DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405 and 491

[CMS–1910–F]

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: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends Medicare certification and payment requirements for rural health clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA). It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limits waivers of certain nonphysician practitioner staffing requirements. This final rule imposes payment limits on provider-based RHCs and prohibits ''commingling'' (the use of the space, professional staff, equipment, and other resources) of an RHC with another entity. The rule also requires RHCs to establish a quality assessment and performance improvement program that goes beyond current regulations. Finally, this final rule addresses public comments received on the February 28, 2002 proposed rule and makes other revisions for clarity and uniformity and to improve program administration.

EFFECTIVE DATE: These regulations are effective on February 23, 2004.

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I. Background

A. General

The Rural Health Clinic Services Act of 1977 (Pub. L. 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 Pub. L. 95–210 was to address an inadequate supply of physicians to serve Medicare and Medicaid beneficiaries in rural areas. The program addressed this problem by providing qualifying clinics located in rural, medically underserved communities with payment on a cost-related basis for outpatient physician and certain nonphysician services furnished to Medicare and Medicaid beneficiaries. (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 health professional shortage area or medically underserved area as designated by the Health Resources and Services Administration or (since the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, Pub. L. 101–239, enacted on December 19, 1989), section 6213(c)) by 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 must employ a nonphysician practitioner and, to meet requirements of the OBRA '89, must 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 3,300 in early 2001. 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 (pre-BBA) RHC legislation, which included a ''grandfather clause'' to promote the development of RHCs. (See section 1(e) of Pub. L. 95–210, 42 U.S.C. 1395x *note.* Also see 42 CFR 491.5(b)(2).) Specifically, 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), is considered as still satisfying the requirement of this 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. 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 (GAO) and the Department of Health and Human Services' Inspector General (DHHS/IG) 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) (Pub. L. 105–33, enacted on August 05, 1997), the Congress responded to these recommendations by amending the grandfather provision to provide protection only to clinics essential to the delivery of primary care.

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 were not 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 were recently designated or updated will qualify for purposes of the RHC program.

Commingling

The growth of RHCs has also been stimulated by industry practices that are designed to maximize Medicare payment by obtaining RHC status for an integrated practice that submits both RHC and non-RHC Medicare claims. 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.

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 could lead to incorrect billing or duplicate payments.

Government Reports

Both the GAO and the DHHS/IG concluded that the growth of RHCs is not proportional to community need and that many RHCs no longer require cost-based reimbursement as a payment incentive. 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).

B. Legislation

Refinement of Shortage Area Requirements

Refinement of the shortage area requirements involves two phases.

1. *Phase I.* Section 4205(d)(1) and (2) of the BBA pertain to 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 (HPSA), an MUA, 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 Secretary. This BBA change will be addressed by our sister agency, the Health Resources and Services Administration (HRSA), under separate rules. 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.* Section 4205(d)(3)(A) 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

Previous to the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, enacted on November 5, 1990), an RHC was required to employ a physician assistant, nurse practitioner, or certified nurse midwife who must furnish their services 50 percent of the time the RHC operates. Section 4161(b)(2) of the OBRA added section 1861(aa)(7) to the Act to provide us with the authority to grant a 1-year staffing waiver of this requirement if the clinic can demonstrate that it has been unable, in the previous 90-day period, to hire one of these non-physician primary care providers.

Section 4205(c) of the BBA amended section 1861(aa)(7)(B) of the Act to restrict our authority to waive RHC staffing requirements. Under section 4205(c) of the BBA, a staffing waiver may only be granted to an RHC that is qualified and participating in the Medicare program.

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.

Section 4205(a) of the BBA 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.

Expanding Access to Rural Health Clinics

Under the BBA, the independent RHC all-inclusive payment methodology and annual payment limit was also used for provider-based RHCs. This BBA provision also provided an exception to the RHC payment limit for those RHCs based in small ''rural'' hospitals.

Section 224 of BIPA expanded the eligibility criteria for receiving an exception to the RHC annual payment limit, effective July 1, 2001. Specifically, this section of BIPA extends the exemption to RHCs based in small urban hospitals. Thus, all hospitals of less than 50 beds (see section 1833(f) of the Act) are now eligible to receive an exception from the per visit payment limit for their RHCs.

Payment for Certain Physician Assistant Services

Sections 4511 and 4512 of the BBA removed the restrictions on the types of areas and settings in which the Medicare Part B program pays for the professional services of nurse practitioners, clinical nurse specialists, and physician assistants. This provision also expanded the professional services benefits for nurse practitioners and clinical nurse specialists by authorizing them to bill the program directly for their services when furnished in any area or setting. However, these BBA provisions maintained the current policy that payment for physician assistant services can be made only to the physician assistant's employer regardless of whether the physician assistant is directly employed or serving as an independent contractor.

Section 4205(d)(3)(B) of the BBA amended section 1842(b)(6)(C) of the Act to provide that payment for physician assistant services may be made directly to a physician assistant under certain circumstances. As an exception to the payment requirement under the physician assistant professional services benefit, this provision permits Medicare to pay a physician assistant directly who was the owner of an RHC (as described in section 1861(aa)(2) for a continuous period beginning before the date of the enactment of the BBA and ending on the date the Secretary determines the RHC no longer meets the requirements of section 1861(aa)(2) of the Act, for those services provided before January 1, 2003).

Section 222 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) (Pub. L. 106–554, enacted on December 21, 2000) amended section 1842(b)(6)(C) of the Act to permit physician assistants who owned RHCs, and subsequently lost RHC status, to receive direct Medicare payment for their services, effective December 21, 2000. This BIPA provision eliminates the January 1, 2003 sunset date.

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.

We recognize that some RHCs are already incorporating a QAPI program into their normal operating activities. Others will begin to search for guidance in developing an appropriate QAPI program as they transition from complying with the current annual evaluation requirement. For some time now, professional and governmental organizations have been engaged in formulating guidance and in providing samples of QAPI related activities to entities interested in developing QAPI programs. In addition, state offices of rural health are excellent resources at a local level.

The Department of Health and Human Services has previously contracted with the National Association of Rural Health Clinics to develop technical assistance materials for Rural Health Clinics to provide guidance in complying with QAPI requirements. The Department, working through the Health Resources and Services Administration's Office of Rural Health Policy (*http://www.ruralhealth.hrsa.gov*), will make those materials available widely and develop other technical assistance material as needed to help RHCs make the transition to the quality requirements of the final rule.

There are additional on-line resources that offer a wide range of support services to RHCs. Some of the more well known are as follows: The Rural Assistance Center (*http://www.raconline.org*), The National Rural Health Association (http://www.nrharural.org), The Rural Policy Research Center (*http://www.rupri.org*), and The National Association for Rural Health Clinics (*http://www.narhc.org*).

We expect RHCs that have no experience with QAPI programs to take advantage of the resources that are available. RHCs are encouraged to explore a variety of resources so that they can become familiar with the variety of approaches that exist to develop a QAPI program. An RHC that chooses to implement the QAPI resources (that is, model QAPI programs) provided by the Department and other on-line resources mentioned in this regulation will be considered to meet the QAPI condition for certification (CfC) provided that the model program chosen is one that is relevant to the RHC and its patient population.

II. Provisions of the Proposed Rule

On February 28, 2000, we published a proposed rule in the **Federal Register** (65 FR 10450) to implement the BBA amendments concerning the participation of RHCs in Medicare or Medicaid programs.

Definition of Shortage Area for RHC Certification

Section 6213 of OBRA '89 amended 1861(aa)(2) of the 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 and those designated as geographic health professional shortage areas under section 332(a)(1)(A) of the PHS Act. The OBRA '89 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 (Pub. L. 104–299) renumbered section 329 of the PHS Act and repealed the requirement for designation of high migrant impact areas.

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

A. Refinement of Shortage Area Requirements

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

Eligibility for an Exception

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

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

Criteria for Exception

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

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

Traditional Community Provider. We also proposed to classify an existing RHC as essential if it is the sole RHC for its community and the only primary care provider that has traditionally served Medicare, Medicaid, and uninsured patients in the community despite the fact that there may be other primary care providers that have recently begun participating within reasonable travel time of the RHC.

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

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

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

B. Payment Limits for Provider-Based RHCs

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

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

C. Staffing Requirements

Practitioners Available 50 Percent of the Time

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

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

Temporary Staffing Waiver

We proposed to amend § 491.8 to provide that only currently participating RHCs (not facilities applying for participation) are eligible for this waiver. We also proposed to amend § 491.8 to include procedures for when the waiver expires.

D. Commingling

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

E. Quality Assessment and Performance Improvement Program

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

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

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

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

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

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

2000 proposed rule, but concerned the implementation of the proposed rule and the potential impact on RHCs financial viability and access to care. Specifically, the loss of RHC status and the cost of additional regulatory requirements on clinics could negatively impact providers, especially small clinics, and their patients.

We share the commenters' concerns with preserving access to care for Medicare and Medicaid beneficiaries and the cost impact of establishing additional regulatory requirements. However, we believe the clarifications and changes that we are making to the regulations will eliminate or significantly reduce negative impact on rural providers and their communities.

Several commenters raised issues unrelated to the provisions of this rule. In this final rule, we only address the comments pertaining to the RHC proposed rule published on February 28, 2000, in the **Federal Register** (65 FR 10450).

Scope and Definitions (§ 405.2401)

Comment: Several commenters indicated that the definition of ''shared space'' should be clarified. For example, can an RHC lease or rent to a specialist during RHC hours of operation? Also, can an independent laboratory operate within RHC space during clinic hours as long as the cost is not included on the clinic's cost report?

Response: We are revising, in § 405.2401(b), the definition of *Rural health clinic (RHC)* to state that the RHC definition applies to physicians and nonphysician practitioners working for the entity to furnish RHC services. These practitioners are prohibited from operating a private Medicare or Medicaid practice during RHC hours of operation. Therefore, a specialist and an independent diagnostic laboratory can operate practices in leased or rented space within the RHC. The RHC definition was never intended to prohibit the operation of a multipurpose facility. The operation of a multipurpose facility and the sharing of common space (for example, waiting room), staff, and other resources is permissible as long as the costs are appropriately excluded from the RHC cost report.

Comment: Several commenters indicated belief that the proposed rule would prohibit RHCs from performing nonprimary care services. The commenters suggested that we not force the provider to set up two separate facilities.

Response: As discussed above, the RHC definition was never intended to prohibit the operation of a multipurpose facility. The operation of a multipurpose facility and sharing a common space, staff, and resources is permissible as long as the costs are appropriately excluded from the RHC cost report. Therefore, in § 405.2401(b)(1), we are revising the regulation to clarify that physicians and nonphysician practitioners working for the RHC cannot operate a private Medicare or Medicaid practice during RHC hours of operation, using clinic resources.

Comment: Several commenters pointed out that problems associated with commingling should be addressed by improving cost reporting. The commenters stated that we should require the fiscal intermediaries to pay close attention to the Medicare Part B services on the Medicare cost report.

Response: We disagree with the commenters. We believe that the issue of commingling cannot be effectively addressed through the cost reports. When a practitioner who is working for an RHC shifts from patient to patient for billing Medicare and Medicaid (for example, simultaneously operates as a private practice under Medicare Part B and as an RHC under Medicare Part A), both the provider and the Medicare fiscal intermediary would have a difficult time accurately apportioning the cost associated with RHC patients. We believe the administrative burden of accurately allocating cost for the Medicare and Medicaid programs, as well as for the provider, would out weigh the benefits derived from this type of commingling.

Comment: One commenter suggested that we prohibit a single health care professional from billing both Medicare Part A and Part B in the RHC setting.

Response: Our proposed policy was established for the primary purpose of prohibiting health care professionals assigned to the RHC from billing Medicare Part B during clinic hours, using clinic resources. Therefore, we are revising proposed § 405.2401(b)(1) to clarify that physicians and nonphysician practitioners working for the RHC cannot operate a private Medicare or Medicaid practice during RHC hours of operation, using RHC space and resources.

