

a State Public Utility Commission or the Surface Transportation Board. These proceedings may be at the Federal or State level depending on the activity regulated.

**§ 102–117.360 May my agency appear on its own behalf before transportation regulatory body proceedings?**

Generally, unless so delegated by the Administrator of General Services, no executive agency may appear on its own behalf in any proceeding before a transportation regulatory body. The statutory authority for the Administrator of General Services to participate in regulatory proceedings is in section 201(a)(4) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 481(a)(4)).

**§ 102–117.365 When or under what circumstances would GSA delegate authority to appear before transportation regulatory body proceedings?**

GSA will delegate authority to appear before transportation regulatory body proceedings when it does not have the expertise, or when it is out of GSA's scope, to make determinations on issues such as protests of rates, routings or excessive charges.

**§ 102–117.370 How does my agency ask for a delegation to represent itself in a regulatory body proceeding?**

You must send requests with enough detail to explain the circumstances surrounding the need for delegation of authority for representation to:

General Services Administration, Office of Governmentwide Policy (MT), 1800 F Street, NW., Washington, DC 20405.

**§ 102–117.375 What oversight authority does GSA have on transportation?**

(a) The GSA has oversight of public utilities used by the Federal Government including transportation. There are specific requirements a TSP must go through on the State level, such as the requirement to obtain a certificate of public convenience and necessity.

(b) Further, a TSP must obtain an affidavit from those agencies that would use the TSP. As an oversight mandate, GSA coordinates this function.

(c) GSA has a list of TSPs, which meet certain criteria regarding insurance and safety, approved by the Department of Transportation. You must furnish GSA with an affidavit to determine if the TSP meets the basic qualification to protect the Government's interest. For further information contact:

General Services Administration, Federal Supply Service, Office of Transportation and Property Management, Transportation Management Division (FBF), Crystal Mall Bldg. #4, Room 814, Washington, DC 20406.

**Subpart J—Reports**

**§ 102–117.380 Is there a requirement for me to report to GSA on my transportation activities?**

(a) Yes, GSA will work with your agency and other agencies to develop reporting requirements and procedures. In particular, GSA will develop a Governmentwide transportation reporting system by October 1, 2002.

(b) Preliminary reporting requirements may include an electronic formatted report on the quantity shipped, locations (from and to) and cost of transportation. The following categories are examples:

- (1) Dollar amount spent for transportation;
- (2) Volume of weight shipped;
- (3) Commodities shipped;
- (4) HAZMAT shipped;
- (5) Mode used for shipment;
- (6) Location of items shipped (international or domestic); and
- (7) Domestic subdivided by East and West (Interstate 85).

**§ 102–117.385 How will GSA use the reporting requirements?**

(a) Reporting on transportation and transportation related services will provide GSA:

- (1) The ability to assess the magnitude of transportation within the Government;
- (2) Information on best practices;
- (3) Data to analyze and recommend changes to policies, standards, practices, and procedures to improve Government transportation; and
- (4) A better understanding of how your activity relates to other agencies and your influence on the Governmentwide picture of transportation services.

(b) In addition, this information will assist you in showing your management the magnitude of your agency's transportation program and the effectiveness of your efforts to control cost and improve service.

**Subpart K—Governmentwide Transportation Policy Council (GTPC)**

**§ 102–117.390 Is there a Government forum where I can share my concerns and receive information on the challenges of transporting freight and household goods?**

Yes, the Office of Governmentwide Policy sponsors a Governmentwide Transportation Policy Council (GTPC) to help agencies in the establishment, improvement and maintenance of effective transportation management policies, practices and procedures. The council:

- (a) Collaborates with private and public stakeholders to promote

solutions that lead to effective results and develop valid measures of performance; and

(b) Provides assistance in developing the Governmentwide transportation reporting system (see § 102–117.10).

**§ 102–117.395 Where can I get more information about the GTPC?**

If you or a TSP have questions, comments or suggestions to help increase the effectiveness of Government transportation policy, contact:

General Services Administration, Office of Governmentwide Policy (MT), 1800 F Street, NW., Washington, DC 20405.  
Web site: <http://policyworks.gov/transportation>

Dated: February 15, 2000.

**G. Martin Wagner,**

*Associate Administrator for Governmentwide Policy.*

[FR Doc. 00–4060 Filed 2–25–00; 8:45 am]

BILLING CODE 6820–24–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**42 CFR Parts 405 and 491**

[HCFA–1910–P]

RIN 0938–AJ17

**Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program**

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend our regulations to revise certification and payment requirements for Rural Health Clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA 1997). It would include new refinements of what constitutes a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that can continue to be approved as Medicare RHCs in areas no longer designated as medically underserved; and limit waivers of certain nonphysician practitioner staffing requirements. It also would impose payment limits on provider-based RHCs and prohibit “commingling” the use of the space, equipment, and other resources of an

RHC with another entity. Finally, the rule would require RHCs to establish a quality assessment and performance improvement program that goes beyond current regulations.

This proposed rule would make other revisions for clarity and uniformity and to improve program administration.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 28, 2000.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1910-P, P.O. Box 26676, Baltimore, MD 21207-0476.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1910P@hcfa.gov. For e-mail comment procedures, see the beginning of **SUPPLEMENTARY INFORMATION**. For further information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** David Worgo, (410) 786-5919 or Mary Collins (quality issues) (410) 786-3186.

#### **SUPPLEMENTARY INFORMATION:**

#### **E-mail, Comments, Availability of Copies, and Electronic Access**

E-mail comments must include the full name, postal address, and affiliation (if applicable) of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1910-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

**Copies:** To order copies of the **Federal Register** containing this document, send

your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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#### **I. Background**

##### **A. General**

The Rural Health Clinic Services Act of 1977, Public Law 95-210, enacted December 13, 1977, amended the Social Security Act (the Act) by enacting section 1861(aa) to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at a rural health clinic (RHC) by physicians and certain nonphysician practitioners, and for services and supplies incidental to their services. "Nonphysician practitioners" included nurse practitioners and physician assistants. (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, and certified nurse midwives).

According to House Report No. 95-548(I), the purpose of Public Law 95-210 was to address an inadequate supply of physicians to serve Medicare beneficiaries and Medicaid recipients in rural areas. The program addressed this problem by providing qualifying clinics located in rural, medically underserved communities with Medicare beneficiaries and Medicaid recipients with payment on a cost-related basis for outpatient physician and certain nonphysician services. (The Medicare payment provisions for rural health clinics are in sections 1833(a)(3) and 1833(f) of the Act and in our regulations beginning at 42 CFR 405.2462.)

Qualifying clinics, among other criteria, had to be located in a nonurbanized area as defined by the Census Bureau and in a medically underserved area as designated by the Health Resources and Services Administration or (since the Omnibus Budget Reconciliation Act of 1989, section 6213(c)) the chief executive officer of the State. (See section 1861(aa)(2) of the Act, following subparagraph (K).) There are three types of shortage area designations applicable to RHC qualification: health professional shortage areas, medically underserved areas, and governor-designated shortage areas. The clinic's service area must have, in addition to being located in a nonurbanized area, one of these shortage area designations if the clinic is to qualify to receive RHC status.

Qualifying clinics also had to employ a physician assistant or nurse practitioner and, to meet requirements of the Omnibus Budget Reconciliation Act of 1989, had to have a nurse practitioner, a physician assistant, or a certified nurse midwife available to furnish patient care services at least 50 percent of the time the RHC operates.

#### **Growth of RHCs in the Medicare Program**

After a slow start, the program has recently grown at a rapid rate—from less than 1,000 Medicare-approved RHCs in 1992 to more than 3,500 in early 1998. While part of this increase has improved access to primary care services in rural areas for Medicare and Medicaid beneficiaries, there are instances in which these additional RHCs have not expanded access.

#### **Continuing Participation**

A significant factor in the growth of RHCs stems from the original RHC legislation, which included a "grandfather clause" to promote the development of RHCs. (Section 1(e) of Public Law 95-210, 42 U.S.C. 1395x

note. Also see § 491.5(b)(2).) In addition, the third sentence of section 1861(aa)(2) of the Act stated that:

A facility that is in operation and that qualifies as a rural health clinic \* \* \* [under the Medicare or Medicaid program] and that subsequently fails to satisfy the requirements of clause (i) [in the second sentence of section 1861(aa)(2), pertaining to the rural and underserved location requirement], shall be considered \* \* \* as still satisfying the requirement of such clause.

