DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, and 491

[CMS–1910–P2]

RIN 0938–AJ17

Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish location requirements including exception criteria for rural health clinics (RHCs). It would also require RHCs to establish a quality assessment and performance improvement (QAPI) program. In addition, it would: Clarify our policies on ''commingling'' of an RHC with another entity; revise the RHC and Federally Qualified Health Centers (FQHC) payment methodology and exceptions to the per-visit payment limit to implement statutory requirements; revise RHC and FQHC payment requirements for services furnished to skilled nursing facility (SNF) patients; allow RHCs to contract with RHC nonphysician providers under certain circumstances; and update the regulations pertaining to waivers to the staffing requirements. This proposed rule would also add requirements for RHCs and FQHCs to maintain and document an infection control process and to post RHC or FQHC hours of clinical services. In addition, this proposed rule would update the requirements under the emergency services standard and patient health records condition for certification (CfC) to reflect advancements in technology and treatment. Finally, this proposed rule solicits comments on payment for high cost drugs and the appropriateness of a mental health specialty clinic as an exception to the location requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 26, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1910–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the CMS–1910–P2 to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1910–P2, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1910–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Corinne Axelrod, (410) 786–5620. Rural health clinic location requirements and exceptions, staffing and payment. Mary Collins, (410) 786–3189 and Scott Cooper (410) 786–9465. Quality assessment and performance improvement and health and safety standards.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Abbreviations and Acronyms

AED—Automated External Defibrillator
BBA—Balanced Budget Act of 1997
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAH—Critical Access Hospital
CDC—Centers for Disease Control and Prevention
CfC—Condition for Certification
CMS—Centers for Medicare & Medicaid Services
CNM—Certified Nurse-Midwife
CNS—Clinical Nurse Specialist
CoP—Condition of Participation
CP—Clinical Psychologist
CSW—Clinical Social Worker
DRA—Deficit Reduction Act
DSMT—Diabetes Self-Management Training
FI—Fiscal Intermediary
FQHC—Federally Qualified Health Center
GAO—Government Accountability Office
GDSC—Governor-Designated and Secretary-Certified Shortage Areas
HHS—Department of Health and Human Services
HPSA—Health Professional Shortage Area
HRSA—Health Resources and Services Administration
MAC—Medicare Administrative Contractor

MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MUA—Medically Underserved Area
MUP—Medically Underserved Population
NP—Nurse Practitioner
OBRA—Omnibus Budget Reconciliation Act
OIG—Office of the Inspector General
OMB—Office of Management and Budget
PA—Physician Assistant
PHS—Public Health Service
PPS—Prospective Payment System
PRA—Paperwork Reduction Act
QAPI—Quality Assessment and Performance Improvement
RFA—Regulatory Flexibility Act
RHC—Rural Health Clinic
RO—Regional Office
RUCA—Rural Urban Commuting Area
SCHIP—State Children's Health Insurance Program
SNF—Skilled Nursing Facility
UA—Urbanized Area
UIC—Urban Influence Code
USDA—United States Department of Agriculture

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I. Background

A. Publication and Suspension of the December 24, 2003 Final Rule

On February 28, 2000, we published a proposed rule in the **Federal Register** (65 FR 10450) entitled ''Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program.'' This proposed rule revised certification and payment requirements for rural health clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA), Public Law 105–33, enacted on August 5, 1997. We issued the final RHC rule on December 24, 2003 (68 FR 74792).

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted. Section 902 of the MMA amended section 1871(a) of the Social Security Act (the Act) and requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that ''[s]uch timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances.''

To comply with the MMA requirement to publish a final rule not more than 3 years after a proposed rule, we suspended the effectiveness of the December 24, 2003 final rule on September 22, 2006 (71 FR 55341). The Code of Federal Regulations currently reflects the regulations in effect before December 2003.

While section 902 of the MMA did not explicitly prohibit the Secretary from finalizing all proposed rules that were published as an interim or proposed rule more than 3 years before December 8, 2003, we chose to take this opportunity to propose additional updates and clarifications of the provisions published in the previous rule, and provide the public with the opportunity to comment on these proposals.

B. Summary of the Provisions of the December 24, 2003 Final Rule

The December 24, 2003 final rule addressed comments received on the February 28, 2000 proposed rule, and finalized policies regarding RHC and federally qualified health center (FQHC) payment and participation in the Medicare program. It established: (1) Criteria and a process to decertify RHCs which no longer serve rural or medically underserved areas (MUAs), as required by the BBA; (2) a policy that would have prohibited the commingling of RHC resources with another entity's resources; and (3) a requirement that RHCs establish a quality assessment and performance improvement (QAPI) program.

The December 24, 2003 final rule also updated payment policies and regulations to conform to statutory requirements of the Omnibus Budget Reconciliation Acts (OBRA) '86, '87, '89, and '90 and the MMA.

For the reasons specified in section I.A. of this proposed rule, these provisions have been suspended.

C. Origin of the RHC/FQHC Programs

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210) enacted on December 13, 1977, amended the Act by adding section 1861(aa) of the Act to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at an RHC by physicians and certain ''nonphysician practitioners,'' and for services and supplies incidental to their services. ''Nonphysician practitioners'' included nurse practitioners (NPs) and physician assistants (PAs). (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse-midwives (CNMs).)

