CMS Manual System

Department of Health & Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare & Medicaid Services (CMS)

Transmittal 139 **Date: April 24, 2015**

SUBJECT: Revisions to the Medicare State Operations Manual (SOM), Chapter 2, Rural Health Clinic Certification

I. SUMMARY OF CHANGES: Provisions in Chapter 2 of the SOM concerning certification of a Rural Health Clinic (RHC) are being clarified, and associated Exhibit 26 is being revised accordingly.

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 24, 2015
IMPLEMENTATION April 24, 2015

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
R	2/2242A – General
R	2/2242A1 - Location of Clinic
R	2/2242A3 - Physician Assistant, Nurse Practitioner, and/or Certified Nurse Midwife Staff
R	2/2242B - Clinic is Determined Ineligible
D	2/2242C - Basic Requirements are Met
R	2/2242D - Identifying Clinic as Provider-Based
R	2/2249 - RO Notification of RHC Initial Certification Approval
R	9/Exhibit 26 - Model Letter to Rural Health Clinic Ineligible to Participate

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2014 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction

	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Chapter 2 - The Certification Process

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(Rev. 139, Issued: 04-24-15)

Transmittals for Chapter 2

Rural Health Clinics (RHCs)

2242A – General

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

Applicants seeking initial certification as an RHC must, among other requirements, satisfy certain location and staffing requirements in order to participate in Medicare. In order to facilitate an efficient survey and certification process for applicants, State Survey Agencies and CMS, CMS requires an RHC applicant to complete and submit Form CMS-29, Verification of Clinic Data – Rural Health Clinic Program, as part of its application for certification. To make efficient use of survey resources, State Survey Agencies (SAs) make a preliminary assessment of the information contained on the Form CMS-29 prior to conducting a survey, to avoid conducting a survey of an ineligible location. Likewise SAs conduct a preliminary assessment of the information contained on the Form CMS-29 prior to forwarding a certification packet to the RO when the RHC applicant is seeking to participate via deemed status accreditation. However, since only the CMS RO may make a determination whether the RHC applicant has satisfied all Federal requirements, including the location and staffing requirements, the SA must not notify the applicant of the results of the SA's preliminary assessment of the Form CMS-29.

The SA or an accrediting organization (AO) may not conduct a survey before receiving a positive recommendation from the Medicare Administrative Contractor (MAC), issued after the MAC has completed its review of the RHC applicant's Form CMS-855A application to enroll in Medicare. An AO must receive a copy of the MAC's notice to the applicant that it has concluded its review before conducting an accreditation survey.

CMS makes RHC location determinations only after an RHC applicant has submitted an application to enroll in Medicare and is open and operating at the site identified in the application. CMS does not provide advance or preliminary determinations about whether a location satisfies the RHC criteria, even if interested parties request one. SAs also may not issue any preliminary or final assessments about a location's potential eligibility for RHC status.

2242A1 - Location of Clinic

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

Subpart A of 42 CFR *Part* 491 sets forth the conditions that RHCs must meet in order to qualify for certification under Medicare. *Question I on Form CMS-29 identifies the location of the clinic and defines location as "the location at which health services are furnished."*
*In accordance with 42 CFR 491.5, t*he clinic must be located in a rural area that is designated as a shortage area.

- *A rural area is defined in 42 CFR 491.2 as an area that is not delineated as an "urbanized area" by the US Census Bureau. An "urban cluster" is not considered an urbanized area. CMS relies upon the information in the US Census Bureau's American FactFinder tool, http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml, when determining whether a location falls within a rural area. Note that once a RHC is certified for Medicare participation, it may continue to participate as an RHC even if the US Census Bureau subsequently changes the classification of its location to an urbanized area.*

- A shortage area is a defined geographic area designated by *the Health Resources and Services Administration (HRSA) on behalf of* the Secretary as having either a shortage of personal health services or *an area or population group with a* shortage of primary medical care manpower. *HRSA may also designate at the request of a* State governor *specified* areas of *a* State as having a shortage of personal health services. *CMS uses data from HRSA's Data Warehouse, http://www.hrsa.gov/shortage/find.html, supplemented as needed by information obtained via telephone or e-mail from HRSA, when determining whether a location falls within a shortage area.*

SAs may use these same on-line tools when conducting their preliminary assessments of an RHC applicant's location prior to conducting a survey, but the results of their assessments are not considered determinations by CMS. AOs may also use these tools when deciding whether to accept an application for RHC accreditation and conduct an accreditation survey. However, SAs and AOs are not authorized to provide notice to the RHC applicant of the results of their assessments. Further, the fact that the SA, or an AO with a CMS-approved Medicare RHC accreditation program, conducts a survey of the RHC applicant does not constitute a determination by CMS that the applicant's location satisfies the regulatory criteria. Only the CMS RO may make such a determination and notify the applicant whether or not it has been determined to meet participation requirements.