This provision protected the clinic's RHC status despite any possible changes to the rural or underserved status of its service area. It allowed clinics to remain in the RHC program even though their service areas were no longer considered rural or medically underserved.

The Congress established this protection to encourage clinics to attract needed health care professionals to underserved rural areas and to retain them without being concerned about losing the shortage area designation, which would make the clinics ineligible for RHC status and its reimbursement incentives. In other words, once the clinic successfully attracted the needed health care professionals to the area, the Congress wanted to ensure that the service area did not return to its previous underserved status because we removed the clinic's RHC status and reimbursement incentives.

Although the grandfather provision was based on justifiable policy considerations, we are now confronted with RHC participation in some service areas with extensive health care delivery systems where Medicare and Medicaid beneficiaries are not having difficulty obtaining primary care. Both the General Accounting Office and the Department of Health and Human Services' Inspector General recommended the establishment of a mechanism, under the survey and certification process for Medicare facilities, to discontinue RHC status and its payment incentives in those service areas where they are no longer justified. (See the next paragraph.) In section 4205(d)(3) of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33), the Congress responded to these recommendations by amending the grandfather provision to provide protection only to clinics essential to the delivery of primary care.

#### Government Reports

Both the General Accounting Office and the Department of Health and Human Services' Inspector General concluded, based on recent studies, that the number of RHCs is growing out of proportion to the need and some RHCs remain in the program after the need for

payment incentives no longer exists. They also concluded that the payment methodology for provider-based RHCs lacks sufficient cost controls and recommended establishing payment limits and screens on reasonable costs for these providers. (A provider-based RHC is an integral and subordinate part of a Medicare-participating hospital, skilled nursing facility, or home health agency, and is operated with other departments of the provider under common licensure, governance, and professional supervision. All other RHCs are considered to be independent.) For more information on these reports see "Rural Health Clinics: Rising Program Expenditures Not Focused on Improving Care in Isolated Areas" (GAO/HEHS-97-24, November 22, 1996), and "Rural Health Clinics: Growth, Access and Payment" (OEI-05-94-00040, July 1996).

#### Medically Underserved Designations

Another reason for the continued growth of the RHC program was that two types of shortage area designations, specifically the Medically Underserved Area (MUA) and Governor's designations, did not have a statutory requirement for regular review and have not been systematically reviewed and updated for some time. As a result, some new RHCs may have been certified in areas that would no longer be designated as underserved if reviewed with current data. In response, as discussed below, the Congress amended the legislation by requiring that only those clinics located in shortage areas that have been recently designated or updated will qualify for purposes of the RHC program.

#### Commingling

We define the term "commingling" to mean the simultaneous operation of an RHC and another physician practice, thereby mixing the two practices. The two practices share hours of operation, staff, space, supplies, and other resources. Commingling occurs in RHCs that are an integral part of another provider, such as a hospital, as well as in RHCs that are independent.

*Examples of Commingling.* Industry sources have told us that many providers combine provider-based RHCs and non-RHC emergency room staffs and location to furnish services to beneficiaries seeking primary care, emergency services, or both. In such situations, Medicare payment has been made separately on a reasonable cost basis for hospital outpatient department services and for the RHC services. Also, emergency room physician services are

payable according to the Part B physician fee schedule.

We also understand that some providers use skeleton emergency room staffs, routinely assign RHC staff members to the emergency room or other parts of the provider, and bill the Medicare program not only for full RHC costs, but also for non-RHC Part B benefits (hospital outpatient department services and physician services). When these situations occur, Medicare pays the RHC's administrative costs, which include the costs for RHC staff salaries (including physician and practitioner salaries) and for any Part B services performed by the RHC staff, whether performed within the clinic setting or in other provider departments. The provider receives two payments for the cost of services furnished by a particular staff member who had simultaneous assignments.

A common approach taken by independent RHCs is to operate a private physician practice in the RHC at the same time the physician is furnishing RHC services to patients. We believe this creates the opportunity for incorrect bills or duplicate payments.

#### B. Legislation

##### Refinement of Shortage Area Requirements

Refinement of the shortage area requirements involves two phases.

1. Phase I. Paragraphs(d)(1) and (2) of section 4205 of the BBA concern the requirements in the second sentence of section 1861(aa)(2) of the Act that RHCs must be located in a nonurbanized area as defined by the Bureau of the Census, as well as in a Health Professional Shortage Area, a medically underserved area, or in a shortage area designated by a State governor. The Congress amended those provisions to state that the rural area must also be one in which there are insufficient numbers of needed health care practitioners as determined by the Department. The Congress also amended that sentence to specify that, to be used in RHC certification, shortage area designations made by the Department or by a State governor must have been made within the previous 3-year period.

2. Phase II. In paragraph(d)(3)(A) of section 4205 of the BBA, which amended the third sentence of section 1861(aa)(2) of the Act, the Congress revised the "grandfather clause" that permitted an exception to the termination of RHC status for a clinic located in an area that is no longer a rural area or a shortage area. This revision amended the grandfather clause to specify that an exception is available

only if the RHC is determined to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the RHC. These amendments were made effective upon issuance of implementing regulations that the Congress directed us to issue by January 1, 1999.

#### Staffing Waiver

Section 4161(b)(2) of the Omnibus Budget Reconciliation Act of 1990 added section 1861(aa)(7) to the Act to provide us with the authority to grant a 1-year waiver of the requirement that an RHC must employ a physician assistant, nurse practitioner, or certified nurse midwife and must furnish their services 50 percent of the time the RHC operates, if the clinic can demonstrate that it has been unable, in the previous 90-day period, to hire one of these nonphysician primary care providers.

In section 4205(c) of the BBA, the Congress amended, effective January 1, 1998, section 1861(aa)(7)(B) of the Act to restrict further our authority to waive the requirement that each RHC must hire a physician assistant, nurse practitioner, or certified nurse midwife. A waiver may now be granted only to a participating RHC. That is, the waiver cannot be granted before the clinic has been determined by us to meet all the requirements for Medicare participation as an RHC and is actually participating as an RHC.

#### Payment Limits for Provider-Based RHCs

Before the BBA, the payment methodology for an RHC depended on whether it was "provider-based" or "independent." Payment to provider-based RHCs for services furnished to Medicare beneficiaries was made on a reasonable cost basis by the provider's fiscal intermediary in accordance with our regulations at part 413. Payment to independent RHCs for services furnished to Medicare beneficiaries was made on the basis of a uniform all-inclusive rate payment methodology in accordance with part 405, subpart X. Payment to independent RHCs was also subject to a maximum payment per visit as set forth in section 1833(f) of the Act.

The BBA, at section 4205(a), amended section 1833(f) of the Act. It now holds provider-based RHCs to the same payment limit and all-inclusive payment methodology as independent RHCs. This provision also provides an exception to the payment limit for those clinics based in small rural hospitals with fewer than 50 beds.

#### Quality Assessment Program

Currently, quality of RHC care is addressed in § 491.11, which requires a clinic to evaluate its total program annually. The evaluation must include reviewing the utilization of the clinic's services, a representative sample of both active and closed clinical records, and the clinic's health care policies. The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed. The clinic's staff considers the findings of the evaluation and takes the necessary corrective action. These requirements focus on the meeting and documentation of the clinic's evaluation of its quality care and do not account for the outcome of these activities. Section 4205(b) of the BBA amended section 1861(aa)(2)(I) of the Act to authorize us to require that an RHC have a quality assessment and performance improvement program. A quality assessment and performance improvement program enables the organization to systematically review its operating systems and processes of care to identify and implement opportunities for improvement.

## II. Provisions of This Proposed Rule

#### *Definition of Shortage Area for RHC Certification*

Section 6213 of OBRA 1989 amended 1861(aa)(2) of the Social Security Act to expand the types of shortage areas eligible for RHC certification. Until then, the eligible areas included only those designated by the Secretary as areas having a shortage of personal health services under section 330(b)(3) of the PHS Act (medically underserved areas), and those designated as geographic health professional shortage areas under section 332(a)(1)(A) of the PHS Act. The OBRA 1989 amendment expanded the eligible areas to also include high impact migrant areas designated under section 329(a)(5) of the PHS Act; areas containing a population group HPSA designated under section 332(a)(1)(B) of the PHS Act; and areas designated by 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 (Public Law 104-299) renumbered section 329 and repealed the requirement for designation of high impact migrant areas. We would amend section 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.

