a FQHC "Look-Alike," i.e., the Health Resources and Services Administration (HRSA) has notified the facility it has been determined to meet the requirements for receiving a Section 330 grant, even though it is not receiving such a grant; or
- 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.

I. General Enrollment Functions

1. A FQHC applicant seeking to enroll as a Medicare-participating supplier is subject to a filing procedure instead of a SA initial certification survey.
2. The FQHC applicant must attest that it is and will remain in compliance with all applicable Medicare regulations.
3. To attest to being in compliance, the facility must be open and operational when the attestation is signed.

Important Notes:

- 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 another type of provider or supplier. For example, an RHC cannot concurrently be approved for Medicare as both an RHC and FQHC
- Complaints and enforcement actions remain the responsibility of the CMS Locations (see the State Operations Manual (SOM) Chapter 2, Section 2826H - Complaint Investigations).

II. Procedures:

Initial Enrollment when received by the MAC:

1. To participate in the Medicare program, applicants seeking initial enrollment as a FQHC must submit the following documents to the applicable MAC (Note: MAC assignments are detailed in Section IV):

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

    b. Two signed and dated copies of the attestation statement (CMS Exhibit 177 found here: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_177.pdf) that indicates the basis for qualification. (Note: To attest to being in compliance, the facility must be open and operational when the attestation is signed). 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. Note:
        - name of the FQHC applicant, and DBA if applicable, provided in Section 2B of the CMS-855A must match the "Name of Entity" and DBA provided on the attestation, and
        - the address provided on the attestation must match the address provided in Section 4A of the CMS-855a as the "practice location" of the FQHC applicant.

    c. A HRSA Notice of Grant Award or FQHC Look-Alike Designation Memo from HRSA that includes an address for the site of the applicant which matches the practice location reported in Section 4A on the Form 855a, or tribal/Urban Indian organization outpatient healthcare facility is noted on the attestation;

    NOTE: A Notice of Grant Award by HRSA verifies the applicant qualifies as a FQHC grant recipient; the FQHC Look-Alike Designation Memo from HRSA verifies Look-alike status; and a qualifying tribal or Urban Indian organization outpatient healthcare facility must be verified via the IHS website as further described in Section III.

    d. Form CMS-588 Electronic Funds Transfer (EFT) Authorization Agreement;

    e. Clinical Laboratory Improvement Act (CLIA) Certificate (if applicable); and

    f. Copy of State License (if applicable).

2. The MAC will review the application and (1) recommend approval of the application to PEOG, or (2) deny the application based on enrollment criteria.

   NOTE: In the event the enrollment application is denied based on enrollment criteria, the denial will be processed directly by the MAC. MACs are not required to forward denials to PEOG. The MAC will provide the denial letter to the FQHC, with a carbon copy to the applicable CMS Location.

3. If there are discrepancies/missing documentation, the MAC shall communicate with the FQHC applicant to resolve, if applicable. If discrepancies are not resolved, the MAC shall deny the application based on the inability to meet enrollment criteria.

4. If the MAC determines that the FQHC application is complete, it forwards the attestation and recommendation for approval to PEOG. The MAC's recommendation for approval must indicate the date on which the FQHC's application was considered complete. PEOG countersigns the attestation using this date for its signature, and therefore the effective date of the agreement.

   NOTE: The MAC follows the enrollment guidelines for FQHCs in establishing the effective date (see PIM Chapter 10) and per 42 CFR 489.13.