Comment: A commenter indicated that it would be extremely difficult to conduct a pediatric practice in which publicly funded patients and privately funded patients were not treated equally in the same environment at the same time.

Response: The RHC definition prohibits physicians and nonphysician practitioners who are working for the RHC from billing fee-for-service under Medicare and Medicaid during RHC hours, using RHC space and resources. We do not intend to regulate clinic policies for privately insured patients.

Comment: A commenter suggested that we allow more flexibility in the provisions of this regulation to recognize unique rural situations. Improving or maintaining access to care in rural communities requires adaptability to local situations.

Response: RHCs should not be paid for professional and facility costs through the Medicare cost reports while its practitioners simultaneously use RHC space and resources to bill fee-for-service benefits, which include these costs. Furthermore, we believe that the clarifications and changes that we are making to this policy, based on public comments, will provide sufficient flexibility for rural clinics to address access problems within their communities.

Comment: A commenter asked us to clarify § 495.2401(b)(1) that addresses practices other than Medicare, such as Medicaid and private pay, to ensure that practitioners are able to comply with the commingling rule.

Response: The RHC definition will preclude RHC practitioners from operating private Medicare and Medicaid practices during clinic hours, using RHC space and resources.

Comment: A commenter suggested that RHCs eligible for essential provider status should be given an exception to the commingling rules.

Response: The proposed changes to the RHC definition are intended to remove opportunity to duplicate billing and payments. This concern applies to all RHCs. Therefore, all RHCs must comply with the definition as stated in § 405.2401(b).

Comment: A commenter recommended that we provide RHCs with a specific list of CPT codes that should be included in the cost report. Many RHCs provide services beyond primary care and bill these services to Medicare Part B and deduct the costs from the RHC cost report. The commenter believes that an RHC definition specifying CPT codes would resolve the current issue of commingling.

Response: We disagree with the commenter. We do not believe it is appropriate to dictate the scope of the RHC practice by creating a list of medical services that must be billed and paid for outside the RHC benefit. We would run the risk of creating either an incomplete or overly inclusive list for participating RHCs, which vary in size and scope. Moreover, to do so would be contrary to the statute and therefore unenforceable. We believe the best approach for maintaining program

integrity for the RHC benefit is to require that RHC physicians and nonphysician practitioners remain devoted to the RHC and its patients during clinic hours of operation as stated in § 405.2401(b)(1).

Comment: Several commenters suggested that an exception to the commingling rule should be granted to all rural hospitals or at a minimum to small rural hospitals with less than 50 beds. Rural hospitals, other than critical access hospitals (CAHs), experience difficulty recruiting sufficient staff to cover the RHC and emergency room simultaneously.

Response: We wish to clarify that the sharing of staff between hospital and the RHC is not commingling. We agree that any rural hospital with limited resources should be allowed to share staff between its RHC and emergency room. As discussed above, the primary purpose of § 405.2401 is to preclude physicians and nonphysician practitioners working for the RHC from operating a private Medicare or Medicaid practice during RHC hours of operation, using RHC space and resources. Therefore, it is permissible for any hospital-based RHC to share its health care practitioners with emergency rooms, as long as the clinic continues to meet RHC certification requirements and sufficient documentation is provided to allocate costs on consistent and rational basis.

Comment: A commenter expressed belief that the CAH exemption should be expanded to include rural hospitals that meet CAH requirements, but have chosen not to participate in the CAH program.

Also, several commenters suggested that in proposed § 405.2401, we should consider exempting RHCs located in extremely rural communities, such as frontier areas (less than six persons per square mile). These facilities face limitations on their available medical resources similar to CAHs.

Response: We agree that any rural hospital with limited resources should be allowed to share staff between its RHC and emergency room. We removed references to CAH and have clarified the purpose and scope of § 405.2401 to address both concerns.

Comment: Two commenters raised concerns about the necessary documentation to receive an exception to the commingling rule. The commenters suggested that the documentation should be done through the cost reports instead of through detailed practitioner logs, which can be very burdensome.

Response: We revised the regulation to clarify that any rural hospital with limited resources should be allowed to share staff between its RHC and emergency room. With regard to the documentation issue, we will delegate to our intermediaries the decisions regarding acceptable accounting methods for allocation of staff costs between the RHC and other entities to be used in this documentation. We agree that maintenance of detailed practitioner logs on an ongoing basis is very burdensome, and other alternatives exist to achieve the desired results of assuring a proper allocation of costs, on a consistent and rational basis.

Comment: Several commenters recommended that RHCs be allowed to have nonclinic providers and medical specialists in their establishments during RHC hours of operation as long as all expenses are deducted out of the cost report.

Response: We never intended to restrict or preclude these arrangements. We are revising the regulation to clarify that physicians and nonphysicians who are employed to furnish RHC services are precluded from billing fee-for-service under Medicare and Medicaid during RHC hours of operation. Medical specialists who lease or rent space from the clinic can bill for their services during the clinic's hours. RHCs are also allowed to share common space (for example, waiting room), staff, and other resources with these specialists as long as the RHC appropriately removes the costs from its cost report.

Comment: Two commenters asked us to clarify whether RHC physicians who are on-call with an emergency room would violate the commingling rule. RHC physicians who provide on-call services, as opposed to being on-duty, should be allowed under this rule. Failure to amend the regulations to clarify this issue could reduce the availability of emergency room care for many rural communities.

Response: We agree that RHC physicians who provide on-call services for an emergency room should not be considered in violation of the commingling rule. It is clearly permissible for RHC physicians to provide on-call services for an emergency room as long as the clinic continues to meet RHC certification requirements and costs are appropriately excluded from the RHC cost report.

Comment: A commenter believes that sole community providers also need to commingle staff and equipment for financial and operational reasons.

Response: We agree with the commenter. We are revising proposed § 405.2401 to state that any hospital-based RHC is allowed to share its health care practitioners with the emergency room as long as sufficient documentation is provided allocating costs.

Comment: A commenter believes providers should be allowed to operate an RHC and an emergency room in the same facility (especially small rural hospitals). There should be no sharing of staff during the hours of RHC operation, but we should acknowledge there are instances of common resource sharing. For example, it is customary for providers to share medical supply cabinets.

Response: We agree that providers should be allowed to operate an RHC and an emergency room in the same facility. In the case of shared storage space (shared medical supply cabinets), patient care supplies should be clearly distinguishable from those of any other entity in every respect.

Payment for Rural Health Clinic Services and Federally Qualified Health Clinic Services (§ 405.2462)

Comment: Several commenters suggested that the United States Department of Agriculture (USDA) Urban Influence Codes 5 through 7 should also be considered for rural hospital eligibility for the exception. There are many smaller rural communities surrounding cities, but they do not fall within the codes of 8 or 9.

Response: In defining rural for the Medicare program, we have consistently used the definition of Metropolitan Statistical Area (MSA) as established by the Office of Management and Budget (OMB). The available bed definition at § 412.105 is also a longstanding definition used in the Medicare program. We believe that these definitions are reasonable and appropriate for identifying eligible RHCs based in small rural hospitals. The alternative definition of bed size and rural was proposed to accommodate, based on industry concerns, extremely rural hospitals operating under extenuating circumstances. Communities that fall in the levels 5 through 7 are considerably less rural than those in level 8 or level 9. For example, a level 5 is a rural county with a city exceeding a population of 10,000 adjacent to a metropolitan area where a level 8 is a rural county that has a city with a population of less than 10,000 not adjacent to a metropolitan area. In light of the stark differences in rurality of these areas, we see no basis for changing the standard.

Comment: Several commenters strongly urged the adoption of the

broader rural definition under the Balanced Budget Refinement Act of 1999 (BBRA) for the exception to the payment limit for RHCs based in small rural hospitals. This definition, which is purported to be an improvement over the MSA definition, addresses the problem experienced in certain western States.

Response: In 2000, section 224 of BIPA expanded the eligibility criteria for receiving an exception to the RHC annual payment limit, effective July 1, 2001. Specifically, this section of BIPA extends the exemption from the upper payment limit to RHCs based in small urban hospitals. Thus, all hospitals of less than 50 beds are now eligible to receive an exception from the per visit payment limit for their RHCs. Therefore, we are revising § 405.2462(a)(3) to reflect changes made by BIPA. Please note that we will continue to use the bed size definition at § 412.105(b) to determine which RHCs are eligible for the payment limit exception. We will continue to apply to the alternative definition of bed size (patient census) only extremely rural hospitals operating under extenuating circumstances as set forth at § 405(a)(3)(ii)(A).

Comment: A commenter encouraged us to adopt the RHC definition of rural for purposes of exemption to the payment limit. This rural definition resolves the problems with the MSA definition as it relates to western States.

Response: As discussed above, we are revising § 405.2462(a)(3) to reflect changes made by BIPA.

Comment: A commenter recommended that the payment limit exception should be based on whether the provider is in a rural area or whether its average daily census is less than 50 beds.

Response: Although section 224 of BIPA expanded the eligibility criteria for receiving an exception to recognize RHCs based in small urban and rural hospitals, it maintained the bed size test. Consequently, we are retaining that requirement in our rules at § 405.2462(a)(3).

Comment: A commenter believes that allowing any hospitals with an average daily census of 40 is very generous and will probably continue the abuse of the RHC program.

Response: We agree with the commenter; therefore, we will retain the requirement in § 405.2462(a)(3)(ii)(A), which states that the average daily census criterion would apply only to extremely rural, sole community hospitals.

Comment: Several commenters indicated that the 50-bed requirement should be defined using average daily census. Rural hospitals with an average daily census of below 50 beds are the types of facilities the Congress is concerned about. Also, this information is reflective of the number of patients served and the size of the hospital.

Response: Although there are a number of ways to define a hospital bed size (that is, licensed, certified, staffed, or patient census), we believe our available bed definition (staffed) is appropriate and generous compared to the other existing definitions. We believe it is the most reflective method for identifying the actual size of a hospital. As a general measure, the average daily census definition for counting inpatient hospital beds would be too generous for this provision, as it is less reflective in terms of identifying the actual size of a hospital. For example, this definition could qualify hospitals staffed or licensed for 75 beds or more. We believe qualifying those hospitals for the RHC payment limit exception would be inconsistent with the congressional intent.

Comment: Several commenters suggested changing the proposed threshold pertaining to the fluctuation of patient census at or above 150 percent of the lowest monthly average census to a more reasonable level or eliminating the standard. Many vulnerable hospitals do not have a single period of seasonal fluctuation in census, but instead experience multiple, and unpredictable, fluctuation in patient census.

Response: We share the commenters' concerns that some rural hospitals may experience multiseasonal activity making it impossible, for an otherwise eligible facility, to meet the 150 percent fluctuation occupancy threshold. Therefore, we are revising proposed § 405.2462(a)(3)(ii) to eliminate the proposed 150 percent fluctuation threshold for patient census.

Comment: Two commenters suggested that we use the ambulatory payment classification (APC) system when defining rural for the payment limit exception. The commenters believe that this system would allow physicians in the rural census tracks of MSAs to be considered rural. The commenter asked us to use the same rural definition being used for the APC system.

Response: The current APC system uses the OMB ''rural'' definition as well as the Goldsmith modifier. As discussed above, the BIPA expanded the location requirement to include rural and urban areas. Consequently, the Congress has resolved this issue by recognizing small hospitals in urban and rural communities as qualifying for the payment exception.

Comment: Two commenters suggested an automatic exception should be given to small rural hospitals with an average daily census of 15 beds or less, regardless of the number of licensed or staffed beds, and any hospital in a frontier area.

