

participation unless it has been recently designated or updated (within the previous 3 years). The BBA mandates the use of current shortage area designations.

Comment: A commenter suggested the proposed rule should be coordinated with the rules for designating shortage areas. Some RHCs may have a difficult time coping with these regulations if they are finalized all at once.

Response: We are aware of the interrelationship between these regulations and their potential impact on rural providers. HRSA is developing a new proposed rule that would address the major issues raised through the public comment period on its proposed rule published on September 1, 1998 in the **Federal Register** (63 FR 46538) Designation of Medically Underserved Populations and Health Professional Shortage Areas. Although we do not know exactly when a new proposed rule will be issued, the two agencies are in close contact and are striving to establish and coordinate their policies in a way that is sensitive to the needs and concerns of rural underserved communities.

Comment: Several commenters recommended that we revise the proposed 90-day timeframe for submitting an application for an exception.

Several commenters recommended a 6-month timeframe. The commenters believe that the data needed to qualify for exception may not be readily available; therefore, RHCs should be given ample time to gather and submit the necessary information.

Another commenter supported the proposed 90-day timeframe as reasonable, but recommended that we build in some flexibility to extend this application period if the time is too short.

Further, a commenter suggested that the sole and traditional community provider tests are needed, but suggested that the 90-day timeframe for submitting an exception application based on this test be extended. The commenter indicated belief that it will be difficult for providers to research and demonstrate compliance.

Response: Although we believe the proposed 90-day timeframe for submitting an application for an exception is sufficient for most cases, we recognize that some applicants may need additional time. Thus, we revise § 491.3(c)(2) to provide clinics with 180 days to submit an application.

Comment: Several commenters recommended extending the proposed 90-day timeframe for removing RHC status. The adjustment period following

de-certification needs to be longer to allow practitioners who choose to remain after de-certification to establish independent practices. For example, the affected RHCs will need to obtain a new provider number, which could take 4 to 6 months.

Response: Although we believe that the 90-day timeframe for removing RHC status is a sufficient amount of time for most providers to arrange to receive Medicare and Medicaid fee-for-service payments, we acknowledge that some providers may need additional time. Consequently, we are revising § 491.3(c)(5) to provide until the final day of the 6th month from the date of notification for ineligible clinics to transition from RHC status to a different Medicare and Medicaid payment and billing system.

Comment: Several commenters, in addition to extending the timeframe for removing RHC status, suggested making the termination effective date the last day of the month for administrative reasons.

Response: In terms of cost reporting and billing, we see merit in making the effective date for RHC termination the last day of the month. Consequently, we are revising proposed § 491.3(c)(5) to specify that the effective date for termination will be the final day of the 6th month from the date of notification that the clinic's location no longer meets program requirements. However, the RHC may be terminated earlier based on noncompliance with other certification requirements.

Comment: A commenter recommended that the regulation clearly state that we are responsible for notifying a clinic that its RHC status is in jeopardy and the 90-day timeframe should begin after receipt of this notice.

Response: We believe that this final rule is sufficiently clear regarding this issue. Sections 491.3(c)(2) and 491.3(c)(5) state that we notify the clinic of its ineligibility to participate in the Medicare program as an RHC.

Comment: A commenter suggested making an exception permanent unless the community is no longer considered rural. To reapply is an unnecessary waste of the provider's limited time.

Response: Clinics receiving essential provider status must meet certain conditions. Therefore, we believe it is necessary and reasonable to expect these clinics to demonstrate continued compliance with these conditions. Clinics receiving this special status will be required to provide to us, every 3 years, assurances that they continue to meet the conditions for being an essential clinic.

Comment: A commenter asked us to clarify that an exception can be renewed every 3 years.

Response: We are revising proposed § 491.3(c)(3) to clarify that an essential clinic can renew its RHC status every 3 years as long as the facility can provide assurances to us that they continue to meet one of the tests at § 491.5(b).

Location of Clinic (§ 491.5)

Comment: A commenter suggested that we extend the grandfather provision for a limited period of 10 years for existing clinics in areas no longer designated as rural and underserved. A less favorable option would be to implement a phase-out over a minimum of 10 years, with reimbursement reduced from 100 percent to 80 percent. In a 10-year period, an RHC affected by de-designation would have adequate time to plan for its future.

Response: Section 4205(d) of the BBA requires us to terminate RHC status for clinics no longer located in a rural or underserved area. An exception from termination is only available if the RHC is determined to be essential to the delivery of primary care. Consequently, we do not have the authority to grant an automatic 10-year extension from RHC disqualification, nor do we have the discretion to implement a phase-out of RHC reimbursement.

Comment: A commenter believes an RHC should be considered "essential" if there is a lack of resources to absorb and appropriately serve the client population in the absence of the RHC. If an RHC has a Medicaid, Medicare, uninsured payer mix of 60 percent or greater, it should be considered an essential RHC.

Response: The major community provider test is based on the premise that the clinic is essential because it cares for a substantial number of low-income patients (Medicaid and uninsured) within the community and that there are insufficient providers willing or capable of serving these patients. In order to ensure that the major community provider test takes into account this issue, CMS will consider willingness and resources of other providers to accept Medicare, Medicaid, and uninsured patients when determining essential provider status. For example, CMS will look at the size and scope of the other participating providers as well as their level of participation in the Medicaid program. Additional guidance regarding this review criterion will be provided through Medicare manuals following issuance of this final rule. As explained in the proposed rule, the issuance of an