5. PEOG identifies the CCN using the process identified below (Section VI: Issuance of Initial CCNs) using SharePoint.

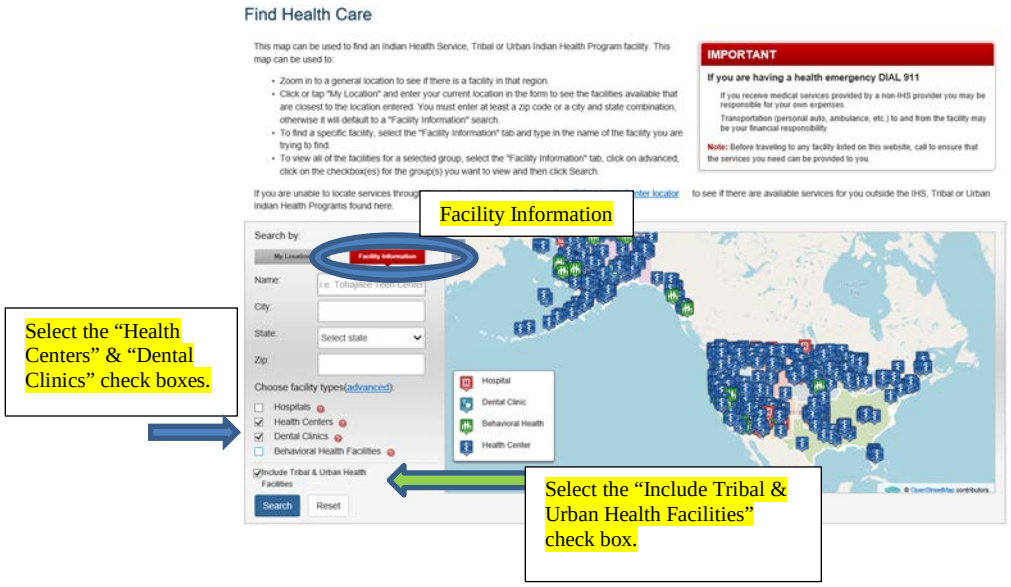
6. PEOG updates the national database system/ASPEN and sends that information back to the MAC.

7. Following, the MAC will provide the approval letter (signed by PEOG) that contains the CCN to the FQHC, with a carbon copy to the CMS Location.

   NOTE: 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 MAC itself will issue the denial per Pub. 100-08, Chapter 10.)

III. Tribal or Indian Health Service (IHS) Specific Enrollment

The MAC will follow the above steps for enrollment. If the MAC determines the FQHC is an outpatient health program or a facility 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 via the IHS website. The MAC may use one of two options to confirm tribal/urban Indian facilities: (1) search by "facility information" here: Find Health Care | Indian Health Service (IHS) as illustrated below or (2) search the IHS listing by the Locations | Indian Health Service (IHS). The MAC must contact IHS directly for applicants not on the list.



The MAC will continue to process the enrollment application after confirmation of the status (following Steps #3-6 above).

IV. Approvals

CMS PEOG is responsible for reviewing and approving requests for Medicare participation as a FQHC.

For approvals:

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

V. Rural Health Clinics (RHCs) Converting to FQHC's

A Rural Health Clinic (RHC) cannot concurrently be approved for Medicare as both an RHC and FQHC. In certain situations, an RHC may choose to convert to an FQHC. In these circumstances, the following process would apply:

1. The RHC would communicate with the applicable CMS Location and provide any necessary information per SOM Chapter 2, Section 2826E - Assigning Applicants a FQHC CMS Certification Number (CCN).

2. The CMS Location would retire the CCN of the RHC. The CMS Location will annotate the retired CCN with a comment of conversion under the CCN Issuance SharePoint Site (see below) under the RHC program tab.

3. The CMS Location will notify PEOG of the RHC who is converting to an FQHC. NOTE: CMS Locations must ensure that the location of the RHC is not the same as the new FQHC (e.g. down to the suite number)

4. Upon notification, PEOG assigns each FQHC permanent site that it approves, a CCN using the 1800-1989 series, following the below process after confirming the FQHC meets enrollment criteria per the above enrollment criteria.