Response: We do not have the discretion to waive the 50-bed requirement for hospitals located in frontier areas. Furthermore, we fail to see the merit, as it relates to the intent of this provision, in providing an automatic exception to hospitals with very low occupancy rates that are staffed or licensed with more than 50 beds. This provision was established to help small rural hospitals and their clinics that represent the sole source of health for their communities remain financially viable. An automatic exception of this type could grant an exception to hospitals with significant excess capacity located in marginally rural areas. Even for hospitals in frontier areas, we do not have the authority to grant an automatic exception to extremely rural hospitals that cannot satisfy the 50-bed requirement.

Comment: A commenter recommended extending the payment limit exception in § 405.2462 to clinics based in rural hospitals with less than 50 beds and to freestanding clinics in the same rural area.

Response: We do not have the authority to grant exceptions to the RHC payment limit for these providers. Only RHCs based in small hospitals with fewer than 50 beds are eligible for the exception.

Comment: Two commenters recommended that the 40 or less average daily patient census requirement should be increased to 45. Hospitals in remote rural areas should not be required to hold their inpatient acute care occupancy to a level that is significantly below the 50-bed maximum requirement in the BBA. Very rural hospitals do not have the ability to transfer, and should not be required to reject patients just to meet this requirement.

Response: We believe this requirement is necessary and appropriate for this provision. The 40 or less average daily patient census requirement was established to meet the needs of small hospitals in extremely rural areas experiencing seasonal fluctuations. Without significant fluctuations in patient census, these hospitals would be operating with less than 50 staffed beds. Hospitals with an average daily patient census in excess of 40, in spite of seasonal fluctuations, would likely have to operate with more

than 50 staffed beds, which is contrary to the statute.

Definition of Shortage Area for RHC Purposes (§ 491.2)

Comment: Several commenters suggested that we clarify in proposed § 491.2 that an area designated as a low-income HPSA would qualify for RHC certification.

Response: We believe the rule is sufficiently clear regarding the applicability of low-income HPSAs for RHC certification. Section 491.2(c) states that population group HPSAs, which include low-income population group HPSAs, meet the definition of shortage area for RHC purposes.

Comment: A commenter asked for clarification of the guidelines that would be used to determine HPSAs. Specifically, will there be changes that would impact those areas that are currently designated as HPSAs?

Response: The designation of HPSAs and medically underserved populations (MUPs) is delegated by the Secretary to HRSA, and is not covered by these RHC regulations. HRSA issued a proposed rule in September 1998 (63 FR 46538) to revise the regulations for designation of shortage areas, but this proposal was withdrawn in July 1999 because of a high level of public concern about its potential impact. HRSA has been conducting further analysis to address these concerns, and plans to issue new proposed rules for designation of HPSAs and MUPs in 2004.

Comment: A commenter pointed out that the BBA amended the RHC provisions to state that ''the rural area must also be one in which there are insufficient numbers of needed practitioners as determined by the Department.'' The January 2000 proposed rule does not address this amendment. There is a need for regulations in this area because current designations do not define an acceptable range for supply of providers to population.

Response: By statute, we are required to rely on HRSA to designate areas as medically underserved. As previously discussed, HRSA is currently developing another proposed rule to revise its methods and standards for designating shortage areas. HRSA's regulation will address the issue of provider supply to population.

RHC Procedures (§ 491.3)

Comment: A commenter pointed out that it is unfair to apply the 3-year currency requirement for MUAs. There is not a systematic review of MUAs. The 3-year requirement should only apply to underserved designations that are systematically reviewed.

Response: Section 4205(d) of the BBA requires clinics entering the RHC program, as well as participating RHCs, to be located in a service area designated or updated within the previous 3-year period. This statutory requirement also applies to all medically underserved designations for RHC qualification purposes. We do not have the authority to exclude certain designations, such as MUAs. However, we believe that affected clinics must be given sufficient time to submit an application to update their service areas. We believe it is imperative that these clinics be given adequate time to submit applications to avoid being unnecessarily disqualified from the RHC program. We also believe these clinics should be protected from RHC disqualification while their applications are under review. Therefore, we are revising § 491.3(b)(2) to clarify that RHCs located in service areas with outdated shortage area designations will have 120 days, from the date we notify the facility about its compliance issue, to submit an application to update its medically underserved designation. In addition, we clarify in new § 491.3(b)(3) that the RHC will be protected from disqualification while its applications are under review. That is, affected clinics will not be considered out of compliance with the 3-year currency requirement for 120 days from the date HRSA formally receives the application. In rare cases where HRSA or the State cannot complete their review within 120 days, clinics will continue to be protected from RHC disqualification until a formal decision is made.

Typically, applications for updating shortage area designations are reviewed within 90 days. We will work closely with HRSA to ensure that all applications are processed within this timeframe.

As stated above, HRSA is responsible for the designation of HPSAs and MUAs, and certification of Governor's designations of eligible areas for the RHC program. HRSA works closely with the State Primary Care Office (PCO) in each State in administering the HPSA and MUA review activity, and in the certification of Governor's designations. Individuals or facilities interested in seeking a new or updated HPSA or MUA, or who wish to inquire regarding a possible Governor's designation, are encouraged to contact the appropriate State PCO. (A list of these contacts is available by calling 1–800–400–2742, or online at *http://www.bphc.hrsa.gov/*.) Information on the HPSA and MUA criteria, procedures, frequently asked questions, and current designation status is also available at this web site. (For further information on HPSAs and MUAs, please contact Andy Jordan, Acting Chief, Shortage Designation Branch, National Center for Health Workforce Analysis, Bureau of Health Professions, at HRSA (301–594–0816).)

Comment: Several commenters indicate belief that an extension from RHC disqualification should be granted to clinics while their medically underserved status is being formally updated. The application process for updating underserved designation may unintentionally disqualify otherwise eligible clinics.

Response: We agree that some clinics, that are otherwise eligible, may be disqualified as an RHC if their service area cannot be updated in a timely manner. In § 491.3, paragraphs (b)(2) and (b)(3), we clarify the regulation to protect RHCs from disqualification that are in the process of formally updating their shortage area designations. Clinics that exceed the 3-year requirement will not be disqualified from RHC participation while their service area is in the process of being formally updated by HRSA or the State.

Comment: Two commenters suggested that the 3-year currency requirement in § 491.3(b) is too short. The costs and structural changes needed to set up an RHC cannot be recouped in 3 years.

Response: Section 4205(d) of the BBA requires clinics entering the RHC program, as well as participating RHCs, to be located in a service area designated or updated within the previous 3-year period. We do not have the authority to modify this requirement.

Comment: A commenter recommended that we require States to contact all providers by mail before an underserved area designation is revoked. If the community or clinic appeal the decision, CMS regional offices should have the authority to stop an RHC from having its designation revoked.

Response: We rely on HRSA to designate shortage areas. HRSA's review process provides affected communities and providers with advanced notice of a designation withdrawal and the right to appeal this decision. Our process for terminating RHC status does not start until HRSA formally withdraws the shortage area designation.

Comment: A commenter suggested that we should continue to recognize an area for RHC certification unless the area has been de-designated two times in a 3-year succession.

Response: We do not have the authority to recognize an area for RHC

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

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

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

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

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

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

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

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

Comment: Several commenters recommended extending the proposed 90-day timeframe for removing RHC status. The adjustment period following de-certification needs to be longer to allow practitioners who choose to remain after de-certification to establish independent practices. For example, the affected RHCs will need to obtain a new provider number, which could take 4 to 6 months.

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

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

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

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

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

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

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

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

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

Location of Clinic (§ 491.5)

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

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

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

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

exception as a major community provider was not intended to be a routine occurrence. We examined the issue of using an absolute Medicare, Medicaid and uninsured payer mix threshold for defining a major community provider and we rejected this idea because it may not accurately determine essential clinics at the community level due to wide variability in population composition and utilization. However, for those clinics applying as major community providers, CMS would require the RHC applicant to have, at a minimum, Medicare, Medicaid and uninsured utilizations rates reasonably consistent with the national average.

The Office of Rural Health Policy, within the Department of Health and Human Services, recently conducted a national RHC survey. Their survey-based data indicate that the average RHC utilization rates are as follows: Medicare (30 percent), Medicaid (25 percent) and uninsured (15 percent). An RHC applicant would be required to demonstrate under the major community provider test that their combined utilization rates for low-income patients (Medicaid and uninsured) would, at a minimum, equal or exceed 31 percent to even be considered eligible to apply for a major community provider exception. An RHC applicant could also meet a combined minimal utilization rate for Medicare, Medicaid and uninsured patient threshold of 51 percent to satisfy this screen. CMS believes the above minimal national utilization patient threshold is reasonable in light of the national average utilization rates and necessary to ensure consistency and fairness with respect to identifying major community providers.

Comment: A commenter suggested that priority be given to clinics that provide a real medical home for their patients. For example, clinics that have a full time physician with hospital admitting privileges and provide 24-hour coverage for their patients should be granted priority as essential clinics.

Response: The proposed tests for identifying an essential clinic are based on whether the RHC is the sole or major source of primary care for Medicare beneficiaries and low-income patients (Medicaid beneficiaries and uninsured). Although we believe that an after hours coverage system and full time physician care are important factors, the clinic must still demonstrate that it has an open door policy regarding low-income patients. As discussed above, CMS is requiring that these essential provider tests must take into account the willingness and resources of other providers to accept and treat Medicare and Medicaid beneficiaries and the uninsured.

Comment: Several commenters believe clinics that have lost their rural status should be allowed to apply for an exception as an essential clinic. The regulation could exclude some RHCs that are still in medically underserved communities but fail to meet the rural location requirement. The CMS proposed policy could result in the loss of an essential RHC for uninsured and Medicaid patients.

Response: We agree with the commenters that an RHC that has lost its rural status but is still located in a valid shortage (geographic and population-based HPSAs, MUAs, and areas designated by the Governor of the State) area should be permitted an opportunity to apply for an exception from RHC disqualification. CMS recognizes that there may be some RHCs located in small, isolated urbanized service areas that are marginally above the minimum population threshold for qualifying as non-urbanized but represent the sole or major source of outpatient physician care for outlying rural areas designated as medically underserved. Consequently, we are revising § 491.5 to allow RHCs located in medically underserved ''urban'' service areas to apply for an exception as a sole, major, or specialty community provider. However, we believe that these clinics should also be required to demonstrate that they are an essential provider of primary care for patients residing in a rural area. The RHC program was established for the purpose of improving and maintaining access to primary care for ''rural'' underserved communities. In order to retain RHC status, CMS believes every RHC must be able to show that it continues to satisfy this basic program objective. It would be inconsistent with Congressional intent to grant exceptions from RHC disqualification to clinics non-essential to the delivery of primary care for rural patients. Consequently, CMS is requiring that at least 51 percent of the applicant's clinic patients reside in rural areas. We believe that a rural patient origin threshold of 51 percent is very reasonable in light of the statutory objective of the RHC.

Comment: Two commenters suggested that we conduct an extensive needs assessment of each community before rescinding the clinic's designation. If RHC status is removed, it may diminish the quantity and quality of health care services to an already underserved population.

Response: We believe that an extensive needs assessment is unnecessary in light of the fact that HRSA already has made a determination that the area is no longer medically underserved. Furthermore, the purpose of granting essential provider status to RHCs is to ensure that access to quality care for Medicare, Medicaid, and uninsured patients is preserved despite the fact that the area is no longer considered rural or medically underserved.

Comment: A commenter suggested that the grandfather protection regarding essential provider status should be extended to rural clinics that lose their medically underserved designation. The commenter believes that if protection cannot be provided to these clinics in this manner, we should amend the exception process by including poverty level and access problems to transportation as eligibility factors.

Response: Section 4205(b) of the BBA requires us to determine whether a clinic is essential despite the fact that its area is no longer considered rural or medically underserved. We believe it would be inconsistent with congressional intent to provide an automatic exception to every clinic no longer located in a designated shortage area without making a determination whether the clinic is essential.