Section 330(b)(3) of the PHS Act defines medically underserved populations (MUPs) to include both areas and population groups designated by the Secretary as having a shortage of personal health services. However, Section 1861(aa)(2) of the Social Security Act specifically limits eligibility for the rural health clinic program to areas designated under this statute (known as medically underserved areas, MUAs). Thus, a clinic located in an area which contains only a population group designation under section 330(b)(3) is not eligible for participation in the Medicare or Medicaid programs as an RHC. Accordingly, our amendment of the regulation reflects inclusion of medically underserved areas (MUAs) but exclusion of medically underserved population groups (MUPs) for RHC certification.

Although the expansion of eligible areas by section 6213 of OBRA 1989 and the exclusion of population groups (MUPs) for RHC certification have already been implemented by regional office and State operation manuals, we need to conform the regulations.

#### *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 propose to implement this by amending § 491.3(b) to refer to "a current shortage area whose designation has been made or updated within the current year or the previous 3 years."

Before the BBA, clinics entering the RHC program were required to be located in a shortage area designated by the Health Resources and Services Administration or by the State. If the clinic's service area was on the Health Resources and Services Administration's or the State's list of designated shortage areas, the clinic satisfied the definition of shortage area for purposes of Medicare participation. Any clinic now applying for Medicare participation as an RHC must be located in a shortage area that has been so designated or updated within the current year or 1 of the previous 3 calendar years.

Although these changes have already been implemented in a memorandum to our regional offices on February 6, 1998, we need to conform the regulations. Therefore, we would include the 3-year provision in § 491.3(b) to provide that all RHCs applying for Medicare

participation must be located in a current shortage area in order to be approved for participation in Medicare as an RHC.

Under the provisions of the BBA, existing RHCs whose locations no longer meet rural and/or shortage area requirements must be disqualified from further participation in the Medicare program as RHCs unless they are deemed essential to the delivery of primary care that would otherwise be unavailable in the geographic area served by the clinic. Under these statutory requirements, we propose to establish, in §§ 491.3 and 491.5, 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

We would specify, in § 491.3, 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.

We believe that to extend the grandfather provision to clinics in nonrural areas through the exception process would be contrary to the fundamental definition of an RHC as an entity located in a rural area.

*Process.* We would specify, in § 491.3(c), the following procedures for submitting an exception request:

- In order to apply for an exception from the requirement that it meets the criteria in section 1861(aa)(2)(I) of the Act, the affected RHC must submit a request to its HCFA regional office for review.
- An RHC will have 90 days, from the date of notification from HCFA that its location no longer meets the definition of shortage area, to submit an exception request to the HCFA regional office.
- The HCFA regional office will have authority to grant a 3-year exemption to any RHC that it determines, under the criteria discussed below, is essential to the delivery of primary care that would otherwise be unavailable in the geographic area served by the clinic. The 3-year exemption time period is consistent with the shortage redetermination period of 3 years and would be administratively easy to manage.

*Termination of RHCs located in areas that lose their shortage area designation.* RHCs ineligible for an exception would be denied RHC participation in the Medicare program

90 days following the initial HCFA notification that its location no longer meets the definition of a shortage area.

RHCs eligible to apply for an exception but unable to satisfy the criteria for an exception would be denied RHC participation in the Medicare program 90 days following the HCFA notification that its application for an exception has been rejected. We are allowing this period in part to permit the health care professionals of these clinics time to arrange to receive payment from the Medicare carrier for their services under other Medicare payment provisions for which they may qualify. An RHC that does not request an exception will have its Medicare participation as an RHC terminated 90 days following the initial HCFA notification that its location no longer meets shortage area requirements.

#### Criteria for Exception

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

*Sole Community Provider.* We are proposing to classify an existing RHC as "essential" if it is the only Medicare or Medicaid primary care provider within the service area. To determine whether it is the only participating provider, we would apply a time and distance standard that would be measured by a travel time greater than 30 minutes from the RHC applying for the exception to other Medicare and Medicaid participating primary care providers. The standard that primary care services should be available and accessible within 30 minutes travel time has been in use by Health Resources and Services Administration programs, which deal extensively with primary care providers and access to these services, since the 1970s. For purposes of this test, primary care provider means an RHC, a Federally Qualified Health Center (FQHC), or a physician practicing in either general practice, family practice, or general internal medicine.

The following criteria could potentially be used in determining distances corresponding to 30 minutes travel time: under normal conditions with primary roads available—20 miles; in areas with only secondary roads available—15 miles; in flat terrain or in areas connected by interstate highways—30 miles.

The geographic test would address the principal reason the Congress established the original grandfather provision: to ensure that the service area does not return to its previous medically underserved status because of the removal of the clinic's RHC status and reimbursement incentives.

This test is being proposed because RHCs are currently the sole providers for many underserved rural communities in this country that could lose their status as underserved with the addition of one or two health care professionals. When these RHCs' successful recruitment of additional health care professionals results in a dedesignation of the shortage area, we want to make sure that the RHC and its new professionals remain in the service area as viable providers. Without the clinic's presence in the community, the area could potentially return to its medically underserved status. RHCs applying for an exception under this test would be expected to demonstrate that they accept Medicare (where applicable), Medicaid and uninsured patients that present themselves for treatment.

*Traditional Community Providers.* We are also proposing 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. We believe it is necessary to accord these RHCs an exception if the recent presence of other primary care provider(s) caused the shortage area to lose its designation as underserved. In this situation, where the recent presence of other primary care providers, such as one or two new physician practices, in the service area triggered the shortage area dedesignation. We believe such an area may be too unstable in terms of access to primary care to warrant the removal the clinic's RHC status and cost-based reimbursement. We believe this is particularly true if the sole RHC has been serving its community for many years and has accepted Medicare, Medicaid, and uninsured patients that presented themselves for treatment.

However, if there are several primary care providers who have been actively treating Medicare, Medicaid, and uninsured patients for a number of years and these providers are within 30 minutes travel time of the RHC, we believe the RHC should not be granted an exception as an essential clinic because the service area would now appear to be stable. For example, if the RHC's service area (30 minutes travel time) has two or more participating primary care providers that have been actively treating Medicare, Medicaid, and uninsured patients for a minimum of 5 years, we would not grant the exception. Consequently, we would

only accord an exception to sole RHCs that are actively treating Medicare and Medicaid beneficiaries and the uninsured located in unstable service areas as described above.

**Major Community Provider.** We are also proposing 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. We are proposing this test to address the situation (as reported by the General Accounting Office, DHHS Inspector General, and State Medicaid agencies) of RHC concentrations, such as RHCs located next door to or across the street from each other.

Concentrations of RHCs have developed in a number of service areas since 1990, and it is possible that some of these communities have already lost or will lose their medically underserved designation. It is also possible that no RHCs within the cluster would be able to qualify for an exception, under the criteria described above. However, within this group there may nonetheless be an "essential" RHC. To address this situation, we are proposing this test to identify whether there is a major community provider within a concentration of RHCs.

The premise behind this test is to grant an exception to an RHC that is a major community provider to Medicare and Medicaid beneficiaries and the uninsured in service areas where other RHCs do not provide or limit services to these groups. Granting an exception to a clinic under this test is not meant to be a routine occurrence. The RHC applying for an exception would have to make a compelling case that services it provides would be otherwise unavailable in the geographic area served by the clinic.

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

The purpose of this test is to recognize RHCs that are providers of pediatric or OB/GYN health care for their communities. In general, clinics applying for an exception are in jeopardy of losing RHC status because their service areas are no longer designated as medically underserved, which means there is an adequate supply of health care professionals within the community. Although the local delivery system may consist of several primary care practitioners, it may be that the RHC is the only provider furnishing pediatric or OB/GYN care for the community. If the

specialty clinic(s) cannot remain financially viable, the community could be left without any OB/GYN or pediatric services. Therefore, in rural communities where these services are limited despite an otherwise adequate supply of health care professionals, we would classify the specialty clinic as essential to the delivery of primary care and grant it an exception. RHCs applying for an exception under this test would be expected to demonstrate that they accept Medicare (where applicable), Medicaid, and uninsured patients that present themselves for treatment.

