

*Comment:* A commenter encouraged us to establish an extension process for the RHC certification of the area losing its underserved designation if it can be demonstrated that with the closure of the RHC, the areas would qualify as an underserved area.

*Response:* We believe the proposed conditions for being considered essential addresses this type of situation. However, as discussed above, we are clarifying § 491.5 to require that the proposed tests for determining essential provider status must take into account the willingness and resources of other providers to accept and treat Medicaid, Medicaid, and uninsured patients.

*Comment:* A commenter encouraged us to look at why and how the service area has solved its shortage problem. It may be due the RHC recruiting additional providers.

*Response:* We believe that our proposed conditions for granting essential provider status speak directly to this issue. This is particularly true for the sole community provider test. We will grant an exception when the successful recruitment of additional health care professionals by an RHC results in the dedesignation of the shortage area. This was proposed to make sure that these sole community clinics and their new practitioners remain viable providers.

*Comment:* A commenter encouraged us to more clearly define "community" as it is used in the exception process. For example, does it mean the service area of the RHC or the town in which the clinic operates?

*Response:* The RHC's service area for determining essential provider status is based on 30 minutes travel time from the RHC applicant. We are revising proposed § 491.5(b)(1) to clarify this determination at it relates to all the essential provider tests.

*Comment:* A commenter questioned whether more than one RHC could qualify for an exception in a given geographic area, assuming that each RHC meets the requirements for an exception.

*Response:* It is very possible that more than one RHC within a particular service area could receive essential provider status. In other words, there is no restriction on granting multiple exceptions within a specific service area as long as each RHC meets the conditions for receiving an exception.

*Comment:* Several commenters believe special consideration should be given to clinics that make house calls and provide after hours coverage for their community. These providers may

be essential in communities with inadequate transportation services.

*Response:* We believe that these are important factors, but supplementary to the provider's overall importance to community. In other words, providers that have devoted their practice to treating Medicare beneficiaries and low-income patients (Medicaid beneficiaries and the uninsured) should be able to satisfy one of the tests in this final rule without relying on an after hours coverage system or on making house calls. Our proposed essential provider tests were designed to recognize clinics that are the sole or major source of primary care for Medicare beneficiaries and low-income patients (Medicaid beneficiaries and the uninsured.)

*Comment:* The commenter suggested that special consideration should be given to clinics that provide pharmacy, x-ray, and lab services that otherwise would be unavailable.

*Response:* Although these are important services, we believe that essential provider status must focus on the professional services of physicians and nonphysicians, which are core RHC services. We also believe that these exceptions must be based on the clinic's dedication towards treating low-income patients (Medicaid beneficiaries and the uninsured).

*Comment:* Several commenters believe that the criteria for identifying essential clinics should factor in rural service areas with inadequate transportation services.

*Response:* We believe the proposed tests for identifying essential providers should address the issue of inadequate transportation services. However, since this condition cannot be easily measured or identified on a national level, we believe the best way of addressing this issue is by allowing for more than one RHC in a given service area to receive an exception as an essential clinic under the major and specialty provider tests. As discussed below, we are revising the proposed rule to permit, when warranted, multiple exceptions in a service area.

*Comment:* A commenter suggested that in counties that lose their underserved classification, we should apply a standard deviation or percentage test to determine if the county is so vulnerable that they should be granted an exception.

*Response:* Section 4205(d) of the BBA requires us to determine whether the facility is essential to the delivery of primary care for its community.

Although the tests in this final rule indirectly take into account these issues, we cannot grant an exception without assessing the importance of the clinic to

primary care for Medicare, Medicaid, and uninsured patients within that community. In other words, we are obligated by statute to determine whether the facility is essential to the delivery of primary care.

*Comment:* A commenter believes that we should provide our regional offices the authority to grant an exception on a case-by-case basis. There may be legitimate circumstances that would warrant an exception as an essential clinic that cannot be properly identified under our specific tests.

*Response:* We disagree with the commenter. We believe that the proposed specific tests and the additional refinements that we have made to these conditions, based on provider comments, will minimize or eliminate any negative impact on access to care for rural communities. We also believe the additional clarifications and changes to the essential provider tests should provide our regional offices with enough flexibility to recognize these circumstances.

*Comment:* Several commenters believe clinics located in very rural areas should automatically be granted an exception. We should recognize frontier areas and consider at least the inclusion of level 8 and level 9 USDA urban influence codes. Recruiting and retaining practitioners in remote areas is a constant struggle and we should eliminate the anxiety and cost associated with the possible loss of RHC status.

*Response:* We believe this suggestion has merit. Rural areas that are sparsely populated are more vulnerable to losing their shortage area designations. For example, the recruitment of just one additional practitioner in a frontier area could trigger a disqualification of the area's underserved status. In light of this, we believe clinics located in very rural areas should receive an exception. Consequently, we are revising § 491.5 to grant an exception to any RHC located in a frontier county or a rural area or in a level 8 or level 9 nonmetropolitan county using urban influence code as defined by the USDA. However, we will only provide an exception to these very rural clinics if they can demonstrate that they have traditionally served Medicare, Medicaid, and uninsured patients and continue to maintain an open door policy.

*Comment:* A commenter suggested that any RHC 50 miles or more from the next nearest hospital should be granted an exception.

*Response:* We believe that these clinics will qualify as an essential RHC under one of the tests. The commenter seems to be describing a situation where