
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 85

Date: July 19, 2013

SUBJECT: Federally Qualified Health Center (FQHC) Medicare participation

I. SUMMARY OF CHANGES: Clarification is provided regarding Medicare participation requirements for FQHCs, including determination of the effective date of participation. Chapter 2, Sections 2826C through 2826F have been revised and Exhibit 177 and Exhibit 179 have been revised.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 19, 2013
IMPLEMENTATION DATE: July 19, 2013

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged

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/FQHCs/Section 2825B/Description
R	Chapter 2/FQHCs/Section 2826C/Request to Participate
R	Chapter 2/FQHCs/Section 2826D/Processing Requests
R	Chapter 2/FQHCs/Section 2826F/Effective Date
R	Exhibit 177/Attestation Statement for FQHC
R	Exhibit 179/Information on Medicare Participation FQHC

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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.

2826C - Request to Participate

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

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 is being phased out as CMS implements the MAC contracts, and all new FQHC applications are to be assigned to the applicable MAC, as described above. In the case of a new applicant that is a permanent unit owned and operated by an existing FQHC in a different location in the same state, this could mean that each permanent unit would have a different MAC until the transition to MACs has been completed nationwide. However, accommodations have been made for a set of FQHCs that straddle MAC jurisdiction boundaries to continue filing a consolidated cost report.)*

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>
- <http://www.cms.gov/medicare-coverage-database/indexes/contacts-part-a-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAAA&>

The following documents must be included in the application:

- A signed and completed application Form CMS-855A enrollment application;
- Two signed and dated copies of the attestation statement ([Exhibit 177](#)). 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 the Regional Office.
- 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 State Operations Manual 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/FI nor the Regional Office makes 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.85, Issued: 07- 19-13, Effective: 07-19-13, Implementation: 07-19-13)

The MAC/FI 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. Upon completion of its review, the MAC/FI will either: (1) forward its recommendation for approval to the RO, or (2) deny the application (with a cc: to the RO on the denial letter). *If the MAC recommends approval, it forwards to the RO with its approval letter: a copy of the Form CMS-855A, both original attestation statements, a copy of the HRSA Notice, a copy of the applicant's State license if applicable, and a copy of its CLIA certificate, if applicable.*

Upon receipt of a recommendation for approval, the RO verifies that the application package *contains all applicable documents listed above. If the RO finds that documents are missing, e.g., there is no attestation, or no copy of a State license but the RO is aware that the State requires a license, the RO contacts the MAC and requests that it resolve the discrepancy and send a revised recommendation letter. Lack of a copy of a CLIA certificate, however, is not a basis for the RO to contact the MAC.*

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 RO confirms the applicant's attestation by using the IHS lists of facilities or organizations provided by CO, or by contacting CO or the IHS for applicants not on the list.

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

2826F - Effective Date

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

If the RO determines that the FQHC application meets all requirements, the RO signs *and dates* the applicant's Attestation Statement for Federally Qualified Health Centers (Exhibit 177). *The RO uses as the date for its signature, and therefore the effective date of the agreement, the date the MAC's written recommendation for approval indicates the FQHC's application was complete. In accordance with Section 15.4.1.4, chapter 15, of Publication 100-08, the Medicare Program Integrity Manual, "When sending a recommendation for approval letter to the RO for an initial FQHC application, the contractor [MAC] shall indicate in the letter 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; the contractor thus requested additional information. The two elements were submitted on March 30. The contractor shall therefore indicate the March 30 date in its letter."*

If the completeness date is not included in the written recommendation, the RO requests the MAC to send a revised recommendation letter that provides this information.

If the MAC forwarded an incomplete documentation package to the RO and the MAC determines, when asked to resolve the discrepancy, that the MAC did not receive all required documentation from the FQHC, the MAC must request the additional required documentation from the FQHC and must send the RO a revised recommendation letter reflecting the new date the FQHC's application was determined complete. On the other hand, if the MAC determines that the FQHC submitted all required documentation but the MAC did not forward all of it to the RO, the completeness date in the MAC's original recommendation letter continues to be used as the effective date of the agreement.