Comment: A commenter believes that any clinic that received its underserved designation to establish an RHC should be able to retain its status. Providers that have established clinics in very rural areas and successfully recruited physicians to these areas should receive an exception.

Response: We believe clinics that can demonstrate that they are essential based on the proposed conditions should be granted an exception. With regard to expanding the exception process to include clinics located in very rural areas, we believe this suggestion merits consideration. Please see the discussion below on how we intend to address this concern.

Comment: A commenter pointed out that some of the proposed exception tests may not be based on community need. Some of the tests do not distinguish between clinics with one physician and clinics with several physicians.

Response: We agree that the proposed tests need to take into account the willingness and resources of other providers to accept and treat Medicare, Medicaid, and uninsured patients. In light of this, we are requiring that the essential provider test must take into account the willingness and resources of other providers to treat and accept Medicare and Medicaid beneficiaries, and the uninsured.

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

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

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

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

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

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

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

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

Comment: Several commenters believe special consideration should be given to clinics that make house calls and provide after hours coverage for their community. These providers may be essential in communities with inadequate transportation services.

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

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

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

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

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

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

Response: Section 4205(d) of the BBA requires us to determine whether the facility is essential to the delivery of primary care for its community. Although the tests in this final rule indirectly take into account these issues, we cannot grant an exception without assessing the importance of the clinic to primary care for Medicare, Medicaid, and uninsured patients within that community. In other words, we are obligated by statute to determine whether the facility is essential to the delivery of primary care.

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

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

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

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

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

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

the area is very remote and has limited health care resources. Because our proposed tests target these situations, we see no reason for changing the regulation.

Comment: Several commenters indicate that we should automatically recognize essential provider status for clinics affiliated with critical access hospitals (CAHs), Medicare dependent hospitals (MDHs), and sole community hospitals (SCHs). The criteria for essential provider status are extensive, ranging from shortage area status to treating the uninsured. Consequently, it would seem appropriate and consistent with essential provider status for the RHC program.

Response: Although we agree that some of the criteria for CAH and SCH status are consistent with essential provider status for the RHC program, clinics applying for this special status should not automatically receive an exception because of their hospital affiliation. There could be cases where the clinic of the CAH or SCH would not satisfy the requirements for being an essential RHC. Therefore, the RHC should be required on its own to demonstrate compliance with the essential provider conditions.

Comment: Several commenters suggested that we should reduce the time and distance standard, for example, change it to 20 minutes or 15 miles. Many Medicare and Medicaid patients have a barrier to transportation services in rural areas. Furthermore, some rural communities have special populations, such as prison, indigent, or Medicaid.

Response: We agree that the proposed tests for identifying essential providers should address the issue of inadequate transportation services. However, regarding this specific issue, we believe it more appropriate and effective to grant an exception to more than one RHC in a given service area under the major and specialty provider tests than reducing the time and distance standards. Consequently, we are revising § 491.5 to clarify that we will, for the major and specialty provider tests, grant multiple exceptions within a specific service area as long as each RHC meets the conditions for receiving an exception.

Comment: A commenter suggested that we should establish a special population exception criteria to reflect certain populations (for example, the Amish) and rural communities with a high proportion of elderly or low-income residents. Additionally, rural areas designated as a low income HPSA or MUA should also qualify for the special population exception.

Response: The proposed essential provider tests already address the issue of special populations. All of the tests focus on the clinic's devotion to treating Medicaid, Medicaid, and uninsured patients. For establishing a special population exception for low-income HPSAs or MUAs, rural clinics located in service areas that have a current (within the previous 3 years) designation of this type are not in jeopardy of RHC disqualification.

Sole Community Provider Test

Comment: Several commenters suggested that the sole community provider test should be applied to clinics that are the sole source of primary care for their small rural town that are 8 to 10 miles apart from other small rural towns. The commenter believes that, under the proposed 30-minute test, the time and distance of the roundtrip may deny access to care for Medicare and Medicaid patients.

Response: Although we believe the time and distance standards in the proposed rule are reasonable, we acknowledge the need to preserve RHC status for sole community clinics located in small rural towns. The residents of these rural towns, especially those who lack access to transportation, may experience difficulty obtaining needed health care if the clinic cannot remain financially viable. Consequently, we are revising proposed § 491.5(b) at § 491.5(b)(l)(ii) to clarify that we will, when appropriate, grant an exception to more than one RHC within a specific service area, as long as each RHC meets the conditions for receiving an exception. We believe this will allow RHCs that are the major or primary source of health care for their small rural town to receive an exception.

Comment: A commenter believes the our proposed 30-mile test is inconsistent with published HPSA criteria of 25 miles.

Response: We agree that HRSA applies a 25-mile test for areas connected by interstate highways. We are revising proposed § 491.5(b)(1)(iii) to correct this inconsistency.

Comment: A commenter asked how the distances would be measured for determining the sole community provider test. The commenter questioned, for example, whether the distance will be based on actual driving time or on results from a mapping software program.

Response: For administrative efficiency, we will apply the time and distance test using a mapping software program.

Comment: A commenter pointed out that using the RHC as the geographic center does not take into account the distance a large percentage of patients travel in the opposite direction of the ''other'' primary care practice.

Response: We believe the proposal to use the RHC as the geographic center for identifying sole community provider status is reasonably accurate and feasible from an administrative standpoint. We have applied this method for the SCH and CAH programs. Therefore, we believe it is also appropriate for the RHC program.

Comment: A commenter believes that we need to provide a standard definition under this rule for the terms such as ''secondary roads'' and ''primary roads.'' The use of these terms without providing a clear definition could lead to misinterpretation.

Response: HRSA has consistently applied the definitions in the Rand McNally Road Atlas for identifying primary, secondary, and interstate highways for purposes of the 30-minute travel test. We will also apply these standard definitions when reviewing essential provider applications.

Comment: A commenter recommended that RHCs requesting exception status should be immune from the 30-minute test if they have a formal sliding fee scale in place and 10 percent or more of their encounters are indigent patients.

Response: The sole community provider test already requires the applicant to demonstrate that it accepts Medicare, Medicaid, and uninsured patients that present themselves for treatment. Therefore, to waive the 30-minute test would simply make the sole community provider test a weakened form of the major community test, and would mean that it would no longer be focused on clinics that are the sole source of primary care for Medicare and Medicaid patients in their community.

This specific essential provider test recognizes clinics as sole community providers for Medicare beneficiaries and low-income patients (Medicaid beneficiaries and the uninsured). For example, a clinic could receive this sole clinic status if it is the sole source of primary care for Medicaid and uninsured patients. If the clinic is not the sole source of care for Medicare, Medicaid, or uninsured patients, it can qualify as a major community provider by demonstrating it is a significant source of health care for indigent patients, such as Medicaid and uninsured patients.

Comment: A commenter recommended that the ''participating primary care provider'' language under

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

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

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

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

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

Response: Our proposed time and distance criteria are based on published HPSA criteria because these shortage area designations represent a core qualification requirement for RHC participation. In light of this linkage, we believe it is more appropriate to apply the HRSA criteria instead of the SCH standards.

Traditional Community Provider Test

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

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

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

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

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

Response: In addition to combining the traditional and major community provider tests, we are revising the major community provider test to address this issue. We acknowledge that there could be a situation where a rural community may have more than one RHC that represents a major source of primary care for its Medicare, Medicaid, and uninsured patients. We are revising proposed § 491.5(b) at (b)(1)(ii) to clarify that more than one RHC in a given service area may receive an exception as a major community provider.

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

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

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

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

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

Major Community Provider Test

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

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

and uninsured patients, and continues to maintain this open door policy. Furthermore, the clinic's utilization rates for low-income patients would have to be consistent with the claim that it is a major source of primary care for its service area. For example, if there are three RHCs located in a rural town, which is no longer considered medically underserved, and two of the RHCs claim to be major community providers because their utilization rates for low-income patients exceed 45 percent, we would consider these RHCs with the higher utilization rates as major community providers if the third RHC has utilization rates of less than 10 percent for low-income patients. Also, as explained above, CMS would require the RHC applicant to have, at a minimum, Medicare, Medicaid and uninsured utilization rates consistent with the national minimal patient utilization threshold. An RHC applicant would be required to demonstrate under the major community provider test that their combined utilization rates for low-income patients (Medicaid and uninsured) would, at a minimum, equal or exceed 31 percent to be eligible to apply for a major community provider exception.

Comment: Several commenters pointed out that multiple RHCs may be necessary to share the uncompensated and indigent care load. Multiple RHCs do not necessarily mean excess capacity.

Response: We acknowledge that there may be a situation where more than one RHC in a particular rural area represents the major source of primary care for Medicare, Medicaid, and uninsured patients. For example, there may be three RHCs located in a rural town that is no longer considered medically underserved, but only two of the three RHCs treat the Medicaid and uninsured population for that rural community. Therefore, we are revising proposed § 491.5(b)(1)(ii) to clarify that more than one RHC in a given service area can receive an exception as a major community provider. However, as discussed above, there must be supporting evidence that the applicants represent a major source of primary care for the patient population of the service area.

Comment: A commenter recommended that if we establish a national minimum utilization standard for the major community provider test, it should be set no higher than a combined Medicare, Medicaid, and uncompensated care rate of 60 percent.

Response: We rejected the idea of using a specified Medicare, Medicaid, and uninsured payer mix for defining a major community provider because it may not accurately determine essential clinics at the community level due to a wide variability in utilization from region to region. We believe the best approach is to require the clinic to demonstrate that it represents a significant source of primary care for Medicare and indigent patients (Medicaid and uninsured).

Comment: Several commenters requested clarification of the situation when a ''provider'' may not be limited to one discreetly certified site.

Response: Health care entities that own and operate multiple RHCs would not be permitted to submit one application on behalf of all its clinics. The essential provider tests can only be appropriately applied on a facility specific basis.

Comment: A commenter believes we should state, for the major community provider test, that a disproportionate share of Medicare, Medicaid, and uninsured patients is defined as serving a higher percentage of these patients than the percentage in the community at large.

Response: The goal of this essential provider test is to identify clinics that are the major source of primary care for Medicare, Medicaid, and uninsured patients. We believe the test must *not* be solely based on whether the clinic is serving a higher percentage of these patients compared to other RHCs in the community, but based on whether the clinic represents a major source of primary care for these patients. The test, for example, will identify whether, without the presence of the clinic, other RHCs have the capacity or willingness to fill the void in terms of furnishing care to Medicare, Medicaid, and uninsured patients.

Comment: A commenter asked whether the RHC applying for the exception would be compared to other RHCs or all primary care providers.

Response: Clinics applying under this exception test will be compared only to other RHCs. However, in situations where the clinic is the only participating RHC, the test will compare the RHC to other primary care providers.

Specialty Provider Test

Comment: Several commenters expressed belief that the specialty provider test should be expanded to include mental health services. Recent reports have indicated a serious need for mental health services in rural underserved areas.

Response: We acknowledge that many rural areas are seriously underserved in terms of mental health services. We see the merit of expanding the specialty provider test to include RHCs that provide mental health services. Therefore, we are revising proposed § 491.8(a)(6) to expand this essential provider test to recognize RHCs that employ a clinical psychologist or clinic social worker. We are expanding the specialty provider test in § 491.5 to grant exceptions to RHCs that represent the sole source of mental health care for their communities and that furnish these covered mental health services on-site.

Comment: Several commenters recommended that the exclusive provider language under the specialty provider test should be changed to give exemptions to specialty providers that see the majority of Medicare, Medicaid, and uninsured patients. There could be two pediatric clinics in the community, but only one clinic sees a disproportionate share of Medicare, Medicaid, and uninsured patients.