Relocating an Existing RHC

An existing Medicare-certified RHC that has relocated must submit a CMS-855A updating the location information to the appropriate MAC within 90 days after it relocates. (See section 15.10.1 of the Medicare Program Integrity Manual, CMS Pub. 100-08). CMS also does not provide advance determinations on the location eligibility of a potential relocation site. Rural and shortage area location determinations are only made after the relocation has occurred and the CMS-855A has been submitted to the appropriate MAC. The RHC must also submit to the SA a Form CMS-29 reflecting its new location at the same time that it submits the CMS-855A update to the MAC. The SA forwards this information to the RO, which reviews it to determine whether the RHC at the new location continues to meet the location requirements. If it does not, the RO will issue a termination notice to the RHC. If the new location does continue to meet the RHC requirements, the RO does not need to take any further action, beyond documenting its determination in the RHC's certification file. However, based on the information on the Form CMS-29, the RO also has the discretion to require an on-site survey of the RHC at the new location.

If the RHC is only changing suites within the same building, CMS would not consider this a relocation. However, the RHC must still report the change of information to the MAC using the CMS-855A.

2242A3 - Physician Assistant, Nurse Practitioner, and/or Certified Nurse Midwife Staff

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

*Q*uestion III.B. and/or III.C. on Form CMS-29 *indicates* whether the clinic's staff includes a physician assistant, nurse practitioner, and/or certified nurse-midwife. A nurse practitioner, a physician assistant, or certified nurse-midwife must be available to furnish patient care services at least 50 percent of the time the clinic operates. (See Appendix G.) The SA contacts the clinic for clarification if the combined full-time equivalent entries in question III.B. and C. (and/or D., if D. is used to indicate a nurse-midwife) do not equal 50 percent of the clinic's scheduled hours of operation. In computing the full-time equivalents, *the SA* use*s* only the time personnel are present in the clinic or are providing RHC services away from the clinic site. *The results of the SA's preliminary assessment of the staffing information on the Form CMS- 29 do not constitute a determination by CMS, and the SA may not provide notice to the applicant of the results of its assessment. Likewise, any information or advice provided by an AO to the applicant about meeting the basic staffing eligibility requirements does not constitute a determination by CMS.*

The SA (or AO) may proceed to conduct a survey of the RHC applicant based on the results of its preliminary assessment of the applicant's staffing information, but the fact that the SA or AO conducted a survey does not constitute a determination by CMS that the RHC applicant meets the basic staffing requirements.

An RHC which is already certified and participating in Medicare may request a temporary waiver of these staffing requirements for a one-year period, if it demonstrates that it has been unable to hire a physician assistant, nurse-practitioner, or a certified nurse-midwife in the previous 90-day period. *However, staffing waivers are not available to RHC applicants seeking initial enrollment in the Medicare program.*

A subsequent request for a waiver cannot be made less than 6 months after the expiration date of any previous waiver of staffing requirements for the facility.

2242B – Clinic is Determined Ineligible

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

If the SA's preliminary assessment of the Form CMS-29 suggests that the RHC applicant's location does not satisfy the RHC eligibility requirements, the SA must notify the RO of this, forwarding the Form CMS-29. The RO will independently assess the location requirements, and if it concurs with the SA, the RO will issue a denial of initial certification to the applicant based on its determination regarding the applicant's location.

Likewise, if the SA's preliminary assessment of the Form CMS-29 suggests that the applicant does not have the minimum required physician assistant, nurse practitioner and/or certified nurse/midwife staff, the SA must notify the RO of this, forwarding the Form CMS-29. The RO will independently assess the staffing information contained on the Form CMS- 29, and if it concurs with the SA, the RO will issue a denial of initial certification to the applicant based on its determination regarding the applicant's self-reported staffing information.

