



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-29

DATE: August 1, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revision of Publication 100-07, State Operations Manual (SOM) - Federally Qualified Health Centers (FQHCs)

Memorandum Summary

- Sections 2002, 2003A, 2005, and 2825-2826 of the SOM are being revised to update general Medicare enrollment information, as well as the process for enrolling FQHCs in Medicare, and for handling complaints about FQHCs.
- A new Exhibit 179, Information on Medicare Participation, FQHCs, is introduced and is to be made available by Regional Offices (ROs) or State Agencies (SAs) to potential FQHC applicants.

Facilities that participate in Medicare as FQHCs are subject to unique enrollment and enforcement processes, which are detailed in Chapter 2, particularly in sections 2825 and 2826 of the SOM. (Medicare enrollment requirements in general are detailed in Chapter 10 of Publication 100-08, the Medicare Program Integrity Manual.)

Unlike other health care facilities that participate in Medicare as a provider or supplier, FQHCs self-attest to their compliance with the regulatory requirements at 42 CFR 405 Subpart X and 42 CFR Part 491, except for §491.3. Attached is an advance copy of revisions to Chapter 2 of the SOM, revised Exhibit 177, and new Exhibit 179. The revisions reflect current regulatory requirements and enrollment processes. The final version will be released as a Publications Manual transmittal later this year and may differ slightly from this advance copy.

Among the changes are the following:

Revised Exhibit 177

- An omission in the language concerning tribe or tribal organization FQHCs has been corrected.

New Exhibit 179

- Information on Medicare Participation, Federally Qualified Health Centers, has been created for ROs and SAs to distribute to potential FQHC applicants. This document provides information intended to make applicants aware of the FQHC enrollment process, and of the regulatory standards to which they must self-attest when applying to participate in Medicare.

Changes to Section 2825

- The facility eligibility criteria for participation in Medicare as an FQHC has been revised to include facilities treated by CMS as a comprehensive federally funded health center as of January 1, 1990. Although it is unlikely new FQHC suppliers would qualify under this criterion, it is nevertheless included to correctly reflect the regulatory language.
- More information is provided on the process by which CMS designates FQHC “Look-alikes.”

Changes to Section 2826

- The regulatory requirement for separate enrollment in Medicare by each permanent FQHC unit or site, regardless of whether it is owned and operated by a “parent” FQHC entity, has been highlighted. This is apparently an area of confusion among existing FQHCs that operate “satellite” sites as permitted by Section 330 of the Public Health Service Act and the Health Resources and Services Agency (HRSA).
- More information is presented on FQHCs that are provider-based to a main provider (a hospital or CAH), including the fact that it is unlikely new FQHCs will qualify for provider-based status, given current HRSA governance requirements for FQHCs.
- As a result of CMS’ Medicare Administrative Contractor (MAC) initiative, FQHCs are transitioning away from a system that uses one national intermediary for all FQHCs. As part of this transition, all newly-enrolled FQHCs are to be assigned to the MAC or fiscal intermediary having responsibility for the geographic area in which the FQHC is located, with the exception of those FQHCs operated by an Indian tribe or tribal organization under Indian Self-Determination authorities. The latter will be assigned to the MAC for jurisdiction #4. New Urban Indian FQHCs, however, are to be assigned to the MAC or fiscal intermediary having responsibility for the geographic area in which they are located.

- The process for handling complaints about FQHCs has been clarified to distinguish complaints concerning compliance with 42 CFR 405 Subpart X and 42 CFR Part 491, which are to be investigated by CMS, from other complaints, which are to be referred to HRSA or IHS, as applicable. For investigations by CMS, the interpretive guidelines for Rural Health Clinics, Appendix G, also apply to complaint surveys of FQHCs.