**Graduate Medical Education (GME) Test.** We are proposing to classify an existing RHC as "essential" if it is actively participating in an accredited GME program. We would accord an exception to any RHC located in a rural area that is part of a medical residency training program approved by the Accreditation Council for Graduate Medical Education of the American Medical Association.

Under section 4625 of the BBA, the Congress specifically recognized RHCs as qualified non-hospital providers for GME payments, to encourage more training of future physicians in non-hospital settings. Without RHC status, rural clinics that are part of a GME program would lose their Medicare funding for primary care medical education. This could cause a clinic to discontinue its training, which is currently in high demand and needed in rural communities. Therefore, RHCs that are actively serving as rural primary care training sites should be accorded an exception. For additional information regarding eligibility as nonhospital providers for GME payments, see the **Federal Register**, May 8, 1998.

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

We would 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 would also 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. Although these statutory changes have already been implemented in administrative instructions, we need to conform the regulations.

To implement this provision, we released Program Memorandum A-97-20, "Per-Visit Rates in Rural Health Clinics and Federally Qualified Health Centers," in January 1998. That instruction directed Medicare fiscal intermediaries to determine which

RHCs are eligible for the exception by counting the number of a provider's beds in accordance with the regulations at § 412.105(b). That regulation is part of the provisions on calculating a teaching hospital's indirect medical education adjustment under the prospective payment system for inpatient hospital services and is based on "available bed days." The latter term means that the bed must be permanently maintained for lodging inpatients and must be available for use and housed in patient rooms or wards. Section 2405.3.G of the Medicare Provider Reimbursement Manual contains further administrative guidance on "available bed days."

In defining rural and urban areas for the Medicare program, we have consistently used the definition of "Metropolitan Statistical Area" (MSA) established by the Office of Management and Budget. For example, the MSA definition is applied to identify hospitals eligible for an exception to the prospective payment system as rural referral centers. It is also used to determine an institution's eligibility for the critical access hospital program and for many other purposes.

Section 4205(a) of the BBA provides an exception to the RHC payment limit for clinics of small rural hospitals (fewer than 50 beds) for the purpose of helping them remain financially viable. RHCs affiliated with small rural hospitals were targeted by this provision because they are typically located in very rural areas and represent the sole source of health care for their communities.

As mentioned above, we issued a Program Memorandum to implement this new payment provision, which instructed Medicare fiscal intermediaries to use the available bed definition at § 412.105(b) for determining eligibility for the exception. Despite its reasonableness, we recognize that some very rural providers may not qualify for an exception using the available bed definition. To assure continued access to primary care services in thinly populated rural areas where the hospital and its clinic(s) are the primary source of health care for their communities, we are proposing to adopt an alternative definition of hospital bed size.

For hospitals that are the primary source of health care in their community as defined at § 412.92, we are proposing 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. We believe average daily census may be a more appropriate measure of inpatient capacity in certain situations (for example, rural areas that

experience seasonal fluctuations due to logging or commercial fishing). To identify hospitals located in thinly populated rural areas, we propose to use the Urban Influence Codes, a 9-category measure developed by the U.S. Department of Agriculture. These Codes rank all U.S. counties, ranging from 1 for large, densely populated metropolitan counties to 9 for the most remote, sparsely populated counties. This definition takes into account each county's largest city or town and its proximity to counties with large urban areas. We propose to accept an 8-level and 9-level Urban Influence Code for purposes of this provision. An 8-level code is a county not adjacent to a metropolitan area, but has a town with a population of 2,500 to 9,999. A 9-level is a county not adjacent to a metropolitan area, with no place greater than a population of 2,500. A list of the Urban Influence Codes is available on the United States Department of Agriculture website at the following address: <http://www.econ.ag.gov/briefing/rural/data/urbinfl.txt>. We believe an 8 or 9-level reflects a degree of rurality to sufficiently target hospitals located in extremely remote areas that may need the flexibility in the bed definition to accommodate potentially significant fluctuations in patient census.

To assure that hospitals possess the unique characteristics of significant fluctuations in its average daily census, we are proposing a specific fluctuation threshold for patient census at or above 150 percent of the lowest monthly average daily census. We believe this demonstrates a degree of fluctuation sufficient to warrant an alternative definition of hospital bed size.

This proposed alternative definition for the aforementioned hospitals would recognize the needs of extremely rural hospitals with an average daily census of 40 or less to carry a larger number of available beds in order to address seasonal fluctuations. Absent seasonal fluctuations in patient census, it would be reasonable to expect a hospital with an average daily census of 40 acute care inpatients to require no more than 50 beds to meet random fluctuations in patient census. A hospital seeking an exception on this basis would have to submit with its cost report a summary by month of its average acute care census. This alternative definition should afford every RHC that was truly targeted—clinics of sole community hospitals located in sparsely populated rural areas—an opportunity to receive an exception to the RHC payment limit.

### C. Staffing Requirements

#### Practitioners Available 50 Percent of the Time

Under our current regulations at § 491.8(a)(6), a nurse practitioner or physician assistant 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 1989 amended the staffing requirements for an RHC, described in section 1861(aa)(2)(J) of the Act, to require that a nurse practitioner, physician assistant, or certified nurse midwife be available to furnish patient care services at least 50 percent of the time the RHC operates.

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

#### Temporary Staffing Waiver

As noted, section 1861(aa)(2)(J) of the Act requires an RHC to have a nurse practitioner, physician assistant, or certified nurse midwife available to furnish patient care services at least 50 percent of the time the clinic operates. In addition, clause (iii) of the second sentence of section 1861(aa)(2) of the Act requires an RHC to employ a nurse practitioner or physician assistant. Section 1861(aa)(7) requires us to waive one or both of these requirements for a 1-year period, if the facility has been unable, despite reasonable efforts, to hire a nurse practitioner, physician assistant, or certified nurse midwife in the previous 90-day period. Before the BBA, temporary staffing waivers were available both to RHC applicants and participating RHCs. However, section 4205(c)(1) of the BBA amended section 1861(aa)(7)(B) of the Act to limit waivers to RHCs that have been found qualified for Medicare participation. Therefore, we would amend our regulations at § 491.8 to provide that only currently participating RHCs (not facilities applying for participation) are eligible for this waiver.

#### Procedures

We would also amend § 491.8 to include procedures for when the waiver expires. We would terminate an RHC from participation in the Medicare program if the RHC has not recruited the required mid-level practitioner. We would notify the RHC 15 days before the termination date, which cannot be earlier than the day after the waiver expires.

### Six-month Interim Period

Section 1861(aa)(7)(B) of the Act prohibits the Secretary from granting a waiver if the RHC requests the waiver before 6 months after the expiration of any previous waiver has elapsed. During this interim 6-month period, some facilities with physicians or other medical personnel who are authorized to furnish Part B services outside of the RHC setting and to bill Medicare on a fee-for-service basis may choose to continue operations, while other facilities may choose to cease operations.

#### Subsequent Waivers

The granting of a waiver under § 491.8(d) in the past would not preclude the granting of subsequent waiver requests if a waiver again becomes necessary. There would be no limit to the number of staffing waivers that a participating RHC would be able to obtain as long as the subsequent waiver is requested no earlier than 6 months after the expiration of the previous waiver and the clinic demonstrates it has made a reasonable effort over the previous 90-day period to hire the required staff.

### D. Commingling

#### Proposed Policy

In order to achieve a clear distinction between an RHC and another entity when the RHC is open to furnish services, and in order to remove opportunities for duplicate billing and payments, we propose to prohibit the use of RHC space, professional staff, equipment, and other resources by another health care professional. This would mean that physicians, nonphysician practitioners, and mental health professionals (clinical psychologists and clinical social workers) cannot bill Part B for payment for their services furnished in RHC space when the RHC is open to furnish services to its patients.

Our proposal would prohibit these health care professionals from using RHC space, staff, supplies, records, and other resources to conduct a private Medicare practice. However, physicians, nonphysician practitioners, and mental health professionals can bill Part B as long as they clearly separate their private practices from RHC hours of operation.

To assure that all RHC services furnished by the clinic are billed as RHC services, we propose to revise § 405.2401(b) of our regulations, "Scope and definitions," to clarify that the term "rural health clinic" means, in part, a facility that, in addition to filing an



agreement with us to furnish RHC services under Medicare and being approved as a Medicare RHC it is not operated simultaneously with, and does not share professional staff, space, supplies, records, and other resources with another entity.