5. PEOG assigns the new FQHC CCN and updates the national database.

VI. Issuance of Initial CCNs

The below provides general CCN guidance, which may be subject to change in the future based on the transition of enrollment actions from the CMS Locations to PEOG. The process outlined below is for FQHCs related to the issuance of initial CCNs, however as the transition of other providers is processed through PEOG, CMS will update the CCN guidance and will communicate the finalized process for all parties involved.

For this SharePoint Platform, each Excel under the respective state has the State and Provider Identifiers annotated per Chapter 2 of the SOM.
NOTE: SharePoint access is limited to CMS employees only (for access, please email QSOGAccessRequests@cmssharepointmail.cms.local).

Per Chapter 2 of the SOM:

- New State codes must only be used when all of the existing assigned numbers have been assigned within each of the CCN ranges available for a facility type.

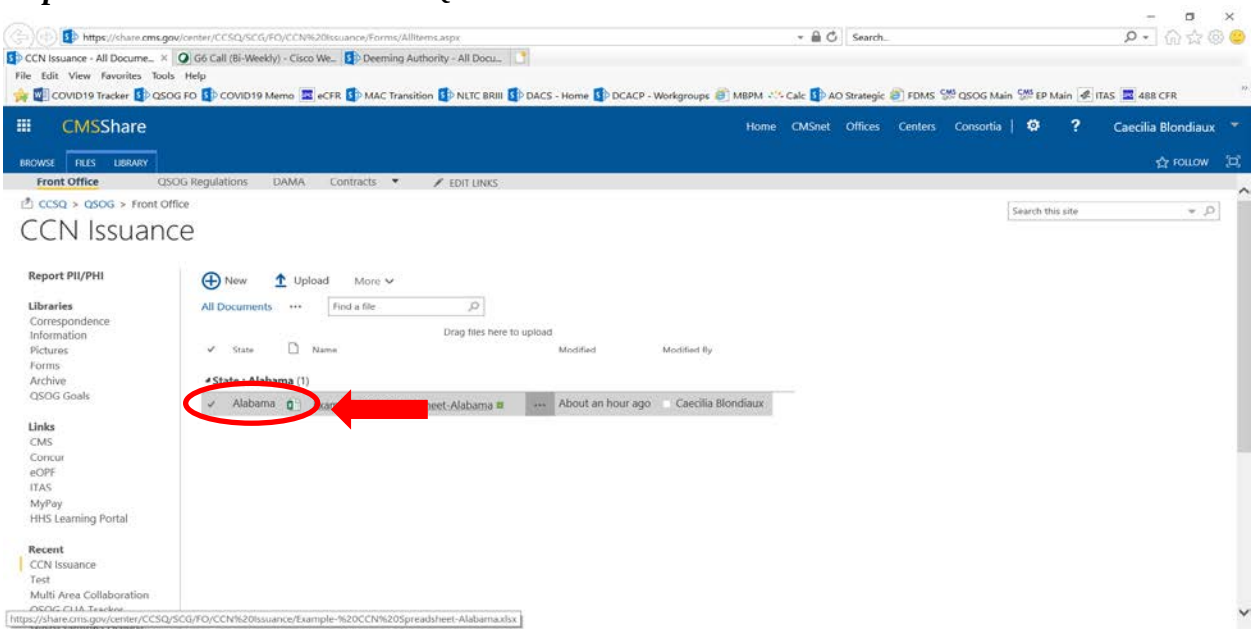
Alabama	01	New Hampshire	30
Alaska	02	New Jersey	31, 83
Arizona	03, 00	New Mexico	32, 96
Arkansas	04, 89	New York	33, 57
California	05, 55, 75, 92	North Carolina	34, 86
Colorado	06, 91	North Dakota	35
Connecticut	07, 81	Ohio	36, 72
Delaware	08	Oklahoma	37, 90
District of Columbia	09	Oregon	38, 93
Florida	10, 68, 69	Pennsylvania	39, 73
Georgia	11, 85	Puerto Rico	40, 84
Hawaii	12	Rhode Island	41
Idaho	13, 54	South Carolina	42, 87
Illinois	14, 78	South Dakota	43
Indiana	15	Tennessee	44, 88
Iowa	16, 76	Texas	45, 67, 74, 97
Kansas	17, 70	Utah	46
Kentucky	18	Vermont	47
Louisiana	19, 71, 95	Virgin Islands	48