EXHIBIT 177

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

ATTESTATION STATEMENT FOR FEDERALLY QUALIFIED HEALTH CENTER

INSTRUCTIONS FOR COMPLETING

1. **Name of Entity:** *The FQHC applicant must fill in its legal business name of the FQHC entity, as reported to the Internal Revenue Service. The legal business name must match the information listed in section 2B of the Form CMS 855A.*
2. **D/B/A Name:** *If the FQHC applicant does business under a different name than its legal business name, it must enter that name here. If the applicant does not have a different D/B/A name, this space should be left blank. If the applicant enters a D/B/A name, it must match the information entered in section 2B of the Form CMS 855A if the “doing business as” block is checked.*
3. **Address:** *The FQHC applicant must enter the same address as it entered in Section 4A of the Form CMS 855A as the “practice location” of the FQHC. The applicant must enter the street name and number, the city/town, state and zip code. If there is a suite number, this must be entered as well.*
4. **Type of FQHC:** *The FQHC applicant must check one, and only one, of lines (A)(i), (A)(ii), (B) or (C), indicating the basis on which it qualifies to be an FQHC.*
5. **Signature:** *The attestation must be signed on behalf of the applicant by one individual whose name and signature appears in the Form CMS 855A, either in Section 15 as an authorized individual, or in Section 16 as a delegated official, if the FQHC has identified any delegated officials. The individual’s name, title and date of signature must be entered. Before signing the individual must review the regulations at 42 CFR Part 405 Subpart X, and Part 491, as described in §405.2434(a), since the signature attests to compliance with these regulations. The regulations may be found at http://www.ecfr.gov/cgi-bin/text-idx?sid=614cb89fc17db8dae88af84c6b174bf1&c=ecfr&tpl=/ecfrbrowse/Title42/42tab_02.tpl*

ATTESTATION STATEMENT FOR FEDERALLY QUALIFIED HEALTH CENTER

*This attestation statement applies to _____
(name of entity)*

D/B/A _____

located at:

(address, including street name and number, suite number if applicable, city, state, zip code).

The *above-named entity* complies with all applicable Federal requirements related to the following provision of §1861(aa)(4) of the Social Security Act (check the appropriate box):

___ (A)(i) Is receiving a grant under §330 of the Public Health Service Act, or

___ (ii)(I) Is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under §330 of such Act;

___ (B) *Has been notified by the Health Resources and Services Administration that it has been* determined to meet the requirements for receiving such a grant: or

___ (C) 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.

The *above-named entity* agrees to remain in compliance with the all of the federally qualified health center requirements specified in 42 CFR Part 405 Subpart X, and Part 491, as described in §405.2434(a).

I certify that I have reviewed each Federal requirement in §1861(aa)(4) of the Social Security Act and the federally qualified health center requirements specified in 42 CFR Part 405 Subpart X, and Part 491, as described in §405.2434(a) and that *the above-named entity* is currently in compliance with these requirements and regulations and has been in compliance with these requirements and regulations. *The above-named entity* agrees to inform the Centers for Medicare & Medicaid Services of any changes that result in noncompliance.

Attention: Read the following provisions of Federal law carefully before signing:

STATEMENTS OR ENTRIES GENERALLY: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years or both. (18 U.S.C. §1001).

Attestation on behalf of the above-named entity by:

Signature _____ *Title* _____

Printed Name _____ *Date* _____

Accepted for the Secretary of Health and Human Services by:

Signature _____ *Title* _____

Printed Name _____ *Effective Date* _____

Exhibit 179

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

INFORMATION ON MEDICARE PARTICIPATION FEDERALLY QUALIFIED HEALTH CENTER (FQHC)

CMS recognizes the essential role FQHCs play in promoting access to preventive and primary care among medically underserved populations by utilizing a streamlined Medicare enrollment process. This streamlined process allows an FQHC applicant to use a self-attestation (see below) to confirm that it meets Medicare health and safety standards instead of having an on-site initial and subsequent recertification, survey to assess the FQHC's compliance. The FQHC attests to its eligibility to participate in Medicare and agrees to remain in compliance with all of the FQHC requirements specified in Medicare regulations at 42 CFR Part 405 Subpart X, and at 42 CFR Part 491, with the exception of §491.3.

Medicare Definition of an FQHC:

For purposes of enrolling in Medicare, an FQHC is defined as an entity that has entered into an agreement with CMS and:

- Is receiving a grant under §330 of the Public Health Service (PHS) Act; or
- 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; or
- Is an FQHC “Look-Alike,” i.e., Health Resources and Services Administration (HRSA), has *notified it that it* meets the requirements for receiving a §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.

Medicare Agreement:

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

- CMS receives a complete application Form CMS 855A, Medicare Enrollment Application, Institutional Providers;

- CMS receives a copy of the applicant's Notice of Grant Award *or* FQHC Look-Alike Designation *notice issued* by HRSA, or the applicant is confirmed as a qualifying tribal or Urban Indian organization outpatient healthcare facility;
- The applicant assures CMS that it satisfies the regulatory requirements at 42 CFR 405 Subpart X, and 42 CFR Part 491, except for §491.3; and
- The applicant terminates other Medicare provider agreements it has, unless it assures CMS that it is not using the same space, staff and resources simultaneously as an FQHC and as a physician's office or other type of provider or supplier. For example, a rural health clinic (RHC) cannot concurrently be approved for Medicare as both an RHC and FQHC.