#### Problems With Commingling

Both independent and provider-based RHCs must meet the RHC staffing requirements in section 1861(aa)(2)(J) of the Act. The statute requires a nonphysician practitioner to be present in the RHC to furnish services more than 50 percent of the time the clinic is open. Providers that routinely reassign RHC mid-level practitioners to other parts of the provider risk failure of meeting the RHC staffing requirements. Also, when RHC professionals and other resources are shared, they are not available to the RHC. Therefore, the RHC is no longer meeting the Medicare participation requirements. A complaint investigation, undertaken by a Medicare State survey agency, could find an RHC deficient. That deficiency could result in the termination of the RHC's Medicare participation agreement if the RHC does not resolve the deficiency quickly.

When RHC staff members use RHC space and resources to conduct a private practice, Medicare could provide two payments for the administrative cost of services furnished by a particular staff member who had simultaneous assignments. We do not want to continue an environment in which duplicate payments could result, because the cost, both direct and indirect, for professional services is included in setting the RHC payment rate. We believe that the Congress never intended to provide opportunities for RHCs to shift between functioning as RHCs and as other entities, such as private physician practices, merely to achieve higher payment.

We studied several proposals to address the consequences of commingling because we do not believe it is consistent with the statute and often lends itself to abusive, fraudulent practices. It is an intolerable situation that requires action on our part to eliminate its effects. If commingling is not eliminated, incorrect and duplicate payments could continue to be made to RHCs and physicians.

The beneficiary is disadvantaged when commingling occurs. When the physician's billing decisions for services are based on which Medicare payment for the services is higher (the RHC's all-inclusive rate, or the amounts payable under the non-RHC Part B payment provisions), the result is an inflated

Medicare payment and an inflated coinsurance amount charged to the beneficiary.

Commonly, RHCs maintain a unit record for each patient, but patient visits to the RHC and to the physician practice are not well differentiated. By combining patient records, these RHCs call into question the correctness of their payments, the proper maintenance of records as required by § 491.10(a), and the appropriateness of payment to the physician.

#### Exception to Commingling

Although we believe strong action is needed, we want to make sure our proposed policy does not create hardship for physicians and patients in rural underserved communities, such as frontier areas with limited medical resources. Therefore, with sufficient documentation allocating costs associated with the sharing of staff, we propose offering critical access hospitals the option to share common staff between the RHC and the emergency room. We believe this exception is necessary because recruitment of physicians into rural communities is very difficult. An isolated community often does not have the ability to hire and maintain a sufficient number of practitioners to staff both the RHC and emergency room simultaneously within a critical access hospital. We are also inviting the public to offer additional suggestions regarding how to address the negative effects of commingling.

#### Cost Reports

To assure that physicians clearly separate their private practices from the RHC, we have revised the Medicare cost report for independent and provider-based clinics to collect information that may be used by the fiscal intermediary to determine if commingling exists at an approved RHC. This will help assure that RHCs do not claim the cost of services that Medicare is paying for outside the RHC payment system. This cost report information, which includes describing any other entity that occupies RHC space and hours of operation, would alert the fiscal intermediary to the existence of possible commingling and allow the fiscal intermediary to determine if it should examine the costs reported in more detail.

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

During the last decade, the health care industry has moved beyond the problem-focused approach of quality assurance in favor of focusing on systemic quality improvement. We have

followed suit. Our revised approach to our quality assurance responsibilities is linked closely both to the Administration's commitment to reinventing government. Our revised quality initiatives are now focused on stimulating improved health outcome and patient satisfaction. To achieve this objective, we are now developing revised requirements for several health care providers; that is, hospitals, hospices, end-stage renal disease facilities, and home health agencies. These requirements are directed at improving outcomes of care and satisfaction for patients while eliminating unnecessary procedural requirements. This was, largely, the impetus for the revised legislation concerning requiring a quality improvement program for RHCs discussed above.

A quality assessment and performance improvement (QAPI) program should be based on a continuous, proactive approach to both managing the RHC and improving outcomes of care and satisfaction for patients.

Instead of continuing to prescribe the structure and processes by which an RHC evaluates its services, we have identified the outcome expected of an RHC that assesses its performance and improves the services that it provides to beneficiaries. For this condition of certification, we are proposing to eliminate structural or process-oriented requirements that we believe are no longer necessary (such as prescriptive details concerning policies and procedures, reviewing medical records, etc.). At this time, we are not making changes to all of part 491 to make it outcome oriented. Maybe, in the future, we will change all of part 491 to focus on outcomes.

A recent study of the Institute of Medicine (IOM) of the National Academies discussed medical errors as one of the nation's leading causes of death and injury. The study estimated that more people die from medical errors each year than from highway accidents, breast cancer, or autoimmune deficiency syndrome. We have been concerned about medical errors for some time and are exploring how to address this issue through our rulemaking process.

We want to make it clear that the requirements of QAPI set forth in this proposed rule for RHCs will address the issues of measuring and prioritizing the medical errors of underuse, overuse, and misuse. These issues are clearly concerns of the public, healthcare providers, and others, as highlighted by the IOM study. RHCs will be required to



develop and implement programs that will foster continuous and proactive approaches to discovering and prioritizing opportunities to improve patient outcomes. Medical errors would clearly be a priority area for improvement actions.

We are proposing to replace the current requirements in § 491.11 with the proposed QAPI condition that contains three standards: the first addresses the components of a performance improvement program; the second addresses monitoring performance activities; and the third addresses program responsibilities.

#### Clinical Effectiveness

The first proposed standard charges each RHC with the responsibility to carry out a performance improvement program of its own design to improve the quality of care furnished to its patients. Each clinic would have to develop, implement, maintain, and evaluate an effective, data-driven, QAPI program based on its individual needs and resources. This requirement would stimulate an RHC to monitor and improve its own performance continuously and to be responsive to the needs and desires of its patients to ensure their satisfaction. The program would be required to reflect the complexity of the RHC's organization and services. We believe that the gathering and reviewing of data are important steps in the process to improve the quality of services provided to beneficiaries of the Medicare and Medicaid programs. As a result of the evaluation of improvement measures, RHCs would be able to support the sharing of best practices among their peers.

The RHC's QAPI program should achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical services that can be expected to affect the population it serves. With an effective QAPI program, the RHC would, on a continuous basis, be able to identify and reinforce activities that it is doing well and identify and respond to opportunities for improvement.

We would not prescribe the structures and methods for implementing this requirement and would focus the condition for certification on the expected results of the program; that is, improved quality of care. This would provide flexibility to the RHC, as it would be free to develop a creative program that meets the RHC's needs and reflects the scope of its services.

**Key Elements.** The RHC should develop its program that meets the

RHC's needs (and reflects the scope of its services) with four key elements in mind:

- Identify and prioritize opportunities to improve health status and health care.
- Conduct intervention(s) developed to target specific populations.
- Include documentation of results.
- Identify additional opportunities to improve health status and health care.

We would require that an RHC set priorities for performance improvement based on the prevalence and severity of identified problems. Of course, we expect that an RHC would immediately correct problems that are identified through its quality assessment and performance improvement program that actually or potentially affect the health and safety of patients. For example, if a clinic's QAPI process identifies problems with accuracy of medication administration, it would not be enough for the clinic to consider this area a candidate for an improvement program that may or may not be chosen from a priority list of potential projects. Rather, since accuracy of medication administration is critical to the health and safety of patients, the clinic would have to intervene with a correction and improvement program immediately. Overall, a clinic would be expected to give priority to improvement activities that most affect clinical outcomes.

**Critical Areas.** Specifically, we would require that an RHC objectively evaluate the following areas that we believe are critical to an RHC's performance:

#### Domain 1. Clinical Effectiveness

- **Appropriateness of Care.** This area evaluates the appropriateness of care provided to the patients. That is, it evaluates whether needed tests, procedures, treatment, and services are provided to a patient in a timely and appropriate manner.
- **Prevention.** There are no requirements for the provision of preventive health services for an RHC. However, if these services are provided, there should be continuous evaluation of the areas as part of the clinic's QAPI program. Preventive health services may include medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, perinatal services, well-child services, preventive health screenings, immunizations, and voluntary family planning services.

#### Domain 2. Access to Care

Access is a multifaceted concept that encompasses transportation and geographic location, outreach, cultural relevance, financial barriers, patient

acceptance, and convenient practice hours. By identifying quality concerns and the development of corrective actions in this area, it is anticipated that access to covered services would improve. Also, patient satisfaction should increase.