If you have additional questions or concerns, please contact Shonte Carter at 410-786-3532 or via email at shonte.carter@cms.hhs.gov

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal

ADVANCE COPY

Date:

SUBJECT: Revisions to State Operations Manual/Sections 2825 – 2826(H)/Federally Qualified Health Centers/and Exhibits

I. SUMMARY OF CHANGES: Sections of Chapter 2 and Exhibit 177 are being revised to provide greater clarity about provisions pertaining to Federally Qualified Health Centers (FQHCs). New Exhibit 179 provides information for potential FQHC applicants.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Publication

IMPLEMENTATION DATE: Upon Publication

Disclaimer for manual changes only: 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/§/SUB§/TITLE
R	Chapter 2/Table of Contents
R	Chapter 2/§2002/Meaning of Providers and Suppliers
R	Chapter 2/§2003A/Assisting Providers and Suppliers
R	Chapter 2/§2005/Medicare Health Care Provider/Supplier Enrollment
D	Chapter 2/§2005G/Specialty Intermediaries
R	Chapter 2/§2825 FQHCs – Citations and Description
R	Chapter 2/§2825A – Citations
R	Chapter 2/§2825B – Description
R	Chapter 2/§2826/RO 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 – RO Assigning Applicants an FQHC CMS Certification Number (CCN)
R	Chapter 2/§2826F – Effective Date

R	Chapter 2/§2826G – RO Completion of Forms
R	Chapter 2/§2826H – Complaint Investigations
R	Exhibit 177/Attestation Statement for Federally Qualified Health Centers
N	Exhibit 179/Information on Medicare Participation/Federally Qualified Health Centers

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

***Unless otherwise specified/the effective date is the date of service.**

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* * *

2002 - Meaning of Providers and Suppliers

(Rev. XXXXX)

The Medicare law differentiates between providers and suppliers. The general distinction between providers and suppliers is that providers are parties who care for patients awaiting, receiving, or recuperating from treatment by intervening practitioners. The term suppliers” includes those who furnish goods and services used in care and treatment. Medicaid terminology, by contrast, uses “provider” generically to include all health care vendors. (See 42 CFR 431.107(a) and 433.37.) Medicare providers and suppliers are defined at 42 CFR 498.2.

In Medicare, as specified in §1861(u) of the Act, providers include hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), home health agencies (HHAs), hospices and comprehensive outpatient rehabilitation facilities (CORFs). Under §1835(a)(2) of the Act, clinics, rehabilitation agencies, or public health agencies are included as providers if such clinic or agency meets the requirements of §1861(p)(4)(A).

Community Mental Health Centers (CMHC) are providers of services for partial hospitalization services only. Providers must meet CoPs or Requirements for SNFs to participate in Medicare. (See definitions 42 CFR 498.2.)

Portable x-ray services, end stage renal disease (ESRD) facilities, ambulatory surgical centers (ASCs), and organ procurement organizations (OPOs) are suppliers that must meet conditions for coverage to participate in Medicare; *rural health clinics (RHCs) are suppliers that must meet conditions for certification to participate in Medicare.*

Federally Qualified Health Centers (FQHCs) are also recognized as suppliers of services and provide ambulatory care services similar to those provided by RHCs. FQHCs may be located in urban, as well as rural, areas. *FQHCs are required to meet the same health and safety standards as RHCs, with the exception of the certification procedures. FQHCs self-attest to their compliance with Medicare conditions for coverage and are only surveyed by CMS in connection with complaint investigations.*

These types of suppliers are distinguished from other suppliers, e.g., pharmacies, prosthesis suppliers, etc., for which there are no conditions for coverage or certification, and which qualify for Medicare through the enrollment process. Laboratories 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 are yet another category of suppliers and must meet Clinical Laboratory Improvements of 1988 Act (CLIA) requirements.

As previously stated, Medicaid does not distinguish between providers and suppliers. Section 1902(a)(27) of the Act provides for agreements with every person or institution providing services under the State plan. 42 CFR 431.107(a) refers to all providers of services (including individual practitioners and groups of practitioners).

* * *

2003A - Assisting Applicant Providers and Suppliers

(Rev. XXXX)

Pre-certification assistance to prospective providers and suppliers is a proper certification-related activity. It may take the form of providing them with a copy of the applicable regulations. The objective is to assist the party in attaining compliance as early as possible, since the effective date of participation can be no earlier than the date on which the party meets all the federal requirements, including compliance with the CoPs, *Conditions for Coverage, Conditions for Certification, or Requirements, as applicable. Except in the case of an FQHC, the supplier or provider demonstrates compliance with all applicable conditions or requirements via an initial certification survey by the State Survey Agency or by a CMS-recognized accreditation organization. If on that survey the supplier or provider does not demonstrate full compliance, then its compliance date is the date it meets all conditions and submits an acceptable PoC for lower level deficiencies, or meets all conditions and submits an approved waiver request, or both. For SNFs, the effective date is the date the SNF is in compliance with all the requirements for SNFs or the date it is in substantial compliance and submits, if applicable, an approvable waiver request. (See 42 CFR 442.13 and 489.13(c).) Since there is no certification survey for FQHCs, the effective date for these entities is the date the RO countersigns the FQHC self-attestation of compliance with the applicable Medicare standards and Conditions for Coverage, after determining that all other Medicare requirements, including enrollment, are met.*