2242D - Identifying Clinic as Provider-Based

(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

If the RHC applicant submits a Form CMS-29 indicating that it is a provider-based entity of a critical access hospital (CAH) or eligible hospital, the SA confirms the accuracy of the CAH's or hospital's CMS Certification Number (CCN) entered on the form. After conducting a survey and/or receiving notice of an AO's recommendation of RHC deemed status for the applicant, the SA forwards the Form CMS-29 and other certification documentation to the RO for review and a certification determination. If the RHC meets all Federal requirements for certification, and has indicated on its Form CMS-29 that it is provider-based to a hospital or CAH, the RO will issue a Medicare RHC agreement with a provider-based RHC CCN.

Issuance of a Medicare provider agreement with a provider-based CCN to a RHC does not constitute a CMS provider-based determination as provided for in §413.65(b). *Seeking such a provider-based determination is voluntary, and neither the SA nor the RO may require RHC applicants and their affiliated hospitals/CAHs to seek such a determination as a condition to being issued a provider-based RHC CCN.*

However, when CMS issues a provider-based RHC CCN, the letter approving the RHC's provider agreement and issuing the CCN must contain the following disclaimer language: "Issuance of a provider-based RHC CCN does ***not*** *constitute a CMS provider-based determination."*

2249 - RO Notification of RHC *Initial Certification* Approval

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The SA *forwards to the RO its survey report or the AO's notice of accreditation and recommendation of deemed status, along with any other supporting documents required in the RHC certification packet. The RO reviews all documentation to* determine *whether* the *applicant* is or is not in compliance with all RHC requirements*. The RO notifies an applicant of its approval or denial of certification in writing. If the applicant is approved, the RO countersigns, dates and issues the Form 1561A, Health Insurance Benefits Agreement, Rural Health Clinic, along with a cover letter indicating the RHC's CCN and the effective date of the Agreement. See §2784 which governs how the RO determines the effective date of participation.*

- The RO sends a copy of Form CMS-2007 to the Medicare *Administrative Contractor (MAC)* and another to the *State Medicaid Agency (SMA)* that has billing jurisdiction for RHCs.

- The RO sends a copy of the letter *issuing* the clinic's agreement to the Regional Health Administrator, HRSA, so that appropriate notification may be given to components of the PHS engaged in program support for rural health service activity.

The RO adds the following paragraph to the letter accepting the RHC's agreement:

> Your participation as an RHC under the Medicare program will also be accepted as certification as an RHC under the Medicaid program. If you need information about payment for RHC services under the State plan for medical assistance, contact (name, address, and telephone number of appropriate SMA).

*If a provider-based CCN is being issued, the approval letter must contain the following explicit language: "Issuance of a provider-based RHC CCN does **not** constitute a CMS provider-based determination."*

EXHIBIT 26

MODEL LETTER TO RURAL HEALTH CLINIC INELIGIBLE TO PARTICIPATE
(Rev. 139, Issued: 04-24-15, Effective: 04-24-15, Implementation: 04-24-15)

(**Date**)

Administrator
Applicant Clinic Name
Address
City, State, ZIP Code

Dear _____:

This is to inform you that, on the basis of information submitted *by your clinic* to *the Centers for Medicare & Medicaid Services (CMS)*, the (**name of health clinic**) *located* at (*clinic's* ***address***) has been identified as not meeting eligibility requirements *to participate in the Medicare program as a* rural health clinic *(RHC)*. *As a result, your request for certification as a RHC is denied.*

This determination is based on the following:

A. [___] The clinic is not located in an area that is designated as a non-urbanized area.

B. [___] The clinic is not located in an area designated either as a primary medical shortage area or an area with a shortage of personal health services.

C. [___] The clinic does not employ either a nurse practitioner or a physician assistant.

D. [___] The clinic does not have a physician providing medical direction.

If you *believe this initial determination is not correct, you may request that it be reconsidered. The request must be submitted in writing within sixty days of the date you receive this notice, in accordance with 42 CFR 498.22, to:*

(ARA name, title and address)

The date of receipt of this letter will be presumed to be five (5) days after the date of the notice unless there is a showing that it was, in fact, received earlier or later. The request should state the legal and factual reasons why you consider the decision to be incorrect and should include any documentation supporting these legal and factual conclusions.

Sincerely,

Regional Office DSC

cc: ***(State Agency)***
(if applicable, Accrediting Organization)