In accordance with 42 CFR 491.5(a)(3)(iii), each permanent site at which an FQHC offers services requires a separate agreement with Medicare.

- This means that an FQHC that operates several health centers at different sites but under one management must have each site separately enrolled in Medicare as an FQHC. While this requirement for a separate agreement with CMS for each permanent site does not prevent an FQHC which has several permanent sites from consolidating Medicare claims and cost report data, it would be a violation of Medicare regulations for the FQHC to submit claims for services provided at a site for which there is no specific Medicare agreement.
- Mobile units of an FQHC are not required to be separately enrolled in Medicare, but are treated as part of the FQHC. Mobile units must also comply with the Medicare health and safety standards.

Medicare Enrollment Application:

To participate in the Medicare program as an FQHC, applicants must submit to CMS:

- A signed and completed application Form CMS-855A, Medicare Enrollment Application, Institutional Providers. Form CMS-855A may be downloaded from CMS' Web site at: <http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf>.
Applications must be submitted as follows:
 - *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 is being phased out as CMS implements the MAC contracts, and all new FQHC applications are to be assigned to the applicable MAC, as described above. In the case of a new applicant that is a permanent unit owned and operated by*

an existing FQHC in a different location in the same state, this could mean that each permanent unit would have a different MAC until the transition to MACs has been completed nationwide. However, accommodations have been made for a set of FQHCs that straddle MAC jurisdiction boundaries to continue filing a consolidated cost report.)

An on-line application option is also available.

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>
- <http://www.cms.gov/medicare-coverage-database/indexes/contacts-part-a-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAAA&>
- Two copies of the standard attestation statement, each with an original signature and date. When countersigned by CMS, this statement serves as the Medicare FQHC agreement. One signed copy will be returned to the FQHC by CMS. A template attestation statement *with instructions* may be downloaded from CMS' Web site at:
http://www.cms.hhs.gov/manuals/downloads/som107_exhibit_177.pdf
- In the case of applicants eligible to be an FQHC on the basis of: 1) receiving a HRSA §330 grant; or 2) receiving funding under a contract with an FQHC receiving a HRSA §330 grant; or 3) FQHC Look-Alike designation, *the* HRSA Notice of Grant Award to an FQHC or *the notice of* FQHC Look-Alike designation. *The notice must indicate the approved or designated practice location, which must be the same as that reported on the Form CMS 855A;*
- *Form CMS-588 Electronic Funds Transfer (EFT) Authorization Agreement;*
- *Copy of 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 State Operations Manual 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/FI nor the Regional Office makes a determination as to whether the FQHC applicant must obtain and submit a CLIA certificate; and

- *Copy of State License (if applicable).*

Medicare Regulatory Requirements:

- The FQHC must remain in substantial compliance with all of the FQHC regulatory requirements specified in 42 CFR Part 405 Subpart X, and at 42 CFR Part 491, with the exception of §491.3. The FQHC's are encouraged to access the on-line Code of Federal Regulations to download a copy of the regulatory requirements at the following Web site: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl>
- **42 CFR Section 405.2436 provides that CMS may terminate an agreement with an FQHC if it finds that the FQHC is not in substantial compliance with the Medicare regulatory requirements**
- Medicare regulations governing FQHCs include health and safety requirements found in 42 CFR Part 491, setting standards for such things as:
 - Compliance with applicable Federal, State and local laws and regulations;
 - Policies and lines of authority and responsibilities are clearly set forth in writing;
 - Provision of medical direction to the FQHC by a physician;
 - Clinical staff and staff responsibilities;
 - Provision of services and patient care policies;
 - Patient health records;
 - Program quality assessment/improvement;
 - The construction and maintenance of the FQHC 's physical plant; and
 - Handling of non-medical emergencies in the FQHC.
- There are also other Medicare regulations found at 42 CFR Part 405, Subpart X governing:
 - Definition of an FQHC
 - Entering into an FQHC agreement with CMS
 - Content of the Medicare agreement, including but not limited to:
 - Agreement to accept Medicare beneficiaries for care and treatment in the same way that it provides care for non-Medicare beneficiaries;
 - Maintaining compliance with Part 491, except for §491.3;
 - Promptly reporting to CMS any changes that result in noncompliance;

- Effective date of the agreement; and
 - Charges to Medicare beneficiaries, including agreement not to charge beneficiaries for services that they are entitled to have Medicare pay for.
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- Scope of services covered by Medicare and payment provisions, including supplemental payments to FQHCs;
 - Beneficiary appeals;
 - Report and maintenance of records;
 - Termination of the agreement with CMS, including notice to the public and conditions for reinstatement after termination; and
 - Change of ownership.
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- **Before signing the FQHC attestation statement, applicants should carefully review the regulations cited above to ensure the accuracy of their attestation of compliance.**