Maine	20	Virginia	49
Maryland	21, 80	Washington	50, 94
Massachusetts	22, 82	West Virginia	51, 58
Michigan	23	Wisconsin	52
Minnesota	24, 77	Wyoming	53
Mississippi	25	Canada	56
Missouri	26, 79	Mexico	59
Montana	27	American Samoa	64
Nebraska	28	Guam	65
Nevada	29	Commonwealth of the Northern Marianas Islands	66
Foreign Countries (exceptions: Canada and Mexico)	99		

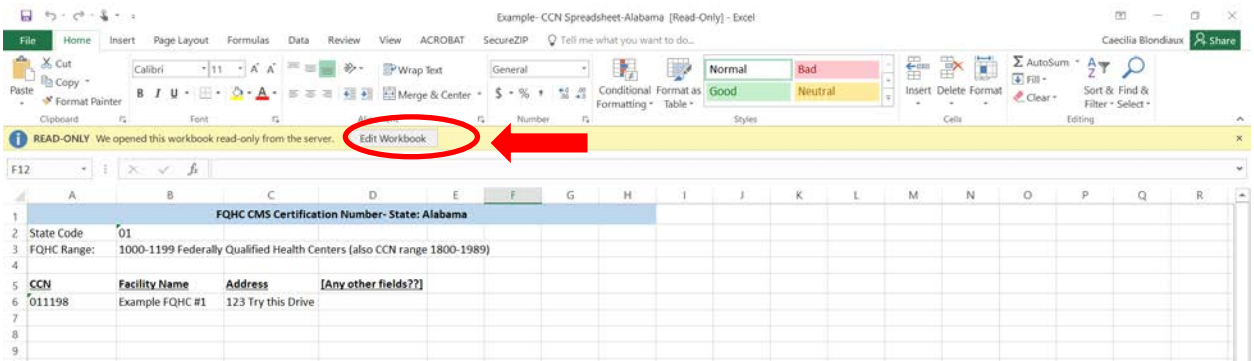
VII. CCN Issuance Process Instructions

***Step 1**: Access SharePoint*
https://share.cms.gov/center/CCSQ/SCG/FO/CCN%20Issuance/Forms/AllItems.aspx

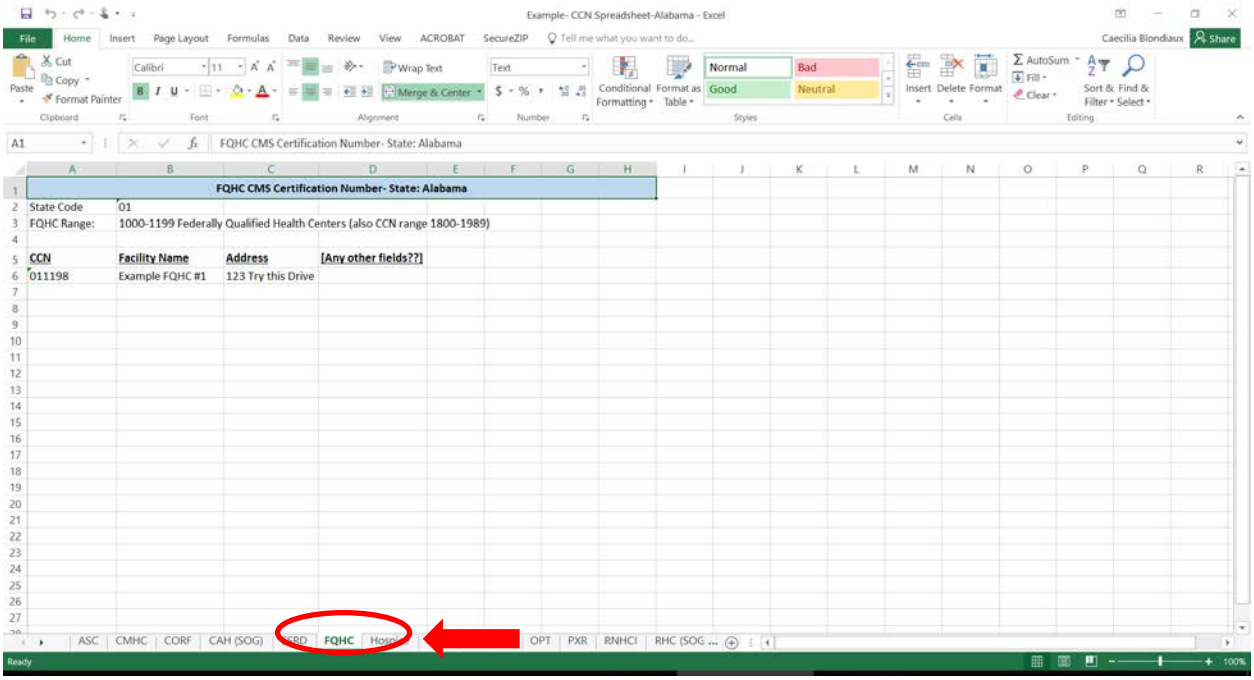
***Step 2:** Select the State that the FQHC is located.*