- **Availability and Accessibility.** The RHC would have to assure that all services are available (that is, it has employed appropriately qualified practitioners and providers) and that these practitioners and providers have sufficient capacity to make services available to the patient population. The RHC would also have to ensure accessibility: that is, patients could obtain available services in a timely fashion, with consideration of travel time, waiting time, and potential access barriers for special populations, such as the disabled or non-English speaking members.

- **Cultural Competency.** This includes the attainment of knowledge, skills, and attitudes that enable administrators and practitioners within systems of care to provide and support effective health care delivery for diverse populations. Focuses for Domain 2 could include: decreasing the waiting times when appointments are scheduled and after arriving at the clinic; improving the access rates for patients with chronic disorders or patients with special needs; examining the effectiveness of an outreach program for a specific population; identifying current and potential barriers to care; evaluating staffing needs to ensure service availability.

- **Emergency Intervention.** An RHC is required to provide medical emergency procedures as a first response to common life-threatening injuries and acute illnesses. The definition of first response is service that is commonly provided in a physician's office. There are no specific requirements for an RHC to directly provide on call coverage. However, the RHC would have to arrange for access to care; that is, referral to a hospital outpatient department. Therefore, focuses could include follow-up activities to examine the effectiveness of the initial assessment and treatment.

#### Domain 3. Patient Satisfaction

Soliciting feedback from patients on the quality of care they receive (including complaints and grievances) is not only reflective of good patient care, but it is also a sound business practice.

Quality of care can typically be categorized in two ways: perceived and technical. We have discussed the technical aspects of measuring quality in the section "Clinical Effectiveness."

Perceived quality deals with the assessment of quality as experienced by the patient. Patients often base their satisfaction on how well they were treated by the staff—the amount of time spent waiting to be seen, and the time and attention given to their concerns.

The clinic could utilize a standardized survey instrument for purposes of determining whether the patients served by the clinic are satisfied with the care received, or they may design their own survey instrument. Elements in the survey should capture—

Access, communication and interaction with health care professionals;

- Continuity and coordination of care;
- Preventive care (where applicable);
- Paperwork burden on the patient;
- Complaints and grievances;
- Utilization of health services;
- Health status; and
- Respondent characteristics.

Information collected could be used to improve quality of care or adjust practice patterns to better meet the needs of the patient.

#### Examples of a Quality Improvement Project

We want to assure RHCs, especially clinics that are operating with a limited staff and resources, that our expectations for the use of performance measures are commensurate with the size and resources available to the clinic. Effective improvement programs can be and are often premised on simple, straightforward designs, using measures that are direct and uncomplicated. For example, a patient satisfaction survey could be used to evaluate whether the clinic should alter practice hours to accommodate patients that need evening appointments.

We are not proposing specific language for a minimum level in the regulation text at this time because we recognize that there are many ways in which such a level can be set. We are inviting comments on the best approaches to achieve this minimum level of effort for clinics that currently do not have a performance improvement program and have limited resources to develop a QAPI program.

Among the possible alternatives that we are considering are the following:

- Require RHCs to engage in an improvement project in each domain annually.
- Require a minimum number of improvement projects (for example, two) in any combination of the domains annually. Require a minimum number of projects annually based on patient

population (for example, three projects for every 1,000 patients).

- Rather than requiring a minimum number of projects, require RHCs to demonstrate to the survey agency what projects they are doing and what progress is being achieved.

We are certain there are other ways to approach the “minimum-effort” discussion. The purpose of these examples is to elicit comment and suggestions in this regard, and we welcome alternative approaches. We note that although our intention is to specify in the final rule a minimum level of effort, it is also possible that, after reviewing all the comments, we may conclude that it is neither feasible nor desirable to do so.

#### Monitoring Performance Activities

The second standard proposed at § 491.11(b) states that, for each of the areas listed under standard (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. These measures must be shown to be predictive of desired outcomes or be the outcomes themselves.

When we use the word “measure,” we mean that the RHC would have to use objective means of tracking performance that enables a clinic (and a surveyor) to identify the differences in performance between two points in time. For example, we would not consider a clinic’s subjective statement that it is “doing better” in a given performance area as a result of an improvement process to be an acceptable measure. We would require identifiable units of measure that a reasonably knowledgeable person would be able to distinguish as evidence of change. Not all objective measures would have to be shown to be valid and reliable (that is, subjected to scientific rigor) in order to be usable in improvement projects, but they would have to at least identify a start point and an end point stated in objective terms, most often, numbers that actually relate directly to the objectives and expected or desired outcomes of the improvement project.

#### Program Responsibilities

Under the third proposed standard, § 491.11(c), we are proposing 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. The RHC would have to prioritize areas of improvement, considering prevalence and severity of

identified problems and giving priority of improvement to those activities that affect clinical outcomes.

We anticipate that both large and small RHCs will use a variety of performance measures in their QAPI program. These measures may be designed by the clinic itself or by other sources outside the RHC. Regardless, HCFA intends, through its survey process, to assess the clinic’s success in collecting data on its operation and measuring quality. Each clinic’s professional staff should use its judgement, which is supported by nationally approved standards, practices and reviews of current professional literature, to evaluate the quality of care performed in the clinic. The survey process would focus on the clinic’s ability to demonstrate that it has developed a viable quality assessment and performance improvement program. Also, the clinic should be able to prove with objective data that sustained improvements have taken place in (1) actual care outcomes, patient satisfaction levels, and access to care; and/or (2) processes of care and clinic operations that are predictive of improved outcomes of care and satisfaction for patients. HCFA does not intend and would not be in a position to judge the measures themselves; instead, we would assess their utility for the clinic in its own efforts to improve its performance. As part of oversight, we would expect RHCs to make information on their QAPI program available for surveyors during initial certification, routine recertification, and complaint surveys to demonstrate how they meet the requirement.

#### III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

### *Section 491.3 Rural Health Clinic (RHC) Procedures*

Section 491.3(c)(2) states that an existing RHC located in an area no longer considered a shortage area may apply for an exception from disqualification by submitting a written request to the HCFA regional offices within 90 days from the date HCFA notifies it that it is no longer located in a shortage area. We believe that this information collection requirement is exempt in accordance with 5 CFR 1320.4(a)(2) since this activity is pursuant to the conduct of an investigation or audit against specific individuals or entities.

### *Section 491.8 Staffing and Staff Responsibilities*

Section 491.8(d)(1) states that HCFA may grant a temporary waiver if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

The burden associated with this requirement is the time and effort for the RHC to request a waiver and demonstrate that it has been unable to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates. It is estimated that this requirement will take each RHC 3 hours. There are approximately 45 RHCs that will be affected by this requirement for a total of 135 burden hours.

Section 491.11 *Quality Assessment and Performance Improvement* states that the RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement program. The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate clinical effectiveness, access to care, patient satisfaction, and utilization of clinical services, including at least the number of patients served and the volume of services.

Most of the burden of this section is covered by the paperwork requirements of § 491.9(b)(3), patient care policies, which requires the RHCs to have in place a description of services the clinic furnishes, guidelines for management of

health problems, and procedures for periodic review and evaluation of clinic services. This burden is approved under 0938-0334 and expires in April, 2000.

To maintain the data required by § 491.11, we estimate it will take each clinic one hour per year to meet this requirement. Since there are an estimated 3,528 facilities, the total burden associated with this requirement is 3,528 annual hours.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration,  
Office of Information Services,  
Security and Standards Group,  
Division of HCFA Enterprise  
Standards, Room NO-14-26, 7500  
Security Boulevard, Baltimore, MD  
21244-1850, ATTN.: Louis Blank,  
HCFA-1910-P; and  
Office of Information and Regulatory  
Affairs, Office of Management and  
Budget, Room 10235, New Executive  
Office Building, Washington, DC  
20503, ATTN.: Allison EDT, HCFA  
Desk Officer

## **IV. Response to Comments**

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

## **V. Regulatory Impact Statement**

### *Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small

businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all RHCs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any proposed rule that may result in an expenditure in any one year by State, local, or tribal government, in the aggregate, or by the private sector of \$100 million. The proposed rule would not have an effect on the governments mentioned, and private sector costs would be less than the \$100 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule would not have an effect on the governments mentioned.