Response: We agree with the commenters that this essential provider test should take into account the possibility that there may be more than one specialty clinic furnishing primary care to Medicare, Medicaid, and uninsured patients. We share the commenters' concern that there may be two specialty clinics in the service area that equally share in treating indigent patients or, as described above, there may be two clinics and only one sees the majority of low-income patients. Consequently, we are revising § 491.5(b)(1)(ii) to eliminate the sole source of care requirement. We clarify that more than one RHC within a service area can receive an exception under this test as long as the applicant can demonstrate that it represents a major source of care for indigent patients (Medicaid and uninsured). Furthermore, the RHC applicants would be required to demonstrate that their utilization rates for low-income patients (Medicaid and uninsured) would, at a minimum, exceed equal or 31 percent to even be considered eligible to apply for a specialty clinic test as a major source of pediatric or OB/GYN care. We are making this change to be consistent with the major community provider test.

Comment: A commenter believes clarification may be needed, under the specialty test, regarding general medicine RHCs that include part-time or full-time OB/GYN or pediatric care.

Response: This test was established to specifically target clinics that exclusively provide pediatric and OB/GYN care. We believe the other tests in this final rule will give those clinics that do not limit their practice by gender or

age an opportunity to qualify as an essential provider.

Comment: Several commenters suggested that the specialty provider test should recognize other services, such as geriatrics, cardiology, gastroenterology, orthopedics, oncology, and other specialty services at the discretion of the Secretary.

Response: The specialty provider test was established to specifically target clinics that exclusively provide pediatric and OB/GYN care. Although we agree that these are vital services, they go beyond the intended scope of the RHC program. The only exception to this will be geriatrics, which we believe is addressed by the other essential provider tests.

Comment: A commenter asked us to consider expanding the test over a wider geographic area. RHCs may be the sole providers of specialty services in the surrounding communities.

Response: We are revising § 491.5(b)(2)(iii) for this test to grant exceptions to specialty clinics that are the sole or major source of primary care for their communities. We believe this change diminishes the importance of how we define the boundaries of the clinic's service area.

Comment: A commenter recommended that the definition of specialty clinic provider should be revised to address a defined population rather than the entire census population.

Response: We are revising § 491.5(b)(2)(iii) to grant exceptions to specialty clinics that are the sole or major source of primary care for Medicare (where applicable), Medicaid, and uninsured patients. We acknowledge that pediatric clinics that have lost their medically underserved status may only be able to demonstrate that they are the sole or major source of primary care for Medicaid, and uninsured patients.

Comment: A commenter suggested that this test should be expanded to include women's health services as an essential service provider. In some States, RHCs are the exclusive provider of breast and cervical screening for Medicare, Medicaid, and uninsured patients.

Response: The specialty provider test was established to specifically target clinics that exclusively provide pediatric and OB/GYN care. We believe it is unnecessary to further target other specialties. Rural clinics that provide these important services should easily qualify under one of the other tests as set forth in this final rule.

GME Test

Comment: Several commenters recommended that RHCs providing supervised training to nonphysician practitioners should also be eligible under the GME test. They pointed out that this would bolster the Congress' intent to encourage the use of these practitioners to improve access in rural areas. The commenters also indicated that the Federal government has for many years actively supported training through title VII and title VIII of the PHS Act.

Response: We disagree that this essential provider test should be expanded to include RHCs that are part of a formal training program for nonphysician practitioners. CMS believes that the GME test is no longer needed in light of all the refinements and clarifications made to the other essential community provider tests. In other words, CMS strongly believes that any RHC receiving direct GME payment will now be able to easily satisfy one of the several other tests for being considered essential to the delivery of primary care. When this test was first proposed on February 28, 2000, CMS expected that there would be a significant number of RHCs receiving direct GME payments by the time this test was formally issued. Unfortunately, this has not occurred. In light of this fact and the many refinements to the rule, which have expanded on the other essential community provider tests, CMS is revising the regulation to eliminate the GME test.

Comment: Several commenters suggested that we should expand the GME test to include clinics that have a formal arrangement with a medical school to rotate medical students through the clinic.

Response: As discussed above, we are eliminating the GME test.

Staffing and Staff Responsibilities (§ 491.8)

Comment: A commenter suggested that an RHC that can document ongoing recruitment efforts should be allowed additional time for waivers in filling the vacancy. The commenter stated that for some rural communities it is difficult to attract nonphysician providers.

Response: We disagree with the commenter. Section 4161(b)(2) of the OBRA '90 added section 1861(aa)(7) to the Act to provide us with the authority to grant a 1-year waiver of the mid-level requirement for existing RHCs and RHC applicants. The BBA amended section 1861(aa)(7)(B) of the Act to restrict our authority to allow a waiver for RHC applicants. Therefore, we are retaining the requirement in the new § 491.8(d)(1).

Comment: We received several comments regarding the nonphysician practitioner requirement for RHCs. One commenter recommended that the requirement be eliminated for areas that are no longer health professional shortage areas. The commenter believes that a community that has been successful in recruiting physicians may no longer need a nonphysician practitioner to serve the area. A second commenter believes that the requirement may be difficult to comply with and mandate the hiring of personnel that are not cost effective.

Response: We do not have the authority to eliminate the nonphysician staffing requirement. Both the Federal statute and regulations mandate the use of nonphysician practitioners. Specifically, § 491.8(a)(6) clearly specifies that a nonphysician practitioner must be available to furnish patient care services at least 50 percent of the time the RHC operates.

Comment: A commenter suggested that start-up RHCs in extremely rural areas, such as a designated frontier county (less than six persons per square mile) should receive an exception from the staffing requirements in § 491.8 The difficulty in establishing, much less maintaining providers in frontier areas is well documented.

Response: Section 491.8(a)(6) states that a physician or nonphysician practitioner must be available to furnish patient services at all times during RHC hours of operation. Section 4205(c) of the BBA restricts our authority to grant a waiver to clinics applying for RHC status. The RHC applicant must demonstrate that it employs a nonphysician practitioner before it can receive approval as an RHC.

Comment: A commenter asked us to clarify the term ''operates'' as it relates to the requirement of staffing a nonphysician practitioner 50 percent of the time. For example, does it mean normal business hours and excludes extended hours?

Response: The term ''operates'' in § 491.8(a)(6) means the total operating schedule during which the clinic furnishes RHC services.

Quality Assessment and Performance Improvement (§ 491.11) (Condition for Certification (CFC) for Rural Health Clinics)

Comment: Most of the commenters agree that a quality assessment and performance improvement program is needed for RHCs. They also agreed with the flexibility of RHCs to design and carry out their own performance

improvement programs. One commenter stated support for our interpretation of congressional intent to implement quality assessment and performance improvement (QAPI) programs in RHCs. Another commenter was in favor of replacing the current ''annual evaluation'' process, stating that the current process is of little value.

Response: We appreciate the supportive comments. Our revised quality requirements in § 491.11 are directed at improving outcomes of care and satisfaction for patients while eliminating unnecessary procedural requirements. A QAPI program must be based on a continuous, proactive approach to both managing the RHC and improving outcomes of care and patient satisfaction. As stated in section II. E of this preamble discussion, the BBA requirement, the new QAPI standard will replace the current program evaluation condition for certification at § 491.11.

Comment: Many commenters stated that the requirement, as proposed, is too burdensome and would be counterproductive for clinics with limited staff and resources. They stated the clinics do not have the resources to carry out the volume of evaluation proposed. Further, some commenters stated that a QAPI program would increase the cost to deliver care at a rural health clinic. One commenter suggested a pilot program in provider-based facilities that can be later expanded to independent clinics with a cost allowance. Also, two commenters suggested a phase-in period be considered.

Response: There are two distinct steps to a QAPI program. The first step is to compare care delivered against an identified standard for a particular type of health care provider or delivery system. The second step is to correct or improve processes of care and clinic operations that are predictive of improved outcomes of care or actual care outcomes. Currently, RHCs are required to carry out or arrange for an annual evaluation or assessment of their total program, take necessary actions to correct remedial problems, review policies and guidelines for medical management of health problems, and review the utilization of clinic services. Currently, resources that are allocated to the annual program evaluation can be used to comply with the new QAPI requirement.

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 clinic. We are clarifying proposed § 491.11(b)(3) to state that the RHC will determine the number and frequency of distinct improvement projects it will conduct. The QAPI program could result in some immediate costs to an individual clinic. However, we believe that the QAPI program will result in real, but difficult to estimate, long-term economic benefits to the clinics (such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

We disagree with a phase-in or pilot approach for the QAPI program. Clinics are currently performing, at a minimum, the evaluation or assessment portion of the new standard. The final rule will change the focus in performing the evaluations. Instead of focusing on the processes, we want clinics to focus on improving outcomes and patient satisfaction. Rather than making remedial changes (fixing problems once they occur), we prefer clinics to continuously improve the quality of care they provide. We expect a clinic's assessments to be based on objective data or information that will enable them to assess if changes are needed and to subsequently evaluate the effectiveness of the changes or interventions. Striving to improve care that is given must be the number one priority in delivering care for any provider. As currently permitted in existing § 491.11 for annual evaluation, clinics will be free to arrange for or to solicit outside assistance with their QAPI efforts.

Comment: A few commenters stated many RHCs already have quality assurance programs in place and those current programs should be considered for content and value. To eliminate duplication for provider-based clinics, several commenters recommended that we should accept QAPI programs designed to meet the requirement of an accrediting agency (that is, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) as meeting the minimum level of effort required by the proposed rule.

Response: There are no accrediting organizations that have been approved and granted deemed status for RHCs. Any assertion that RHC meet the QAPI requirements of any accrediting body does not substitute for onsite inspection by State survey agencies to ensure compliance with the Medicare requirements. We believe that the standards in § 491.11 are very basic to any QAPI program. For example, JCAHO's accreditation process for ambulatory care providers requires measurement in areas of clinical effectiveness, access to care, and patient satisfaction. All of these areas are under the umbrella of ''organizational processes, functions and services'' areas in which we require clinics to perform a self-assessment and improve performances. If a clinic currently has a QAPI program that addresses the requirements of this final rule, we do not see a need to require a clinic to duplicate its quality activities. To the extent that clinics are currently evaluating their processes, functions and services, they will be better prepared to comply with our QAPI rule. We expect RHCs that have no experience with QAPI programs to take advantage of the resources that are available. RHCs are encouraged to explore a variety of resources so that they can become familiar with the variety of approaches that exist to develop a QAPI program. An RHC that chooses to implement the QAPI resources (that is, model QAPI programs) provided by the Department and other on-line resources mentioned elsewhere in this regulation will be considered to meet the QAPI CfC provided that the model program chosen is one that is relevant to the RHC and its patient population.

Comment: One commenter stated that because of the physician credentialing process, board oversight process, State sentinel event laws, and malpractice suits, there is very little need for more quality assessment regulations from us. A few commenters stated that the introduction of the issue of specific attention to medical errors is troublesome in that there appears to be no legislative requirement for this specific area. These commenters believe that medical errors should not be addressed or required in the QAPI requirement. Another commenter stated that the responsibility for medical errors should be left to each State's licensing authority.

Response: While we agree that credentialing, oversight, and the reporting of sentinel events are fundamental activities that occur and are required on a State level, we disagree that these activities, or malpractice suits, negate the requirement for RHCs to have a QAPI program. The focus of any QAPI is to improve outcomes and patient care without being prompted by negative activities such as sentinel events or lawsuits. In fact, the prevention of the occurrences must be considered by the clinic when developing its QAPI strategy.

In the 1999 report entitled ''To Err is Human: Building a Safer Health System,'' the Institute of Medicine (IOM) of the National Academy of

Sciences discussed medical errors as one of the nation's leading causes of death and injury. The report estimated that more people die from medical errors each year than from highway accidents, breast cancer, or autoimmune deficiency syndrome. The Administration called for increased awareness and accountability in America's health care system. Further, the Secretary may impose requirements on providers if they are found necessary in the interest of the health and safety of the individuals who receive services from the providers. We believe it is appropriate to include a discussion on medical errors in the preamble language for the QAPI standards. In lieu of proposing a specific standard requiring RHCs to track and analyze medical errors, we believe that errors and the potential for errors will be detected and resolved through the clinic's QAPI activities.

