

than 50 staffed beds, which is contrary to the statute.

Definition of Shortage Area for RHC Purposes (§ 491.2)

Comment: Several commenters suggested that we clarify in proposed § 491.2 that an area designated as a low-income HPSA would qualify for RHC certification.

Response: We believe the rule is sufficiently clear regarding the applicability of low-income HPSAs for RHC certification. Section 491.2(c) states that population group HPSAs, which include low-income population group HPSAs, meet the definition of shortage area for RHC purposes.

Comment: A commenter asked for clarification of the guidelines that would be used to determine HPSAs. Specifically, will there be changes that would impact those areas that are currently designated as HPSAs?

Response: The designation of HPSAs and medically underserved populations (MUPs) is delegated by the Secretary to HRSA, and is not covered by these RHC regulations. HRSA issued a proposed rule in September 1998 (63 FR 46538) to revise the regulations for designation of shortage areas, but this proposal was withdrawn in July 1999 because of a high level of public concern about its potential impact. HRSA has been conducting further analysis to address these concerns, and plans to issue new proposed rules for designation of HPSAs and MUPs in 2004.

Comment: A commenter pointed out that the BBA amended the RHC provisions to state that "the rural area must also be one in which there are insufficient numbers of needed practitioners as determined by the Department." The January 2000 proposed rule does not address this amendment. There is a need for regulations in this area because current designations do not define an acceptable range for supply of providers to population.

Response: By statute, we are required to rely on HRSA to designate areas as medically underserved. As previously discussed, HRSA is currently developing another proposed rule to revise its methods and standards for designating shortage areas. HRSA's regulation will address the issue of provider supply to population.

RHC Procedures (§ 491.3)

Comment: A commenter pointed out that it is unfair to apply the 3-year currency requirement for MUAs. There is not a systematic review of MUAs. The 3-year requirement should only apply to

underserved designations that are systematically reviewed.

Response: Section 4205(d) of the BBA requires clinics entering the RHC program, as well as participating RHCs, to be located in a service area designated or updated within the previous 3-year period. This statutory requirement also applies to all medically underserved designations for RHC qualification purposes. We do not have the authority to exclude certain designations, such as MUAs. However, we believe that affected clinics must be given sufficient time to submit an application to update their service areas. We believe it is imperative that these clinics be given adequate time to submit applications to avoid being unnecessarily disqualified from the RHC program. We also believe these clinics should be protected from RHC disqualification while their applications are under review. Therefore, we are revising § 491.3(b)(2) to clarify that RHCs located in service areas with outdated shortage area designations will have 120 days, from the date we notify the facility about its compliance issue, to submit an application to update its medically underserved designation. In addition, we clarify in new § 491.3(b)(3) that the RHC will be protected from disqualification while its applications are under review. That is, affected clinics will not be considered out of compliance with the 3-year currency requirement for 120 days from the date HRSA formally receives the application. In rare cases where HRSA or the State cannot complete their review within 120 days, clinics will continue to be protected from RHC disqualification until a formal decision is made.

Typically, applications for updating shortage area designations are reviewed within 90 days. We will work closely with HRSA to ensure that all applications are processed within this timeframe.

As stated above, HRSA is responsible for the designation of HPSAs and MUAs, and certification of Governor's designations of eligible areas for the RHC program. HRSA works closely with the State Primary Care Office (PCO) in each State in administering the HPSA and MUA review activity, and in the certification of Governor's designations. Individuals or facilities interested in seeking a new or updated HPSA or MUA, or who wish to inquire regarding a possible Governor's designation, are encouraged to contact the appropriate State PCO. (A list of these contacts is available by calling 1-800-400-2742, or online at <http://www.bphc.hrsa.gov/>.) Information on the HPSA and MUA criteria, procedures, frequently asked

questions, and current designation status is also available at this web site. (For further information on HPSAs and MUAs, please contact Andy Jordan, Acting Chief, Shortage Designation Branch, National Center for Health Workforce Analysis, Bureau of Health Professions, at HRSA (301-594-0816).)

Comment: Several commenters indicate belief that an extension from RHC disqualification should be granted to clinics while their medically underserved status is being formally updated. The application process for updating underserved designation may unintentionally disqualify otherwise eligible clinics.

Response: We agree that some clinics, that are otherwise eligible, may be disqualified as an RHC if their service area cannot be updated in a timely manner. In § 491.3, paragraphs (b)(2) and (b)(3), we clarify the regulation to protect RHCs from disqualification that are in the process of formally updating their shortage area designations. Clinics that exceed the 3-year requirement will not be disqualified from RHC participation while their service area is in the process of being formally updated by HRSA or the State.

Comment: Two commenters suggested that the 3-year currency requirement in § 491.3(b) is too short. The costs and structural changes needed to set up an RHC cannot be recouped in 3 years.

Response: Section 4205(d) of the BBA requires clinics entering the RHC program, as well as participating RHCs, to be located in a service area designated or updated within the previous 3-year period. We do not have the authority to modify this requirement.

Comment: A commenter recommended that we require States to contact all providers by mail before an underserved area designation is revoked. If the community or clinic appeal the decision, CMS regional offices should have the authority to stop an RHC from having its designation revoked.

Response: We rely on HRSA to designate shortage areas. HRSA's review process provides affected communities and providers with advanced notice of a designation withdrawal and the right to appeal this decision. Our process for terminating RHC status does not start until HRSA formally withdraws the shortage area designation.

Comment: A commenter suggested that we should continue to recognize an area for RHC certification unless the area has been de-designated two times in a 3-year succession.

Response: We do not have the authority to recognize an area for RHC