

the sole and traditional community provider test should be expanded to require that these other providers must actively accept and treat uninsured patients, be engaged in full-time practice and be currently accepting new patients. Allowing an RHC to be de-designated because of the presence of other primary care providers who are semi-retired or only work part-time would place access to care for the community at risk.

Response: We agree that the proposed tests need to take into account the willingness and resources of other providers to accept and treat Medicaid, Medicaid, and uninsured patients. In light of this, we are requiring that the essential provider test must take into account the willingness and resources of other providers to treat and accept Medicare, Medicaid, and uninsured patients. The major and specialty provider tests must take into account the acceptance and treatment of Medicare and Medicaid beneficiaries, and the uninsured (regardless of their ability to pay.) The sole community provider test already stipulates that other providers in the community must accept Medicare, Medicaid, and uninsured patients to be considered.

Comment: A commenter suggested consideration for a system of care network under the exception process for essential clinics. A single multisite health care system is often the sole organization providing health care in a rural area. The commenter believes a system's clinics could lose their designation due to the physical location of another clinic.

Response: If the service area is no longer considered medically underserved or rural, each RHC will be required to demonstrate that it is essential based on the specific tests set forth in this final rule. An entity that owns and operates several RHCs would not be permitted to submit one application on behalf of all its clinics. The essential provider tests can only be appropriately applied on a facility specific basis.

Comment: A commenter questioned why we did not establish a time and distance standard based on the standard used for sole community hospitals. The commenter indicated belief that we should make the criteria more consistent to avoid confusion and ensure more equitable treatment of sole community RHCs and hospitals.

Response: Our proposed time and distance criteria are based on published HPSA criteria because these shortage area designations represent a core qualification requirement for RHC participation. In light of this linkage, we

believe it is more appropriate to apply the HRSA criteria instead of the SCH standards.

Traditional Community Provider Test

Comment: Several commenters believe the traditional community provider test should require that new providers must demonstrate that they have been accepting Medicare, Medicaid, and uninsured patients for a 5-year period. In addition, a determination should be made whether the non-RHC providers have the resources to treat an expanded patient population that would be created if the RHC would be closed.

Response: We are folding the traditional community provider test into the major community provider test to streamline and simplify the exception process for potential applicants. CMS believes, based on the many comments and different scenarios presented, that it would be more reasonable to combine these two tests. Clinics with an open door policy that are also the sole participating RHC for its community should be allowed to receive an exception as long as they represent a major source of primary care for its community. With regard to the specific issue of non-RHC providers having sufficient resources, we are requiring that the major community provider test must take into account the willingness and resources of other providers to accept Medicare, Medicaid and uninsured patients.

Comment: A commenter asked for clarification regarding the 5-year status for treating Medicare, Medicaid, and uninsured patients and how it is affected by a change of ownership.

Response: As stated above, CMS is combining the traditional and major community provider test for simplification. Consequently, CMS is no longer explicitly imposing the 5-year requirement. However, CMS expects the sole participating RHC to be a traditional primary care provider compared to other Medicare and Medicaid participating providers within the community.

Comment: A commenter suggested that the traditional community provider test should be expanded to address the situation where the rural community has two RHCs and both see Medicare, Medicaid, and uninsured patients.

Response: In addition to combining the traditional and major community provider tests, we are revising the major community provider test to address this issue. We acknowledge that there could be a situation where a rural community may have more than one RHC that represents a major source of primary

care for its Medicare, Medicaid, and uninsured patients. We are revising proposed § 491.5(b) at (b)(1)(ii) to clarify that more than one RHC in a given service area may receive an exception as a major community provider.

We are also revising this provision to eliminate the requirement that an RHC must be treating a "disproportionately greater share" of Medicare, Medicaid, and uninsured patients compared to other participating RHCs to allow for more than one exception. As stated above, there could be a situation where there are two RHCs in the service area and both equally share the responsibility of treating the indigent patients within the community.

Comment: A commenter asked us to clarify the length of time requirement for treating Medicare, Medicaid, and uninsured patients.

Response: As stated above, CMS is combining the traditional and major community provider test for simplification. Consequently, CMS is no longer explicitly imposing the 5-year requirement.

Comment: Several commenters recommended, for the essential provider tests, independent verification of information submitted by another community provider. This type of information is critical to accurately determining whether the provider has an open or closed practice to Medicaid and uninsured patients.

Response: Our regional offices require supporting information to verify these claims and use, when feasible, their own data (enrollment and billing information) to determine whether the other primary care providers have an open practice to Medicare, Medicaid, and uninsured patients.

Major Community Provider Test

Comment: Several commenters requested specific guidelines for the major community provider. The proposed language could lead to misapplications and misuse. For example, how will the term "disproportionate" be defined and how will the percentages be calculated?

Response: The applicant will not be required to meet an absolute threshold in terms of Medicare and Medicaid utilization. The premise behind this test is to grant an exception to an RHC that has an open practice to indigent patients (Medicaid and uninsured) and represents a major source of health care for these patients when other RHCs in the same service area do not provide or limit services to these patient groups. The applicant will be required to demonstrate that it has devoted its practice to serving Medicare, Medicaid,