***Step 3:** Select the Excel to Open and "Select Edit Workbook"*



***Step 4**: Select the Appropriate Provider/Supplier Tab at the bottom of the Excel*

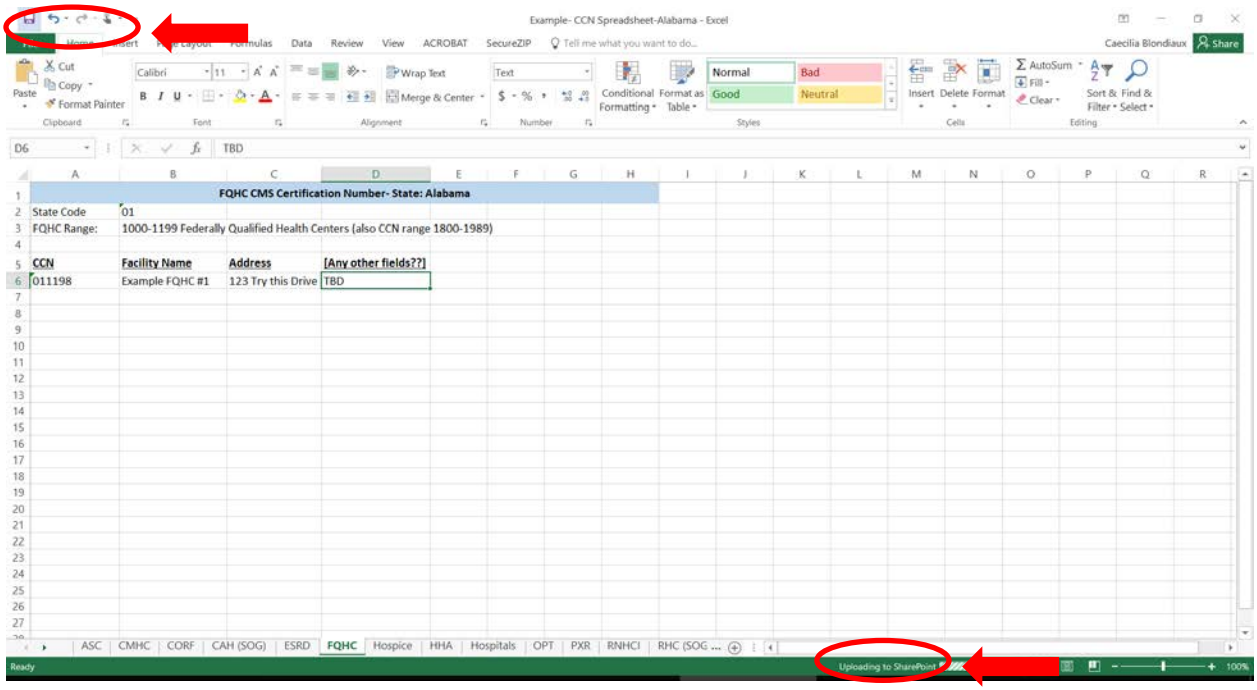


***Step 5:** Enter the facility information, effective date, and next sequential CCNs number.*

- Assign the last four digits, which identify the facility type, sequentially from within the appropriate CCN range. In a State that has more than one State code and/or a facility type that has more than one CCN range available, ensure that all the numbers available in one CCN range have been assigned before implementing the use of a new State code or numbers in a new CCN range.
- For FQHCs Specifically: 1000-1199 Federally Qualified Health Centers (also CCN range 1800-1989)

Example: Alabama FQHC = 011198

***Step 5:** Save using the left side SharePoint save button. You should see an "Uploading to SharePoint" on the bottom.*



Step 6: *Exit and refresh to ensure your items have been saved to SharePoint.* ***Ensure you exit the document so others can edit it!***

NOTE:

- In the event the CMS Location is currently processing an FQHC issuance of a CCN during this transition, please ensure this is annotated in the spreadsheet under the respective state to ensure there is no duplication in CCNs.

REMINDERS:

- 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. 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.

VIII. Resources:

- State Operations Manual (SOM), Chapter 2
- Program Integrity Manual (PIM) Chapter 10
- Adding CCN's in ASPEN (Resource for PEOG)
- Adding a New FQHC Facility Job Aide (Resource for PEOG)

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter 2 for FQHCs

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

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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	Chapter 2/2826 - Approval Process for FQHCs
R	Chapter 2/2826A – General
R	Chapter 2/2826B - Information to Be Provided to Potential Applicants
R	Chapter 2/2826C - Request to Participate
R	Chapter 2/2826D - Processing Requests
R	Chapter 2/2826E - Assigning Applicants a FQHC CMS Certification Number (CCN)
R	Chapter 2/2826F - Effective Date