Comment: Several commenters expressed caution about the elimination of structure and process criteria in favor of outcome measures. They stated that quality of care is a function, as well as a result of all three of the domains (clinical effectiveness, access to care, and patient satisfaction) in the proposed rule. One commenter further stated that there is insufficient evidence and experience to support a comprehensive shift solely to outcome standards. They also stated that care involving low-volume and high-risk procedures should also be a focus of assessment and improvement as needed.

Also, several commenters stated that the QAPI requirement provides very little flexibility and seems to require that improvement projects be done in all clinical and nonclinical areas annually on the basis of performance criteria that have yet to be determined.

Response: The fundamental purpose of the QAPI requirement is to set a clear expectation that RHCs must take a proactive approach to improve their performance and focus on outcomes of care. This does not eliminate the need for improving structures and processes that are indicative of improving outcomes.

However, after further consideration, in response to the commenters' concerns, we have removed, in this final rule, reference to the specific domains: access to care, patient satisfaction, and clinical effectiveness. While the domains are critical areas in which a clinic must evaluate its performance, the final rule allows clinics the flexibility to identify their own areas to address. RHCs are required to use objective measures to analyze organizational processes, functions, and services annually. RHCs are required to develop, implement, maintain, and evaluate an on-going self-assessment of the quality and appropriateness of care provided through their data-driven QAPI program. We do not intend and are not in a position to judge the measures themselves; instead, we will assess their utility for the clinic in its own efforts to improve its performance.

We also believe that it is critically important that RHCs identify opportunities to improve and expand the use of information technology (IT) to prevent medical errors and improve quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (such as, computerized patient records). We encourage RHCs, as they assess their organizational processes, functions, and services, to identify opportunities and make use of information technologies. We believe that the effective use of IT systems could prove invaluable to improving the quality and safety of patient care over time. We will allow RHCs to undertake programs of investment and development of IT systems that are designed to result in improvements in patient safety and quality of care as an alternative to performance improvement projects (see § 491.11(b)(5)). In recognition of the time and resources required to develop and implement these IT programs, we would not require that associated activities have a demonstrable benefit in their initial stages, but would expect that quality improvement goals and their achievement would be incorporated in the plans for these programs. We believe that this modification demonstrates this Administration's deep commitment to patients, high quality care, and flexibility to our partners.

Comment: Several commenters stated that quality assurance programs should be applied to all clinics that provide care to Medicare and Medicaid beneficiaries, not just those in underserved areas.

Response: We agree that all providers must have an effective quality assurance program. The purpose of this final rule is to implement requirements for RHCs as required by the BBA. We plan to systematically update regulations for all Medicare and Medicaid providers to require quality assessment and performance programs. We have already required quality assessment and performance programs for certain Medicare providers.

Comment: Several commenters stated that the proposed rule grossly underestimated the time required to implement the data requirements mandated by the QAPI program. Commenters further stated that it would take approximately 70 to 80 hours per year for an RHC to maintain this program. Commenters requested we minimize the data requirement in light of limited staff time.

Response: Under the Paperwork Reduction Act of 1995, we are required to provide notice and solicit comment before a collection of information requirement is submitted to OMB. In that proposed rule, under section III of that preamble, Collection of Information Requirements, we estimated that it would take each clinic a total of 1 hour per year to maintain the data required by the QAPI requirement. This estimation does not include the time it will take to collect and analyze data or perform the activities for the program. The hour is an estimation of the time it will take a member of the clinic's staff to store or file the documentation of the QAPI program activities. RHC resources that are currently used to comply with existing annual program evaluation can be used to comply with the new QAPI requirement. We have not established a specific amount of data to be collected. The minimum data, or information, required is that which will enable a clinic, with its available staff and resources, to assess change or improvement.

This QAPI CoP will replace the existing program evaluation CoP found at § 491.11. RHCs are currently required to perform an annual program evaluation and the burden reported for the annual evaluation will be used in the new QAPI requirement. We agree that the PRA collection (0938–0334) should be updated to increase burden for RHCs to develop a QAPI program and train staff. The estimation of 70 to 80 hours to maintain a QAPI program may be realistic for the clinic that commented. However, it is difficult to accurately state the impact of the QAPI requirement on RHCs without knowing the size and scope of the clinics and how complex the QAPI program will be for each clinic. We have developed this requirement with the flexibility that allows both large and small clinics to develop a program that reflects the resources and complexity of each clinic's organization and services.

We estimate that on average it will take a clinic approximately 40 hours to develop a QAPI program. For those clinics that are provider based and have experience with the QAPI process, this time will be reduced. This time will also vary based on the simplicity or complexity of the program that a clinic

develops. The QAPI CfC will replace the existing annual program evaluation CfC (42 CFR 491.11). The activities that are currently covered by the existing PRA on file with OMB are found in § 491.9—''Provisions of Services.'' These activities include—Patient care policies; guidelines for medical management of health care problems; and procedures to review and evaluate services furnished by the RHC. In the existing PRA for the current regulations, the burden hours for provisions of services include 10 hours (one time) for initial development, and 2 hours annually for review and revision. The next time we update its PRA submission for Part 491, we will add the 10 hours and 2 hours with the 40-hour initial burden for the QAPI program. We used the previous burden estimate for the annual evaluation, in part, to estimate the new QAPI requirement. It is difficult to accurately state the impact of the QAPI requirement on RHCs without knowing the size and scope of the clinics and how complex the QAPI program will be for each clinic. In developing the requirement, we wanted to assure flexibility for RHCs so that both large and small clinics can develop a program that reflects the resources and complexity of each clinic's organization and services. We estimate it will take a clinic approximately 40 hours to develop a QAPI program from a variety of assumptions. First, the hospital QAPI condition of participation estimates 80 hours for a hospital to develop the program. We expect that at the level-of-effort for a RHC would be less than that for a hospital QAPI program as hospitals provide more services than RHCs. For hospital provider-based clinics, we expect that they would already have experience with the QAPI process. Therefore, their level-of-effort would be reduced. The 40-hour time estimate also recognizes that the time will vary based on the simplicity or complexity of the program that a clinic develops. We also estimate that the RHC will spend an additional 4 hours a year collecting and analyzing data. In addition, we estimate that clinics will spend 3 hours a year training and or updating staff on their QAPI program. Since the QAPI program will replace the current annual evaluation requirement, the administrative burden and annual review of policies and procedures are currently covered by 0938–0334.

Requirement	Annual burden hours	One-time burden hours
Program Development	.....	40 hrs × 3,300 = 132,000
Data Collection and Analysis	13,200	
Training	.....	3 hrs × 3,300 = 9,000
Total	13,200	141,000

These are preliminary projections that may change slightly as we update the PRA submission.

Comment: Most of the commenters recommended that, rather than requiring a minimum number of QAPI projects, we require RHCs to demonstrate to the survey agency what projects they are doing and what progress is being achieved. Some commenters suggested requiring two projects annually, while others suggested only one project annually. Another commenter stated that the minimum level should be defined as requiring the RHCs to choose a single domain in which to undertake an evaluation and to perform a single performance improvement project within that selected domain on an annual basis. Still, other commenters stated that the rule should include specific and limited definition of minimal expectations of the QAPI program, particularly for the smaller clinics. Several commenters wanted clarification on how our expectation that the use of performance measures will be commensurate with the size and resources available to the clinic.

Response: We appreciate the comments regarding what must be the minimum expectation for the quality standard. We believe it is important to allow RHCs the flexibility to fulfill this requirement in a variety of ways. As evidenced by the variance in the comments received, clinics have different views regarding the manner in which a clinic must comply with the standard. Each clinic will approach this requirement differently based on its resources and orientation to performance improvement.

The final rule does not require a specific number of improvement projects to be conducted annually. However, we will require that an RHC conduct distinct improvement projects. The number and frequency of distinct improvement projects to be conducted by the clinic as a result of its self-assessment must reflect the level and complexity of the clinic's organization and services. While large provider-based clinics might be involved in a complex QAPI program with its host facility, small independent clinics might develop very simple straightforward mechanisms to evaluate and improve their performance. The QAPI standard is the same for both large and small clinics but it can be fulfilled in a number of ways. We do not expect or insist that very small independent clinics develop a complex program. In both instances, we expect clinics to be proactive in assessing and improving outcomes and patient satisfaction.

Comment: One commenter stated that proposed § 491.11(a)(2) and (a)(3) are misplaced and inappropriate as regulation. They recommended that these instructions be included in the interpretive guidance for surveyors. They further suggested that we replace ''and'' with ''or'' and remove the ''at a minimum'' statement.

Response: We agree with replacing ''and'' with ''or'' and removing the ''at a minimum'' statement and have done so in the final rule.

We disagree that proposed § 491.11(a)(2) and (a)(3) are misplaced and inappropriate for regulation. However, we have made minor clarifying changes to these provisions. Since we allow flexibility in areas of performance measures and the number and frequency of improvement projects, we maintain that it is important to state in the QAPI standards that RHCs are expected to prioritize their improvement activities that most directly affect patient safety and clinical outcomes. Therefore, we have combined the provisions of proposed § 491.11(a)(2) and (a)(3) and included them at § 491.11(b)(2) under the program activities standard.

In section II of the preamble, page 10459, of the February 28, 2000 proposed rule, we included a discussion clarifying how we would apply the term ''measure'' as it pertains to the QAPI requirement for RHCs. We defined the word ''measure'' to mean that the RHC would have to use objective means of

tracking performance that enables a clinic (and a surveyor) to identify the difference in performance between two points in time. Not all objective measures would have to be shown to be valid and reliable based on scientific methodology in order to be usable in improvement projects. These measures may be designed by the clinic itself or by other sources outside the clinic. We anticipate that both large and small RHCs will use a variety of performance measures in their QAPI program. The proposed standard at § 491.11(b) is now stated in paragraphs (b)(l)(i) and (b)(l)(ii).

In order to promote consistency in the language to describe quality activities, we have replaced the term ''performance criteria'' in the first sentence of the proposed provision at § 491.11(b) with ''performance measures'' in § 491(b)(l)(i). We also replaced the word ''criteria'' in the second sentence of § 491(b) with the word ''measures'' in § 491(b)(l)(ii).

Comment: One commenter recommended that there be requirements for providing preventive health care services. However, a few commenters stated that the issue of prevention should be withdrawn from the rule, unless we would agree to reimburse for preventive services provided.

Response: Section 1861(aa)(1)(A) of the Act describes rural health clinic services as physicians' services and those services and supplies covered under section 1861(s)(2)(A) of the Act if they are furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10) of the Act. We agree that there are no requirements for the provision of preventive primary health services for an RHC and stated so in the February 28, 2000 proposed rule. However, since section 1861(s)(10) of the Act allows RHCs to provide pneumococcal, influenza, and hepatitis B vaccines, the topic of prevention was included under clinical effectiveness as an example of an area to evaluate if clinics were involved in these activities.

Comment: One commenter stated that availability of personnel to communicate with the patients they serve should be included under cultural competency.

Response: We agree that the ability to communicate with the patient population is an important part of cultural competency. However, the list in the February 2000 proposed rule under the ''access to care'' domain was given as an example and was not meant to be all-inclusive. Clinics will be free to identify and concentrate on areas that are priorities for them.

Comment: One commenter asked if emergency intervention meant that the clinic should have staff trained and competent in the delivery of cardiopulmonary resuscitation (CPR) and other services that might be necessary to maintain a very ill patient until care could be transferred to the emergency medical services system.