Although we view the anticipated results of these proposed regulations as beneficial to the Medicaid and Medicare programs as well as to Medicaid recipients and Medicare beneficiaries and State governments, we recognize that some of the provisions could be controversial and may be responded to unfavorably by some affected entities. We also recognize that not all of the potential effects of these provisions can definitely be anticipated, especially in view of their interaction with other Federal, State, and local activities regarding outpatient services. In particular, considering the effects of our simultaneous efforts to improve the delivery of outpatient services, it is impossible to quantify meaningfully a projection of the future effect of all of these provisions on RHC's operating costs or on the frequency of substantial

noncompliance and termination procedures.

We believe the foregoing analysis concludes that this regulation would not have a significant financial impact on a substantial number of small entities, such as RHCs. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

#### *Anticipated Effects*

##### *Effects on Rural Health Clinics*

The total number of participating RHCs under Medicare and Medicaid as of March 1, 1998, was 3,528. Participating RHCs that are no longer located in rural, underserved areas could lose their RHC status and their cost-based reimbursement, which could cause them to reduce services or discontinue serving our beneficiaries. To minimize the impact of this provision on rural health care, the Congress has authorized us to grant, if needed, an exception to clinics essential to the delivery of primary care in these affected areas. Our proposed criteria in § 491.3 would identify the areas and clinics where RHC status and its payment methodology would still be needed despite the fact the service area is no longer considered medically underserved.

Implementing the statutory requirement to replace the current payment method used by provider-based RHCs to the payment method used by independent RHCs will establish payment equity and consistency within the RHC program. Before the BBA, payment to provider-based RHCs was made without considering the number of patient visits provided by the RHC without a limit on the payment per visit. These criteria are applicable to independent RHCs that furnish the same scope of services. Our proposal to codify the statutory requirement to pay all RHCs under an all-inclusive rate per visit also would avoid allocation of excessive administration costs to RHCs. We believe that about a thousand RHCs would be affected by this proposal.

We believe the fiscal impact of limiting payment to provider-based RHCs to the independent RHC rate per visit will result in program savings. Provider-based RHCs that have costs above the all-inclusive cost-per-visit limit required by the law could experience some decrease in their current reasonable cost basis payments. To reduce detrimental impacts of this decrease, the Congress authorized an exception to the annual payment limit

to those clinics affiliated with small rural hospitals; that is, a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This QAPI requirement may increase burden in the short term because resources would have to be devoted to the development of a quality assessment and performance improvement program that covers the complexity and scope of the particular clinic. However, while the proposed requirements could result in some immediate costs to an individual clinic, we believe that the QAPI program will result in real, but difficult to estimate, long-term economic benefits to the clinic (such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

Moreover, we are proposing that the QAPI and utilization review requirements replace the current annual evaluation requirement. Resources that the clinics are currently using for the annual evaluation could be devoted to the QAPI program. Therefore, we believe that there would be no long-term increased burden to the clinics. Currently, a number of RHCS, primarily provider-based, have some type of quality improvement program in place. To the extent that clinics are familiar with collecting data on their operations and measuring quality, the new requirement would not be perceived as a burden.

OBRA 1989 reduced the nonphysician staffing requirement for RHC qualification from 60 percent to 50 percent. This reduction should have a positive effect on RHCs by providing them more flexibility in satisfying their overall staffing needs.

##### *Effects on Other Providers*

We are aware of situations in which an RHC and a physician's private practice occupy the same space and Medicare is billed for the service, either as an RHC or physician service, depending upon which payment method produces the greater payment. Our proposed revision would require an RHC to be a distinct entity that is not used simultaneously as a private physician office or the private office of any other health care professional. As a result, a private physician or other practitioner who has used this approach to take advantage of the Medicare program may experience some change in the operation of their practices from an administrative standpoint.

##### *Effects on the Medicare and Medicaid Programs*

As a result of this proposed rule, most provider-based RHCs would be subject to payment limits and some RHCs would lose their RHC status and cost-based payment rates. Although these proposed changes would likely result in program savings, we believe the aggregate amount would be negligible for both programs. We cannot accurately estimate the payment differential between the new payment system for provider-based RHCs and the previous payments because the old system made payments without considering the number of patient visits. Without these data, we cannot precisely determine the fiscal impact.

However, in light of the fact that total expenditures for this program represent a small fraction of the Medicare and Medicaid's total budget and that less than half of all RHCs would experience changes to their payment rates, we believe any aggregate savings would be insignificant. We also believe an insignificant amount of Medicare and Medicaid program savings would result from the proposed provision that would terminate RHC status for certain providers. Less than 5 percent of all participating RHCS could lose their status, and these affected clinics would continue to participate under Medicare and Medicaid and receive payment for their services on a fee-for-service basis.

##### *Alternatives Considered*

Section 4205 of the BBA imposes new requirements that an RHC program must meet. We considered some of the following alternatives to implement these provisions:

*"Essential" RHCs.* Since the statute mandates an exception process for essential clinics, we considered using a national utilization test to recognize clinics that are accepting and treating a disproportionately greater number of Medicare, Medicaid, and uninsured patients, compared to other participating RHCs, for the purpose of addressing the situation of RHC clusters. For example, using an aggregate threshold based on the average Medicare, Medicaid, and uninsured utilization rates of participating RHCs, applicants would have to demonstrate that their utilization rates exceed the threshold.

Although the test would be administratively feasible, we concluded, based on our analysis of available Medicare and Medicaid RHC data, that it would not accurately determine "essential" clinics at the community level because of the wide variability in

the percentage of services furnished to Medicare and Medicaid patients by RHCs. Despite our rejection of a national utilization test, we are open to suggestions on developing a minimum national percentage, which could be integrated with our proposed major community provider test.

**QAPI Program.** Because the statute mandates that an RHC have a QAPI program, and appropriate procedures for review of utilization of clinic services, no alternatives for the requirement were considered. However, in the preamble section we have proposed alternative ways of satisfying the "minimum level requirement" for the QAPI program and have asked for comments. Among the alternatives that we are considering are the following:

- Require RHCs to engage in an improvement project in each domain annually.
- Require a minimum number of improvement projects in any combination of the domains annually.
- Require a minimum number of projects annually based on patient population.
- Rather than requiring a minimum number of projects, require RHCs to demonstrate to the survey agency what projects they are doing and what progress is being achieved.

#### Conclusion

We would not expect a significant change in the operations of RHCs generally, nor do we believe a substantial number of small entities in the community, including RHCs and a substantial number of small rural hospitals, would be adversely affected by these proposed changes. The commingling provision of this regulation adds little savings. One reason for this conclusion is that the outpatient visit rate for HCPC 99214 was about \$59.00 and the RHC visit was also about \$59.00. Therefore, if an adjustment made for lower physician overhead than that of the RHC, the savings would probably be marginal.

Therefore, we are not preparing analyses for either the regulatory impact analysis or section 1102(b) of the Act since we believe that this proposed rule would not result in a significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. We solicit public comments on the extent to which any of the entities would be significantly economically affected by these provisions.

In accordance with the provisions of Executive Order 12866, this regulation

was reviewed by the Office of Management and Budget.

#### List of Subjects

##### 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

##### 42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, 42 CFR chapter IV would be amended as set forth below:

#### PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

##### Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

1. The authority citation for part 405, subpart X, continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 405.2401(b), the definition of "rural health clinic" is revised to read as follows:

##### § 405.2401 Scope and definitions.

\* \* \* \* \*

##### (b) Definitions.

\* \* \* \* \*

*Rural health clinic (RHC)* means an entity that meets the following criteria:

(1) It does not share space, professional staff, supplies, records, and other resources during RHC hours of operation with a private physician's office or the office of any other health care professional. RHCs physically located on the same campus of a critical access hospital have the option of sharing common staff between the RHC and the emergency room.

(2) It has filed an agreement with HCFA that meets the basic requirements described in § 405.2402 to furnish RHC services under Medicare.

(3) HCFA has determined that the entity meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

\* \* \* \* \*

3. Section 405.2410 is revised to read as follows:

##### § 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible. Medicare applies the Part B deductible as follows:

(i) If the deductible has been fully met by the beneficiary before the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible has not been fully met by the beneficiary before the visit and the amount of the RHC's reasonable customary charge for the service that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC; or

(B) Equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(2) Medicare payment for FQHC services is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for the coinsurance amount that cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service.

(2) The beneficiary's deductible and coinsurance liability, with respect to any one service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular service.