D	Chapter 2/2826G – RO Completion of Forms
R	Chapter 2/2826H - Complaint Investigations

State Operations Manual
Chapter 2 - The Certification Process

Federally Qualified Health Centers

2825 - Federally Qualified Health Centers (FQHCs) - Citations and Description
(Rev. 1, 05-21-04)

2825A - Citations
(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

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 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.

2825B - Description
(Rev. 85, Issued: 07-19-13, Effective: 07-19-13, Implementation: 07-19-13)

The Federally Qualified Health Centers (FQHCs) are considered "suppliers" under Part B of Medicare and are paid Part B benefits for FQHC services. For the purpose 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, and:

- Is receiving a grant under Section 330 of the Public Health Service (PHS) Act; or
- Is receiving funding under a contract with the recipient of a Section 330 grant, and meets the requirements to receive a grant under §330 of the PHS Act; or
- Is an FQHC "Look-Alike," i.e., the Health Resources and Services Administration (HRSA) has notified the facility it has been determined to meet the requirements for receiving a Section 330 grant, even though it is not actually receiving such a grant; or
- 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.

2826 - Approval Process for FQHCs

(Rev. 40, Issued: 03-20-09, Effective: 03-20-09, Implementation: 03-20-09)

2826A - General

(Rev.)

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 FQHCs 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.)

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 *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855a.pdf*; and

- Attestation Statement for FQHCs (Exhibit 177)

2826C - Request to Participate

(Rev.)

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;

- *Two 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.)

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* recommend*ation 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.)

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.)

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.)

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.