Response: A clinic is required to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses. The Emergency Medical Services (EMS) Systems Act defines first response services as a preliminary level of prehospital emergency care that includes CPR, monitoring vital signs and control of bleeding. Therefore, the clinic's staff should be competent in the delivery of first response emergency services.

Comment: One commenter stated that the surveyor should not be the only one to determine what constitutes an ''identifiable unit of measure.''

Response: As stated in section II of the preamble of the February 2000 proposed rule, we will not judge the measures themselves. Instead, we will assess how useful the measures are to the clinic in its overall program.

Comment: One commenter stated that surveyors should not have the authority to require an RHC to demonstrate what projects they are doing and the progress of the projects. Surveyors should only review and offer suggestions.

Response: The authority for surveyors to conduct onsite reviews of RHCs is contained in section 1864(a) of the Act. Surveyors acting on our behalf are expected to interview staff and probe on significant issues to determine if an entity meets RHC qualifications under section 1861(aa) of the Act.

We will develop interpretive guidelines and survey procedures to train surveyors on how to review QAPI program requirements, in addition to all other RHC requirements. As stated above, surveyors will not judge the performance measures but will look at elements that comprise each RHC's QAPI program, such as assessment data, rationale for prioritizing improvement activities, and progress on achieving improvement goals. As part of oversight, we would expect an RHC to make information on its QAPI program available to surveyors during initial certification, routine recertification, and complaint surveys to demonstrate how they meet the requirement.

We have stressed improvement in systems in order to improve processes and patient outcomes. The RHC's QAPI program will be evaluated for its effectiveness on the quality of care provided. Surveyors will not criticize the performance measures that RHCs choose to use in their QAPI program. Rather, surveyors will look at how well the RHC was able to mount an effective QAPI program. The surveyors will look at what the RHC has identified as an area for improvement, what the clinic did to address those areas of concern and what they are doing to maintain their improvement efforts. We will train surveyors on how to survey for an effective QAPI program. QAPI standards are designed to ensure that the providers have an effective process for continually measuring and improving care. The RHC QAPI supports the flexibility to establish, implement, maintain, and evaluate its individual QAPI program. Each RHC can custom-design a program that analyzes its own organizational processes, functions, and services, while maintaining the appropriate accountability. Performance improvement, as the basis for QAPI, fosters a ''blame-free'' environment and encourages providers to be proactive instead of being reactive.

Comment: One commenter suggested that the rule explicitly state that RHCs include the medical director of the clinic, a health care professional with experience in the delivery of services, or other ''reasonable'' individuals in determining appropriate measures.

Response: In § 491.11(c), we state that the RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the development, implementation, and evaluation of improvement actions. In addition, the clinic may develop a QAPI program using staff and resources it deems appropriate in accordance with its policies and procedures.

Comment: One commenter expressed concern regarding the reporting requirements, especially on small clinics. The commenter stated that small clinics should either be exempt from the proposed requirements or we should develop different standards for large and small clinics.

Response: The Congress has mandated that RHCs have a QAPI program as specified by the Secretary of the Department of Health and Human Services. We have not proposed that RHCs report the results of their evaluation and subsequent improvement activities to us. As a result, there is no need for any exemptions. However, as stated in § 491.11(b)(4), we will require a clinic to maintain records on its program and have them available for review by a surveyor.

Comment: One commenter noted that we did not emphasize the importance of pharmacists to quality care. As medication experts, pharmacists can play a significant role in ensuring that appropriate medications are given to patients in RHCs.

Response: We agree that pharmacists play a significant role in ensuring that appropriate medications are given to patients. The focus of the QAPI requirement is for RHCs to have a program to assess its processes, functions and services. If a clinic identifies a medication administration or dispensing problem, or is interested in assessing other quality of care issues, that involves pharmaceutical services, it would be appropriate for the RHC to solicit a pharmacist input into the QAPI activity.

Comment: One commenter stated the current requirements regarding protocols for the mid-level practitioners are restrictive and, in many cases, conflict with scopes of practices permitted in States' law. The commenter believes that midlevels should be allowed to practice to the highest level of scope of practice permitted by State law. This will ensure appropriate care to patients and enhance patient care and satisfaction.

Response: While we appreciate the commenter's concern, this issue is beyond the scope of this final rule.

Comment: Two commenters stated that since § 405.243(a) provides that a Federally Qualified Health Center (FQHC) must agree in its provider agreement with us to maintain compliance with requirements set forth in part 491, it could be read to apply to FQHCs. The commenter requested that we revise the February 2002 proposed rule to specifically state that § 491.11 does not apply to FQHCs stating that it would be duplicative to require FQHCs to meet this QAPI requirement because they are currently required to meet extensive performance standards established by the PHS. Section 330 of the Public Health Service Act requires grantees to undergo a rigorous PHS grant application process and the grantees are answerable to PHS in carrying out their grant activities; it is unnecessary to apply the RHC certification compliance process to FQHCs.

Response: We agree with the commenters that FQHCs currently have a QAPI program, as required under the PHS grant, that is more comprehensive than the requirements for RHCs. FQHCs and other health centers are required to have quality improvement systems to examine topics such as patient satisfaction and access, quality of clinical care, work force, work environment, and health status outcomes. In addition, FQHCs' quality improvement systems must have the capacity to measure performance using standard performance measures and accepted scientific approaches. In analyzing performance data, FQHCs must compare their results with other comparable providers at the State and national level and set realistic goals for improvement.

Since the BBA language did not specifically include FQHCs, and FQHCs are currently required under the section 330 grantees' program to have a continuous quality improvement and performance measurement program, we agree that it would be redundant to require health centers to comply with this condition. Even though FQHCs are required to comply with part 491 of the regulations, there are instances in part 491, based on statutory requirements, where the RHC requirements are different from the FQHC requirements. For example, FQHCs are allowed to contract for midlevels but as specified in § 491.8(a)(3), RHCs are not. Therefore, FQHCs must continue to comply with part 491 of the regulations except where noted.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the February 28, 2002 proposed rule. However, we are making the following changes to the regulations:

We are revising, in § 405.2401(b), the definition of rural health clinic as follows:

- The definition of RHC only applies to physicians and nonphysician practitioners working for the entity to furnish RHC services.
- Those physicians and nonphysician practitioners may not operate a private Medicare or Medicaid practice during RHC hours of operation, using clinic resources.

We are revising § 405.2462 to eliminate a standard used to qualify RHCs that are based in small rural hospitals for an exception to the national RHC payment limit.

We are revising § 491.3(b)(l) to clarify that both participating RHCs as well as applicants must be located in a current shortage area.

We are revising § 491.3(b)(2) to specify that RHCs with outdated shortage area designations will have 120 days to submit an application to update their medically underserved designation with protection from disqualification while the application is under review.

We are revising § 491.3(c)(2) to increase the period that RHCs may apply for an exception from disqualification.

We are revising § 491.5(b) to clarify the test used to determine if an RHC is essential to the delivery of primary care.

We are revising § 491.5(b) to establish rural patient utilization thresholds for RHCs located in nonurbanized areas that demonstrate they are essential to the delivery of primary care.

We are revising § 491.5(b) to combine the traditional community provider test with the major community provider test.

We are revising § 491.5(b) to establish a minimum national utilization patient threshold for RHCs applying for an exception as a major community provider.

We are removing the graduate medical education test at proposed § 491.5(b)(5). This test is no longer needed due to the refinements and clarifications we have made to the other essential community provider tests.

We are revising § 491.11 to clarify the requirements of the quality assessment performance improvement program the RHCs must develop, implement, evaluate, and maintain.

V. Regulatory Impact Analysis

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

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 to $25 million or less annually (see 65 FR 69432). 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 604 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 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1998 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal government, in the aggregate, or by the private sector of $110 million. The rule does not have an effect on the governments mentioned, and private sector costs are less than the $110 million threshold.

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

Although we view the anticipated results of these regulations as beneficial to the Medicaid and Medicare programs as well as to Medicare and Medicaid 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 does 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 February 1, 2001, was 3,341. Using 2000 Census data, there are approximately 100 urban clinics. At least 20 of these urban clinics do ''not'' have valid shortage area designations and would lose their RHC status.

With regard to the participating clinics that are still located in rural areas (about 3,200), at least 100 of these RHCs no longer have valid shortage area designations. Based on the above estimates, we know that about 180 would be eligible to apply for exception from RHC disqualification, but it is impossible to accurately predict how many will qualify for an exception. However, the estimated Medicare savings associated with the disqualification of certain RHCs from the Medicare program would be less than $10 million. 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. We believe, based on a recent study by the Maine Rural Health Research Center, that approximately 150 clinics will lose their RHC status. However, 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 criteria in § 491.5 identify the areas and clinics where RHC status and its payment methodology are still 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, and without a limit on the payment per visit. These criteria are applicable to independent RHCs that furnish the same scope of services. We have codified the statutory requirement to pay all RHCs under an all-inclusive rate per visit, which will avoid allocation of excessive administration costs to RHCs. We believe that about a thousand RHCs are affected by this rule.

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 hospitals, that is, a hospital with fewer than 50 beds.

The QAPI requirement may increase burden in the short term because resources currently used for quality measurement will need to be directed to the development of a quality assessment and performance improvement program that covers the complexity and scope of the particular clinic. However, while the 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 (for example, cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

Moreover, 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 is 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 will not impose significant additional burden.

Impact of the QAPI Provisions

We estimate that the additional one-time impact for the initial development of the QAPI provisions will be as follows:

Hours/Estimated Salary/Number of RHCs	One-time cost	Annual cost
1 physician/administrator at $58/hr × 3 hrs × 3,300 clinics for medical direction and overview of QAPI program	$574,200	
1 Mid-level practitioner (physician assistant, nurse practitioner) at $28/hr × 32 hrs × 3,300 clinics for program development	2,956,800	

Hours/Estimated Salary/Number of RHCs	One-time cost	Annual cost
1 clerical staff at $6/hr × 5 hrs × 3,300 clinics	99,000	
1 mid-level practitioner at $28/hr × 4 hrs × 3,300 clinics for data collection and analysis	.....	369,600
1 mid-level practitioner—3 hrs training	277,200	
Totals	3,907,200	369,000

In developing our estimates, we obtained information on the salaries and wage estimation from the American Medical Association.

OBRA '89 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 revision requires 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, private physicians or other practitioners who have used this approach under 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 final rule, most provider-based RHCs are subject to payment limits and some RHCs will lose their RHC status and cost-based payment rates. Although these changes will likely result in program savings, we believe the aggregate amount is 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 total budget and that less than half of all RHCs will experience changes to their payment rates, we believe any aggregate savings will be insignificant. We also believe an insignificant amount of Medicare and Medicaid program savings will result from the provision that will terminate RHC status for certain providers. Less than 5 percent of all participating RHCs could lose their status, and these affected clinics will 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 will have to demonstrate that their utilization rates exceed the threshold.

Although this 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 major community provider test. We also considered the option of establishing less generous tests for identifying RHCs as essential clinics to the delivery of primary care. That is, the establishment of tests narrowly focused on a few extreme cases, such as an exception test for only sole community providers for a very rural community. We rejected this option because of concern that the disqualification of a clinic from the RHC program could harm access to primary care for the entire community. We believe a comprehensive set of tests is needed to avoid harming access to care for rural areas.

• *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 of the February 28, 2002 proposed rule, we described alternative ways of satisfying the ''minimum level requirement'' for the QAPI program and asked for comments. Among the alternatives that we considered were 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. After considering the public comments, which were not conclusive, we decided not to establish a minimum requirement. We did consider alternatives for the final rule. One alternative was to take a more rigid approach to QAPI whereby the final rule would be more prescriptive in the process RHCs must follow to develop the QAPI program including setting forth specific performance measures to be utilized, the frequency and number of QAPI ''interventions'' that must be done, as well as the type and frequency of data to be collected. While a more rigid approach would increase RHC burden, we realize there would be no assurance that it would result in better or more predictable outcomes.