(3) For any one service furnished by an FQHC, the coinsurance liability may not exceed 20 percent of reasonable amount customarily charged by the FQHC for that particular service.

4. Section 405.2462 is revised to read as follows:

##### § 405.2462 Payment for rural health clinic services and Federally qualified health clinic services.

(a) *General rules.* (1) RHCs and FQHCs are paid on the basis of 80 percent of an all-inclusive rate per visit determined by the fiscal intermediary for each beneficiary visit for covered services, subject to an annual payment limit.

(2) The fiscal intermediary determines the all-inclusive rate in accordance with this subpart and instructions issued by HCFA.

(3) If an RHC is an integral and subordinate part of a rural hospital, it can receive an exception to the per-visit payment limit if its rural hospital is not located in a metropolitan statistical area as defined in § 412.62(f)(1)(ii)(A) of this chapter and has fewer than 50 beds as determined by using one of the following methods:

(i) The definition at § 412.105(b) of this chapter.

(ii) The hospital's average daily patient census count of those beds described in § 412.105(b) of this chapter and the hospital meets all of the following conditions:

(A) It is a sole community hospital as determined in accordance with § 412.92 of this chapter.

(B) It is located in an 8-level or 9-level nonmetropolitan county using Urban Influence Codes as defined by the U.S. Department of Agriculture.

(C) It has an average daily patient census that does not exceed 40.

(D) It has significant fluctuations in its average daily census to the extent that the average daily census for 1 or more months is at least 150 percent of the lowest monthly average daily census.

(b) *Payment procedures.* To receive payment, an RHC or FQHC must follow the payment procedures specified in § 410.165 of this chapter.

(c) *Mental health limitation.* Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in § 410.155(c) of this chapter part 491.

## PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

1. The authority citation for part 491 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 491.2 is revised to read as follows:

### § 491.2 Definition of shortage area for RHC purposes.

*Shortage area* means a geographic area that meets one of the following criteria. It has been:

(a) Designated by the Secretary as an area with shortage of personal health services under section 330(b)(3) of the Public Health Service Act;

(b) Designated by the Secretary as a health professional shortage area under section 332(a)(1)(A) of that Act because of its shortage of primary medical care professionals;

(c) Determined by the Secretary to contain a population group that has a health professional shortage under 332(a)(1)(B) of that Act; or

(d) Designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

3. Section 491.3 is revised to read as follows:

### § 491.3 RHC procedures.

(a) *General.* (1) HCFA processes Medicare participation matters for RHCs

in accordance with §§ 405.2402 through 405.2404 of this chapter and with the applicable procedures in part 486 of this chapter.

(2) If HCFA approves or disapproves the participation request of a prospective RHC, it notifies the State Medicaid agency for that RHC.

(3) HCFA deems an RHC that is approved for Medicare participation to meet the standards for certification under Medicaid.

(b) *Current designation.* Applicants requesting entrance into the Medicare program as an RHC must be located in a current shortage area, whose designation has been made or updated within the current year or within the previous 3 years.

(c) *Exception process.* (1) An RHC's location fails to satisfy the definition of a shortage area if it is no longer designated by the Secretary or by the chief executive officer of the State as medically underserved.

(2) An existing RHC may apply for an exception from disqualification by submitting a written request to the HCFA regional office within 90 days from the date HCFA notifies it that it is no longer located in a shortage area. The request must contain all information necessary to establish whether an exception is warranted.

(3) Based on its review of an RHC request, and other relevant information, if the HCFA regional office determines that the RHC is essential to the delivery of primary care services that otherwise would not be available in the geographic area served by the RHC, consistent with § 491.5(b), the HCFA regional office may grant a 3-year exception to the RHC.

(4) HCFA terminates an ineligible clinic from participation in the Medicare program as an RHC 90 days after HCFA notifies the clinic of its ineligibility under this section.

4. In § 491.5, paragraphs (d) and (e) are removed, paragraph (f) is redesignated as paragraph (d), and paragraph (b) is revised to read as follows:

### § 491.5 Location of clinic.

\* \* \* \* \*

(b) *Exceptions.* If HCFA determines that the RHC has established that it is essential to the delivery of primary care that otherwise would not be available in the geographic area served by the RHC, HCFA does not disqualify the RHC approved for Medicare participation if the area in which the RHC is located no longer meets the definition of a shortage area. HCFA makes this determination when the RHC meets one of the following conditions:

(1) *Sole community provider.* The RHC is the only participating primary care provider within 30 minutes travel time. For purposes of this exception, a participating primary care provider means an RHC, an FQHC, or a physician practicing in either general practice, family practice, or general internal medicine that is actively accepting and treating Medicare beneficiaries and Medicaid recipients. RHCs applying for an exception under this test must demonstrate that they accept Medicare (where applicable), Medicaid, and uninsured patients that present themselves for treatment. HCFA uses the following criteria in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available—20 miles.

(ii) In areas with only secondary roads available—15 miles.

(iii) In flat terrain or in areas connected by interstate highways—30 miles.

(2) *Traditional community provider.* RHC is the only participating RHC within 30 minutes travel time and is actively accepting and treating Medicare, Medicaid, and uninsured patients. HCFA does not grant an exception under this test if the RHC's service area (30 minutes travel time) has two or more participating primary care providers that have been actively treating Medicare beneficiaries and Medicaid recipients for a minimum of 5 years. For purposes of this exception, a primary care provider means an FQHC or a physician practicing in either general practice, family practice, or general internal medicine.

(3) *Major community provider.* The RHC is treating a disproportionately greater share of Medicare, Medicaid, and uninsured patients compared to other participating RHCs that are within 30 minutes travel time.

(4) *Specialty clinic.* The RHC is the sole clinic that provides pediatric or obstetrical/gynecological services and actively serves Medicare (where applicable), Medicaid, and uninsured patients.

(5) *Graduate medical education test.* The RHC is actively part of an approved medical residency training program as defined in §§ 413.86 and 405.2468(f) of this chapter.

\* \* \* \* \*

4. In § 491.8, paragraph (a)(6) is revised and a new paragraph (d) is added to read as follows:

### § 491.8 Staffing and staff responsibilities.

(a) \* \* \*

(6) A physician, nurse practitioner, physician assistant, nurse-midwife,

clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

\* \* \* \* \*

(d) *Temporary staffing waiver.* (1) HCFA may grant a temporary waiver of the RHC staffing requirements in paragraphs (a)(1) and (a)(6) of this section for a 1-year period to a qualified RHC, if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

(2) If the RHC is not in compliance with the provisions waived under paragraph (a)(1) and paragraph (a)(6) of this section at the expiration of the waiver, HCFA terminates the RHC from participation in the Medicare program.

(3) The RHC may submit its request for an additional waiver of staffing requirements under this paragraph no earlier than 6 months after the expiration of the previous waiver.

5. Section 491.11 is revised to read as follows:

**§ 491.11 Quality assessment and performance improvement.**

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The program must be appropriate for the level of complexity of the RHC's organization and services. The program should achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical services.

(a) *Standard: Components of a QAPI program.* (1) The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(i) Clinical effectiveness (for example, appropriateness of care, and prevention).

(ii) Access to care (for example, availability and accessibility of services, cultural competency, and emergency intervention).

(iii) Patient satisfaction.

(iv) Utilization of clinic services, including at least the number of patients served and the volume of services.

(2) Projects that focus on clinical areas should include, at a minimum, high-volume and high-risk services, the care of acute and chronic conditions, and coordination of care.

(3) Projects that focus on nonclinical services should include, at a minimum, criteria to measure convenience and

timeliness of available services and grievances and complaints.

(b) *Monitoring performance activities.* For each of the areas listed in paragraph (a)(1) of this section, the RHC must adopt or develop performance criteria that reflect processes of care and RHC operations. The RHC must use those criteria to analyze and track its performance. These performance criteria must be shown to be predictive of desired patient outcomes or be the outcomes themselves.

(c) *Program responsibilities.* The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for ensuring that quality assessment and performance improvement efforts effectively address identified priorities. They are responsible for identifying or approving those priorities and for the development, implementation, and evaluation of improvement actions. (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 1, 1999.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

Dated: September 2, 1999.

**Donna S. Shalala,**

*Secretary.*

[FR Doc. 00-4389 Filed 2-25-00; 8:45 am]

**BILLING CODE 4120-01-P**