Rural Health Clinics (RHCs)

2240 - RHCs - Citations and Description

(Rev. 1, 05-21-04)

The statutory basis for RHCs is found in §1861(aa) of the Act. The Conditions for Certification are in 42 CFR 491, Subpart A. Appendix G contains interpretive guidelines and surveyor procedures. An RHC is a facility located in a rural area designated as a shortage area and is neither a rehabilitation agency nor a facility primarily for the care and treatment of mental diseases. It meets all other requirements of the RHC regulations at 42 CFR 491, Subpart A. A clinic located on an island may be eligible to be certified as an RHC even though it does not have a physician assistant, nurse practitioner, or certified nurse-midwife. (See §6213 of OBRA 1989.)

2242 - Conditions to Be Assessed Prior to Scheduling RHC Survey

(Rev. 1, 05-21-04)

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, the 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.

2242A2 - Medical Direction

(Rev. 1, 05-21-04)

Question II on Form CMS-29 asks for the name and address of the physician(s) providing the clinic's medical direction. The physician(s) providing medical direction must be a member of the clinic's staff or under agreement with the clinic to carry out the responsibilities required of a physician. If performed in the clinic, the time spent in this medical direction must be included in the answer to question III.A.

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)

Question 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 uses 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."

2242E - Compliance With Civil Rights Statutes

(Rev. 1, 05-21-04)

An RHC that only received Federal funds through Medicare Part B is not required to comply with the various civil rights statutes enforced by the Department of Health and Human Services' (DHHS) Office for Civil Rights. However, if the RHC participates in the Medicaid program or receives any other financial assistance such as grants from DHHS, it must comply with all applicable civil rights statutes. RHCs are not subject to the pre-grant review process required of participants in Medicare Part A.

2242F - Laboratory Services Provided in RHCs

(Rev. 1, 05-21-04)

An RHC must provide primary health care, including laboratory services to its patients. The RHC's laboratory services are subject to the Clinical Laboratory Improvement Amendments (CLIA).

2244 - Preparing for RHC Survey

(Rev. 1, 05-21-04)

Prior to the survey, in addition to reviewing the information and references needed for surveys generally, the SA reviews:

- Listings of formal educational programs for physician assistants, nurse practitioners, and certified nurse midwives; and

- A list of formal educational programs supported under HRSA grants to prepare RNs to perform in an expanded role in the delivery of primary care and any other educational programs that meet the requirements of the regulation.

2246 - Clinic's Request to Provide Visiting Nurse Services

(Rev. 1, 05-21-04)

An approved RHC may also seek approval to provide covered visiting nurse services. An RN, LPN, or licensed vocational nurse must furnish these services.

When a request is received, the SA determines if a shortage of HHAs exists in the area. Refer to 42 CFR Part 405.2417 and consults with the RO, as appropriate. If there is an existing HHA furnishing services in the RHC area, the SA contacts the HHA for a statement of its ability or inability to adequately furnish nursing services in the area. In addition, the SA obtains information from the local or State health planning organization.

If there is not a shortage of home health services for the area, the SA notifies the RO. In such cases, approval to furnish visiting nursing services to homebound patients will not be granted, and the RHC must refer its homebound patients to the HHA serving the area.

If there is a shortage of home health services, the SA notifies the RO and evaluates the qualifications of RHC personnel who are responsible for the delivery of nursing services. This evaluation must include compliance with applicable State licensure/certification requirements for RNs, LPNs, or licensed vocational nurses who provide services for the clinic.

2248 - Clinic's Request for Waiver of Staffing Requirements

(Rev. 1, 05-21-04)

As provided by §1861(aa)(7) of the Act, the Secretary of HHS is required to grant a 1-year waiver to RHCs for staffing requirements that the clinic employ a nurse practitioner, physician assistant, or certified nurse midwife, or that such disciplines furnish services 50 percent of the time that the clinic operates if:

- The facility requests a waiver;
- The facility demonstrates that it has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse midwife in the previous 90-day period; and
- The facility is not making the request less than 6 months after the date of the expiration of any previous such waiver for the facility.

The waiver is applicable to participating RHCs. The SA is responsible for recommending approval or disapproval of the requested waiver to the RO within 30 days of receiving it. The waiver shall be deemed granted unless the waiver request is denied by the RO within **60 days** after the date the SA received the request. In such situations the effective date of the 1-year waiver is the **61st day** after the date the request is received by the SA. The SA uses the date the RO approves the waiver as the effective date of the 1-year waiver period.

2248A - Applying Waiver to Applicants

(Rev. 1, 05-21-04)

The initial packet of information sent to RHC applicants by the SA should include a statement that the applicant cannot request a waiver of the mid-level requirement on initial

application. In §4205(c) of the BBA, the Congress amended, effective January 1, 1998, §1861(aa)(7)(B) of the Act to restrict further our authority to waive the requirement that each RHC must hire a physician assistant, nurse practitioner, or certified nurse midwife. A waiver may now be granted only to a participating RHC. That is, the waiver cannot be granted before the clinic has been determined by us to meet all the requirements for Medicare participation as an RHC and is actually participating as an RHC.

2248B - Applying Waiver to Participating RHCs

(Rev. 1, 05-21-04)

A participating RHC may request a waiver either when it loses its nurse practitioner, physician assistant, or certified nurse-midwife, or when it fails to meet the 50 percent staffing requirement regarding these disciplines.

Some RHCs will probably experience an unexpected loss of staff and therefore will not be able to demonstrate any effort to hire staff in the previous 90-day period. The SA should advise an RHC that it must comply with the staffing requirement within 90 days from the date it informed the SA it no longer met the staffing requirements or be terminated unless a waiver request is submitted by the facility and approved by the RO at the end of the 90-day period.

2248C - Documentation Demonstrating Efforts to Meet Staffing Requirements

(Rev. 1, 05-21-04)

An RHC must submit written documentation to the SA demonstrating its reasonable efforts to hire the required staff. This documentation should evidence ongoing activities throughout the 90-day time period prior to making a waiver request. The following types of documentation would be acceptable:

- Copies of reports of telephone contacts with potential hires, professional schools and organizations, recruiting services, etc.;
- Information about trips to professional meetings, educational institutions, and health care facilities for recruiting purposes;
- Copies of advertisements for recruiting hires; and
- Results of personal interviews with potential hires.

2248D - Monitoring Waivers

(Rev. 1, 05-21-04)

The SA monitors the expiration dates of waivers. When the expiration date of an RHC's

waiver is imminent, the SA must contact the RHC to determine whether the RHC will be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver.

If it is determined that the RHC will not be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver, the SA notifies the RHC that it will be terminated from the Medicare program. The RHC should be given notice of the termination at least 15 days before the effective date of the termination date. The termination date cannot be earlier than the day after the expiration date of the waiver.

If the RHC provides evidence that it has hired the required staff, but the staff will not be available at the clinic until after the expiration date of the waiver, the SA initiates termination action pursuant to §3012. The SA informs the RHC that when it meets the staffing requirement it should notify you immediately.

2248E - Notification

(Rev. 1, 05-21-04)

Both the SA and the ROs should notify an RHC when an RHC's waiver has been approved and include an explanation of the above termination procedures for expired waivers.

2249 - RO Notification of RHC Initial Certification Approval

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

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."