* * *

2005 - Medicare Health Care Provider/Supplier Enrollment

(Rev. XXXXX)

The Centers for Medicare & Medicaid Services (CMS) is authorized to collect the information requested on the CMS-855A and CMS-855B *Medicare enrollment applications* (see §2003.B above) in order to ensure that correct payments are made to providers and suppliers under the Medicare program established by Title XVIII of the Act for payment under Part A of Title XVIII [42 U.S.C. §1395f(a)(1) and 1395g(a)] and §1833(e) [42 U.S.C. §13951(e)] for payment under Part B. In addition, CMS is required to ensure that no payments are made to providers or suppliers who are excluded from participation in the Medicare program under §1128 of Title XVIII [42 U.S.C. §1320a-7], or who are prohibited from providing services to the federal government under §2455 of the Federal Acquisition Streamlining Act of 1994 (P.L. 103-355) [31 U.S.C. §6101 note].

The primary use of this information is to verify the eligibility of providers/suppliers to participate in the Medicare program, which will more effectively prevent fraud and abuse. The protocol that CMS uses to ensure that providers/suppliers meet these requirements is referred to as the enrollment process. The *CMS-855A and CMS-855B enrollment applications* are the documents used to collect information and documentation to be verified to assure that the *applying provider or supplier* is qualified and eligible to participate in the Medicare program. These forms standardize the enrollment process for all providers and suppliers. The enrollment process is also to be used for providers/suppliers that *plan to seek certification for participation in Medicare based on deemed status through a CMS-recognized accreditation organization*. An applicant will complete the CMS-855A or CMS-855B application in order for CMS to obtain certain required information before a *certification* survey is conducted *or, in the case of an FQHC, the RO countersigns the self-attestation*.

The *MAC*/fiscal intermediary will process the CMS-855A and the *MAC*/carrier will process the Form CMS-855B, depending on which contractor is responsible for processing bills or claims for the provider/supplier. The Form CMS-855A or the CMS-855B is available for downloading from the CMS Web site: www.cms.hhs.gov/forms (See §2003). The State *Survey Agency* will be responsible for surveying initial applicants following *the contractor's recommendation for approval*, and providing the initial certification package. Hospitals, CAHs, ASCs, HHAs and Hospices have the option of establishing compliance through deemed status (42 CFR 488, Subpart A).

Providers/suppliers should be informed of the enrollment *and certification* process so that they do not *have unrealistic expectations about the effective date of their provider or supplier agreement with Medicare, e.g., an applicant should not expect its effective date to be the date it submitted its CMS-855A or CMS-855B*. Should the applicant have any questions concerning the enrollment form, the *MAC/FI/Carrier* contacts are available *on the following* Web site: www.cms.hhs.gov/MedicareProviderSupEnroll. *The provider/supplier should submit the CMS-855A or the CMS-855B to the appropriate*

Medicare Administrative Contractor (MAC), legacy Fiscal Intermediary (FI) or legacy Carrier, consistent with the regulation at 42 CFR 421.404, which is explained in more detail in CR 5979 and the attending MLM article.

For detailed information on the Medicare provider/supplier enrollment process, see Publication 100-08, chapter 10.

The Medicare enrollment process is not applicable to the Medicaid program. States use their own enrollment process.

2005G - *Reserved*

Federally Qualified Health Centers

2825 - Federally Qualified Health Centers (FQHCs) - Citations and Description

(*Rev. XXXXXX*)

2825A - Citations

(*Rev. XXXXXX*)

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. XXXXX*)

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 §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., based on the recommendation of the Health Resources and Services Administration (HRSA), it has been determined by CMS to meet 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.

