

the Governor of a State and certified by the Secretary as having a shortage of personal health services. Later, however, the Health Centers Consolidation Act of 1996 (Pub. L. 104-299) renumbered section 329 of the PHS Act and repealed the requirement for designation of high migrant impact areas.

We proposed to amend § 491.2 to conform the regulations to the above statutory changes, by defining shortage areas for RHC purposes to include all four remaining types of designated areas. The types of shortage areas eligible for RHC certification are geographic and population based HPSAs, MUAs, and areas designated by the Governor of the State.

#### *A. Refinement of Shortage Area Requirements*

As noted above, section 4205(d)(1) of the BBA amended the second sentence of section 1861(aa)(2) of the Act to require the use of shortage areas designated "within the previous 3-year period." We proposed to amend § 491.3(b), to refer to "a current shortage area for which a designation is made or updated within the current year or the previous 3 years." In §§ 491.3 and 491.5, we proposed to establish the procedures and standards for granting an exception to clinics essential to the delivery of primary care that would otherwise be unavailable in the geographic area served by the clinic.

#### *Eligibility for an Exception*

In § 491.3, we specified that an RHC located in a rural area that is no longer designated as medically underserved, is eligible to apply for an exception. Those RHCs located in an area no longer designated as a nonurbanized area as defined by the Census Bureau are not eligible to apply for an exception.

Additionally, in § 491.3(c), we specified procedures for submitting an exception request.

#### *Criteria for Exception*

We proposed, in § 491.5, to allow an exception to an existing RHC that can satisfy one of the following tests:

*Sole Community Provider.* We proposed to classify an existing RHC as "essential" if it is the only Medicare or Medicaid primary care provider within the service area. Specifically, it is the only participating provider within 30 minutes travel time.

*Traditional Community Provider.* We also proposed to classify an existing RHC as essential if it is the sole RHC for its community and the only primary care provider that has traditionally served Medicare, Medicaid, and

uninsured patients in the community despite the fact that there may be other primary care providers that have recently begun participating within reasonable travel time of the RHC.

*Major Community Provider.* We also proposed to classify an existing RHC as essential if it is treating a disproportionate greater share of the patients in its community compared to other RHCs that are within 30 minutes travel time.

*Specialty Clinic Test.* We proposed to classify an existing RHC as "essential" if it exclusively provides pediatric services or obstetrical/gynecological (OB/GYN) services for its community.

*Graduate Medical Education (GME) Test.* We proposed to classify an existing RHC as "essential" if it is actively participating in an accredited GME program.

#### *B. Payment Limits for Provider-Based RHCs*

We proposed to amend § 405.2462 to provide payment to all RHCs on the basis of an all-inclusive rate per visit, subject to the per-visit payment limit. We also proposed to include within this section the definition for identifying small rural hospitals with fewer than 50 beds for purposes of the exception to the payment limit.

For hospitals that are the primary source of health care in their rural community as defined at § 412.92, we proposed to look to the hospital's average daily census rather than bed size in determining whether RHC services are subject to the upper payment limit.

#### *C. Staffing Requirements*

##### *Practitioners Available 50 Percent of the Time*

Under our current regulations, an NP or PA must be available to furnish patient care services at least 60 percent of the time the RHC operates. However, section 6213(a)(3) of OBRA '89 amended the staffing requirements for an RHC, described in section 1861(aa)(2)(j) of the Act, to require that a CNM, NP, or PA be available to furnish patient care services at least 50 percent of the time the RHC operates.

Therefore, we proposed to revise § 491.8(a) to require that a nurse practitioner, physician assistant, or certified nurse midwife be available to furnish patient care at least 50 percent of the time the RHC operates.

##### *Temporary Staffing Waiver*

We proposed to amend § 491.8 to provide that only currently participating RHCs (not facilities applying for

participation) are eligible for this waiver. We also proposed to amend § 491.8 to include procedures for when the waiver expires.

#### *D. Commingling*

We proposed to revise § 405.2401(b), "Scope and definitions," to clarify that the term "rural health clinic" means a facility that meets certain other requirements, and does not share professional staff, space, supplies, records, and other resources with another Medicare and Medicaid entity.

#### *E. Quality Assessment and Performance Improvement Program*

We proposed the requirement that an RHC set priorities for performance improvement based on the prevalence and severity of identified problems. We proposed to replace the existing requirements in § 491.11 with the proposed quality assessment and performance improvement (QAPI) program that contains three standards that would address: (1) The components of a performance improvement program; (2) monitoring performance activities; and (3) program responsibilities. In § 491.11(a), the first standard, would require that an RHC objectively evaluate the following critical areas: clinical effectiveness; access to care; and patient satisfaction. We did not propose specific language to set a minimum level of effort for clinics. Instead, we specifically invited comments on the best approaches to achieve a minimum level of effort.

Section 491.11(b), the second standard, would require that for each of the areas listed under the standard in § 491.11(a), the clinic must measure, analyze, and track aspects of performance that the clinic adopts or develops that reflect processes of care and clinic operations.

Section 491.11(c), the third proposed standard, would require that the RHC's professional staff, administration officials, and governing body (where applicable) ensure that there is an effective quality assessment and performance improvement program as well as the current requirement for assessing utilization.

### **III. Analysis of and Responses to Public Comments on the Proposed Rule**

On February 28, 2000, we published a proposed rule on RHCs in the **Federal Register** (65 FR 10450), on which we received 110 letters of comments. Commenters included individuals and health care professionals. A summary of those comments and responses follows:

Several comments were not directed to a specific provision of the February