We decided to promote a more flexible and less prescriptive approach to the QAPI condition. We are more concerned with an RHC identifying its own best practices and the outcomes of an agency individualized QAPI program than in specific steps one takes to achieve the improvement. A more moderate QAPI requirement will allow an RHC the flexibility to utilize staff and other resources in ways that more directly supports its needs. An RHC can design a program to analyze its own

organizational processes, functions and services, while still being held accountable for results. This decision allows clinics the flexibility to fulfill this requirement based on their resources.

Conclusion

We do 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, will be adversely affected by these changes. The commingling provision of this regulation adds little savings. One reason for this conclusion is that the outpatient visit rate for HCPCS code 99214 was about $59.00 and the RHC visit was also about $59.00. If an adjustment is made for lower physician overhead than that of the RHC, the savings will 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 rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the OMB.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the OMB for review and approval. In order to fairly evaluate whether OMB should approve an information collection, 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 our regional offices within 180 days from the date we notify 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 in accordance with the conduct of an investigation or audit against specific individuals or entities.

Section 491.3(c)(4) states that clinics can renew their essential provider status by submitting written assurances to our regional office that they continue to meet the conditions at § 491.5.

The burden associated with this requirement is the time and effort for the clinic to prepare and submit written assurances that they continue to meet the conditions. It is estimated that this requirement will take each clinic 30 minutes. There are approximately 400 clinics that may be affected by this requirement for a total of 200 burden hours.

Section 491.8 Staffing and Staff Responsibilities

Section 491.8(d)(1) states that we 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

Section 491.11 states that the RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement program. The self-assessment and performance improvement program must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

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, 2003.

This QAPI CoP will replace the existing program evaluation CoP found at § 491.11. RHCs are currently required to perform an annual program evaluation and the burden reported for the annual evaluation will be used in the new QAPI requirement. We agree that the PRA collection (0938–0334) should be updated to increase burden for RHCs to develop a QAPI program and train staff. The estimation of 70 to 80 hours to maintain a QAPI program may be realistic for the clinic that commented. However, it is difficult to accurately state the impact of the QAPI requirement on RHCs without knowing the size and scope of the clinics and how complex the QAPI program will be for each clinic. We have developed this requirement with the flexibility that allows both large and small clinics to develop a program that reflects the resources and complexity of each clinic's organization and services.

We estimate that on average it will take a clinic approximately 40 hours to develop a QAPI program. For those clinics that are provider based and have experience with the QAPI process, this time will be reduced. This time will also vary based on how simplicity or complexity of the program that a clinic develops. The QAPI CfC will replace the existing annual program evaluation CfC (42 CFR 491.11). The activities that are currently covered by the existing PRA on file with OMB are found in § 491.9—''Provisions of Services.'' These activities include: Patient care policies, guidelines for medical management of health care problems, and procedures to review and evaluate services furnished by the RHC. In the existing PRA for the current regulations, the burden hours for provisions of services include 10 hours (one time) for initial development, and 2 hours annually for review and revision. The next time we updates its PRA submission for Part 491, we will add the 10 hours and 2 hours with the 40 hr initial burden for the QAPI program. We used the previous burden estimate for the annual evaluation, in part, to estimate the new QAPI requirement. It is difficult to accurately state the impact of the QAPI requirement on RHCs without knowing

the size and scope of the clinics and how complex the QAPI program will be for each clinic. In developing the requirement, we wanted to assure flexibility for RHCs so that both large and small clinics can develop a program that reflects the resources and complexity of each clinic's organization and services. We estimate it will take a clinic approximately 40 hours to develop a QAPI program from a variety of assumptions. First, the hospital QAPI condition of participation estimates 80 hours for a hospital to develop the program. We expect that at the level-of-effort for a RHC would be less than that for a hospital QAPI program as hospitals provide more services than RHCs. For hospital provider-based clinics, we expect that they would already have experience with the QAPI process. Therefore, their level-of-effort would be reduced. The 40-hour time estimate also recognizes that the time will vary based on the simplicity or complexity of the program that a clinic develops. We also estimate that the RHC will spend an additional 4 hours a year collecting and analyzing data. In addition, we estimate that clinics will spend 3 hours a year training and or updating staff on their QAPI program. Since the QAPI program will replace the current annual evaluation requirement, the administrative burden and annual review of policies and procedures are currently covered by 0938–0334.

Requirement	Annual burden hours	One-time burden hours
Program Development	.....	40 hrs × 3,300 = 132,000
Data Collection and Analysis	13,200	
Training	.....	3 hrs × 3,300 = 9,000
Total	13,200	141,000

These are preliminary projections that may change slightly as we update the PRA submission.

To maintain the data required by § 491.11, we estimate it will take each clinic 1 hour per year to meet this requirement. Since there are an estimated 3,341 facilities, the total burden associated with this requirement is 3,341 annual hours.

We have submitted a copy of this final 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 these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Dawn Willinghan (Attn: CMS–1910–F), Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

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, The Centers for Medicare & Medicaid services amends 42 CFR chapter IV 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 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), revise the definition of ''rural health clinic'' to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) *Definitions.*

* * * * *

Rural health clinic (RHC) means an entity that:

(1) Meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in § 405.2402 to provide RHC services under Medicare.

(3) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid practice operated by the same physicians and nonphysician practitioners working for the RHC. Operation of a multipurpose clinic with other types of health providers or suppliers is permissible subject to the provisions in paragraph (4) of this definition.

(4) Appropriately allocates and excludes from the RHC cost report the net non-RHC costs if it operates at a multipurpose location that involves the sharing of common space, medical support staff, or other physical resources with other health care providers or suppliers.

* * * * *

■ 3. Revise § 405.2410 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 Medicare Part B deductible as follows:

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

(ii) If the deductible is not 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 for 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. Revise § 405.2462 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 CMS.

(3) If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per-visit payment limit if the hospital has fewer than 50 beds as determined by using one of the following methods:

(i) The determination of the number of beds 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 or 412.109(a) of this chapter.

(B) It is located in a level 8 or level 9 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.

(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—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. Revise § 491.2 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 is—

(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 the public Health Service 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 section 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. Revise § 491.3 to read as follows:

§ 491.3 RHC procedures.

(a) *General.* (1) CMS processes Medicare participation matters for RHCs as specified in §§ 405.2402 through 405.2404 of this chapter, and with the applicable procedures in part 486 of this chapter.

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

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

(b) *Current designation.* (1) Participating RHCs and an applicant requesting entrance into the Medicare program as an RHC must be located in a current shortage area for which a designation is made or updated within the current year or within the previous 3 years.

(2) RHCs with outdated shortage area designations will have 120 days, from the date CMS notifies the facility that its designation is no longer current, to submit an application to update its medically underserved designation.

(3) RHCs located in service areas with outdated shortage area designations will be protected, for 120 days, from RHC disqualification while their applications for updating the medically underserved designations are under review by HRSA.

(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, or if it is no longer designated as nonurbanized by the Census Bureau.

(2) An existing RHC may apply for an exception from disqualification by submitting a written request to a CMS regional office within 180 days from the date CMS notifies the RHC 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) The CMS regional office may grant a 3-year exception based on its review of an RHC request and other relevant information, if the CMS regional office determines that the RHC is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC as specified in § 491.5(b).

(4) Clinics can renew their essential provider status by submitting written assurances to the CMS regional office that they continue to meet the conditions at § 491.5.

(5) CMS terminates an ineligible clinic from participation in the Medicare program as an RHC, effective the final day of the 6th month from the date CMS notifies the clinic of a final determination of ineligibility (including denial of any exception request submitted). CMS may terminate RHC status earlier based on noncompliance with other certification requirements.

■ 4. In § 491.5, remove paragraphs (d) and (e), redesignate paragraph (f) as paragraph (d), and revise paragraph (b) to read as follows:

§ 491.5 Location of clinic.

* * * * *

(b) *Exceptions.* CMS will not disqualify an RHC approved for Medicare participation located in an area that no longer meets the definition of a shortage or rural area, if it determines that the RHC has established that it is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC. An RHC no longer located in a rural area must have a valid shortage area designation (underserved area or population) and meet the criteria set forth in paragraphs (b)(2)(i), (b)(2)(ii), or (b)(2)(iii) of this setion. The RHC that is no longer located in a rural area must also establish that it is essential to the delivery of primary care for patients residing in a rural area by demonstrating that at least 51 percent of the clinic's patients reside in an adjacent nonurbanized area.

(1) *Essential provider exception criteria.* In order to make the final decision to grant an exception as an

essential provider under this section, CMS will:

(i) Grant an exception to one or more RHCs in a given service area if CMS determines the clinics each meet the criteria set forth in paragraphs (b)(2)(ii) or (b)(2)(iii) of this section.

(ii) Use the following criteria in determining distances corresponding to 30 minutes travel time:

(A) Under normal conditions with primary roads available within 20 miles.

(B) In areas with only secondary roads available within 15 miles.

(C) In flat terrain or in areas connected by interstate highways within 25 miles.

(2) *Conditions for exception.* To receive an exception, the RHC must meet one of the following conditions:

(i) *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 low-income patients (Medicaid beneficiaries and the uninsured, regardless of their ability to pay).

(ii) *Major community provider.* The RHC has Medicare and low-income patient (Medicaid and uninsured) utilization rates equal to or above 51 percent or low-income patient utilization rates equal to or above 31 percent. The RHC is also actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating RHCs that are within 30 minutes travel time; or, if the clinic is the only participating RHC within 30 minutes travel, the RHC is actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers.

(iii) *Specialty clinic.* The RHC (located within 30 minutes travel time) is the sole or major source of pediatric or OB/GYN services for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is actively accepting and treating these patients. Only clinics that exclusively provide pediatric or OB/GYN services can receive an exception under this test. A specialty clinic is also an RHC that is the sole source of mental health services, as defined in § 405.2450. For purposes of meeting this test, mental health services must be furnished onsite to clinic patients. Clinics applying as a major source of pediatric or OB/GYN services must have low-income patient (Medicaid and uninsured) utilization rates equal to or above 31 percent.

(iv) *Extremely rural community provider.* The RHC is actively accepting and treating Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) and is located in a frontier county (less than six persons per square mile) or in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

* * * * *

■ 5. In § 491.8, revise paragraph (a)(6) and add a new paragraph (d) 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) CMS 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) CMS terminates the RHC from participation in the Medicare program, if the RHC is not in compliance with the provisions waived under paragraphs (a)(1) and (a)(6) of this section at the expiration of the waiver.

(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.

■ 6. Revise § 491.11 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 self-assessment and performance improvement program must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

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

(1) Organizational processes, functions, and services.

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

(b) *Standard: Program activities.* (1) For each of the areas listed in paragraph (a)(1) of this section, the RHC must do the following:

(i) Adopt or develop performance measures that reflect processes of care and RHC operation and is shown to be predictive of desired patient outcomes or be the outcomes themselves.

(ii) Use the measures to analyze and track its performance.

(2) The RHC must set priorities for performance improvement, considering either high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of care, convenience and timeliness of available services, or grievances and complaints.

(3) The RHC must conduct distinct improvement projects; the number and frequency of distinct improvement projects conducted by the RHC must reflect the scope and complexity of the clinic's services and available resources.

(4) The RHC must maintain records on its QAPI program and quality improvement projects.

(5) An RHC may undertake a program to develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This activity will be considered to fulfill the requirement for a project under this section.

(c) *Standard: Program responsibilities.* The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the following:

(1) Ensuring that quality assessment and performance improvement efforts effectively address identified priorities.

(2) Identifying or approving those priorities and for the development, implementation, and evaluation of improvement actions.

Dated: February 28, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 28, 2003.

Tommy G. Thompson,

Secretary.

Editorial note: This document was received at the Office of the Federal Register on December 18, 2003.

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