CMS is responsible for designating FQHC Look-Alikes. Although Survey and Certification Staff are not directly involved in the process, they should be aware of it. In accordance with §1905(l) and §1861(aa)(4) of the Act, CMS has the statutory authority and responsibility for designating applicants as FQHC Look-Alikes, based on the recommendation of the HRSA Bureau of Primary Care. HRSA receives applications for Look-Alike designation and develops a recommendation to CMS. After HRSA forwards its recommendation to CMS CO, CO forwards a memorandum to the appropriate RO Medicaid staff, requesting that the applicable State Medicaid Agency be notified, with a 14-day comment period, of the applicant’s pending designation. If CMS receives no comments, the HRSA recommendation will be accepted and the applicant will be designated as an FQHC Look-Alike. The RO issues a decision letter to the State Medicaid Agency, with a copy to CO and HRSA. HRSA notifies the applicant of the final decision.

2826 - RO Approval Process for FQHCs

(Rev. XXXXXX)

2826A - General

(Rev. XXXXXX)

An FQHC 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 must attest that it is in compliance with all applicable Medicare regulations. The SA does not conduct a survey to confirm the FQHC’s compliance with Medicare’s regulations.

FQHC's 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 §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 Aware 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 §491.3;*
- The applicant submits a complete CMS-855A enrollment application (along with all supporting documentation) to its MAC/Fiscal Intermediary, and the MAC/Fiscal Intermediary 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, RO Survey and Certification staff are responsible for reviewing and approving or denying requests for Medicare participation as an FQHC. The RO 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/Fiscal Intermediary determines that the applicant does not comply with the enrollment requirements in 42 CFR § 424.500-525, in which case the contractor itself will issue the denial per Pub. 100-08, chapter 10.) For approvals, the RO shall transmit the Tie-In Notice in accordance with the following instructions:

- A freestanding, non-tribal FQHC, including Urban Indian FQHCs, undergoing initial enrollment is to be assigned to the MAC or legacy FI that covers the State where the FQHC is located.*
- A tribal FQHC undergoing initial enrollment is to be assigned to the Jurisdiction 4 MAC.*

Note: For FQHCs already enrolled in Medicare:

- *In the settled MAC environment (i.e., after the transition to MAC contractors has been completed nationwide) all freestanding, non-tribal FQHCs, including Urban Indian FQHCs, will be assigned to the MAC that covers the State where the FQHC is located.*
- *In the settled MAC environment all tribal FQHCs will be assigned to the Jurisdiction 4 MAC.*
- *In the interim, all existing FQHCs will remain in their current assignments. FQHCs will be moved to their destination MACs after all fifteen A/B MAC contracts have been awarded and implemented. Each move will be dependent on the then-current status of the systems and contractors that support the claims processing, provider enrollment, and cost report audit functions at the department and destination MACs.*

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 fiscal intermediary or MAC, as applicable, as the main provider to which it is provider-based.

The RO reviews FQHC complaints and either refers them to HRSA or the 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 RO 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. XXXXXX)

ROs 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 CMS-855A enrollment application from CMS' Web site at <http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf>; and*
- *Attestation Statement for FQHCs (Exhibit 177)*

2826C - Request to Participate

(Rev. XXXXX)

To participate in the Medicare program, applicants *seeking initial enrollment as an FQHC* must submit to the *MAC jurisdiction 4 contractor, in the case of all applicants that are operated by a tribe or tribal organization; and to the MAC/FI having jurisdiction for the State where the facility is located, in the case of all other applicants:*

- *A signed and completed application 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 signed by the Regional Office.*
- *HRSA Notice of Grant Award or FQHC Look-Alike Designation Memo from CMS (HRSA provides the applicant notice of CMS approval);*
- *In the case of FQHCs receiving a §330 grant, a copy of the form that lists the service sites covered by its HRSA grant, in order to verify that the site covered by the 855A falls under the scope of the HRSA grant;*
- *CMS-588 Electronic Funds Transfer (EFT) Authorization Agreement;*
- *CLIA Certificate;*
- *State License (if applicable);*
- *A copy of the National Provider Identifier notification the applicant received from the National Plan and Provider Enumeration System.*

(NOTE: Previously all FQHC applications and claims payments 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/FI, as described above.)

2826D - Processing Requests

(Rev. XXXXX)

The *MAC/FI* will review *the completed 855A and other documents submitted by the applicant to ensure that all required information and documentation has been provided. 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).*

Upon receipt of a recommendation for approval, the RO verifies that the application package is complete and satisfies the requirements listed in 2826B.

- *For §330 grant-funded FQHCs, the RO confirms the applicant's attestation by reviewing the Notice of Grant Award issued to the applicant by HRSA.*
- *For FQHC Look-Alikes, the RO confirms the applicant's attestation by reviewing the CMS Designation Memo, a copy of which is provided to the applicant by HRSA.*
- *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 Indian Health Care Service (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.

2826E - RO Assigning Applicants an FQHC *CMS Certification* Number (CCN)

(Rev. XXXXX)

The RO assigns each FQHC *permanent site* approved a *CMS Certification Number (CCN)* using the 1800-1989 series. This includes RHCs converting to FQHCs. *The RO retires the CCN of the RHC and notifies the FQHC replacing the RHC of its new CCN.*

2826F - Effective Date

(Rev. XXXXX)

If the RO determines that the FQHC application meets all requirements, the RO signs the applicant's Attestation Statement for Federally Qualified Health Centers (Exhibit 177). The RO will use the date on the intermediary's recommendation letter when signing the Attestation, and this date is the effective date of the FQHC's agreement with CMS.

2826G - RO Completion of Forms

(Rev. XXXXX)

The RO completes appropriate blocks of Part I and Part II of Form CMS-1539. Annotate Item 7 by assigning Code 21 for FQHCs.

The RO completes Form CMS-2007 and *notifies the appropriate MAC/FI* of changes (additions, deletions, and corrections) in their lists of providers. (See [§2783](#).) *Although it is increasingly unlikely that a new FQHC will be provider-based, if the FQHC indicates on the Form CMS-855A that it is part of an existing Medicare/Medicaid provider, the RO sends the tie-in-notice to the main provider's MAC/FI.*

2826H - Complaint Investigations

(Rev. XXXXX)

CMS investigates complaints which raise credible allegations 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 §491.3. In conducting complaint investigations, SAs (or ROs, in the case of tribal FQHCs) use the instructions in Chapter Five, particularly sections 5200 through 5240, and applicable portions of Appendix G of the State Operations Manual 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 RO may initiate termination of the CMS agreement with the FQHC, in accordance with the provisions of 42 CFR 405.2436. The RO 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 RO 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 of 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.

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

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 in 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., based on the recommendation of the Health Resources and Services Administration (HRSA), it has been determined by CMS to meet 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 CMS 855A, Medicare Enrollment Application, Institutional Providers;*

- *CMS receives a copy of the applicant's Notice of Grant Award issued by HRSA, the FQHC Look-Alike Designation Memo from CMS (provided to the applicant 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 in 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 CMS-855A, Medicare Enrollment Application, Institutional Providers. CMS-855A may be downloaded from CMS' Web site at: <http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf>. This form includes instructions about where to submit the application.*
- *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 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, HRSA Notice of Grant Award to an FQHC or FQHC Look-Alike designation approval from CMS (HRSA provides the applicant notice of CMS Look-Alike approval);

- *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, a copy of the form that lists the service sites **approved**, in order to verify that the site covered by the CMS- 855A falls under the scope of the HRSA grant;*
- *Clinical Laboratory Improvement Act (CLIA) Certificate;*
- *State License (If Applicable); and*
- *A copy of the National Provider Identifier notification the applicant received from the National Plan and Provider Enumeration System.*

Medicare Regulatory Requirements:

- *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 §491.3. 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.*

- *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*

- ***Before signing the FQHC attestation statement, applicants should carefully review the regulations cited above to ensure the accuracy of their attestation of compliance.***

EXHIBIT 177
(Rev. XX, XX-XX-08)

Advance Copy

**ATTESTATION STATEMENT FOR
FEDERALLY QUALIFIED HEALTH CENTERS**

Complete the following attestation statement.

The **(name of 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) Based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Centers for Medicare & Medicaid Services 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 **(name of 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 **(name of facility)** is currently in compliance with these requirements and regulations and has been in compliance with these requirements and regulations. I agree 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).

Signature _____ Title _____ Date _____

Printed Name _____

Accepted for the Secretary of Health and Human Service by:

Signature _____ Title _____ Date _____