According to House Report No. 95–548(I), the purpose of the Rural Health Clinic Services Act was to address an inadequate supply of physicians serving Medicare beneficiaries and Medicaid recipients in rural areas. The legislation addressed this problem by authorizing CMS and States to pay qualifying clinics on a cost-related basis for providing Medicare beneficiaries and Medicaid recipients, respectively, with outpatient physician and certain nonphysician services. (The Medicare payment provisions for RHCs are in sections 1833(a)(3) and 1833(f) of the Act and in regulations at § 405.2462 through § 405.2468.) Payment to RHCs for services furnished to beneficiaries is

made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit and annual reconciliation.

Qualifying clinics, among other criteria, must be located in an area that is determined to be nonurbanized by the U.S. Census Bureau. The clinic also must be located in an area designated as a shortage area either by the Health Resources and Services Administration (HRSA) or by the chief executive officer of the State and certified by the Secretary, Department of Health and Human Services (HHS). (See section 1861(aa)(2) of the Act, following subparagraph (K).)

Qualifying clinics also must employ a PA or NP and, to meet requirements of the OBRA '89, must have a NP, a PA, or a CNM available to furnish patient care services at least 5.0 percent of the time the RHC operates.

The FQHC Medicare coverage and payment benefit was provided for in OBRA '90, Public Law 101–508, enacted on November 5, 1990, and implemented in the **Federal Register** (57 FR 24961) on June 12, 1992. On April 3, 1996, we published a final regulation (61 FR 14640) that addressed the issues raised by commenters on the June 1992 rule.

OBRA '90 defines an FQHC as an entity that is receiving a grant under section 329, section 330, or section 340 of the Public Health Service Act (PHS). The definition of an FQHC was expanded by section 13556(a)(3) of OBRA '93 (Pub. L. 103–66) enacted on August 10, 1993, effective as if included in OBRA '90 on October 1, 1991. The expanded definition included outpatient programs or facilities operated by a tribal organization under the Indian Self-Determination Act, or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

The FQHC scope of benefits for core services is similar to the RHC benefit, that is, physician, nonphysician practitioner, and mental health professional services. The FQHC benefit also includes a number of preventive services.

Each FQHC is reimbursed its reasonable costs based on an all-inclusive per-visit methodology subject to tests of reasonableness, and is subject to an overall payment limit similar to RHCs. The national FQHC payment limit is based on the costs of providing primary care physician and prevention services. For FQHC services, there are two upper payment limits: One limit is for centers located in urban areas and the other is for centers located in rural areas.

D. Growth of the RHC Program

The RHC program has grown from less than 1,000 Medicare-approved RHCs in 1992 to more than 3,700 in 2008. However, since 2001, growth in the program has leveled off. While part of this increase has improved access to primary care services in rural areas for Medicare beneficiaries and Medicaid recipients, there are instances in which these additional RHCs have not expanded access.

1. 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 the Health Clinic Services Act of 1977 (Pub. L. 95–210) enacted December 13, 1977, 42 U.S.C. 1395x note. Also see § 491.5(b)(2) of the regulations.) Section 1861(aa)(2) of the Act stated that any RHC that subsequently failed to satisfy the requirements pertaining to the rural and underserved location requirement still would be deemed to have satisfied the requirement of that clause.

These provisions protected the clinics' RHC status regardless of any changes to the rural or underserved status of the service areas. It allowed clinics to remain in the RHC program even though the service areas no longer were considered rural or medically underserved.

The Congress established these protections 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 clause provision was an appropriate policy at the time, we now have RHC participation in some service areas with extensive health care delivery systems that provide adequate access to primary care for Medicare beneficiaries and Medicaid recipients. Both the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) 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. In section 4205(d)(3) of the BBA, the Congress responded to these recommendations by amending the grandfather clause provision to provide protection only to clinics essential to the delivery of primary care in the respective service area.

2. Medically Underserved/Shortage Area Designations

Another reason for the continued growth of the RHC program was that two of the types of shortage area designations that are used for RHC certification, the medically underserved area (MUA) and the Governor-Designated Secretary-Certified Shortage Area (GDSC) designations, did not have a statutory requirement for regular review and were not reviewed systematically and updated after their initial designation. As a result, some RHCs are in areas that no longer would be designated as underserved if reviewed with current data. In response, the Congress amended the legislation in section 4205(d) of the BBA by requiring that only those clinics located in shortage areas that were designated or updated within the previous 3 years would qualify for purposes of the RHC program.

3. Expansion of Eligible Designations for RHC Certification

Section 6213 of OBRA '89 amended section 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 under section 330(b)(3) of the PHS Act (medically underserved areas (MUAs)) and those designated as geographic health professional shortage areas (HPSAs) 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. However, later, 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 impact migrant areas.

4. Commingling

The growth of RHCs may have also been stimulated by the practice of

''commingling.'' The term ''commingling'' is used to describe the sharing of RHC space, staff, supplies, records, or other resources with a private Medicare practice or other entity operated by the same physician and nonphysician practitioners working for the RHC, during RHC hours of operation. We recognize that providing care in rural areas that have limited infrastructure and providers requires the coordination of scarce resources, and permit the sharing of resources in certain situations. In some of these situations, however, it is believed that commingling has been used to maximize Medicare payment by obtaining RHC status for an integrated practice that submits both RHC and non-RHC Medicare claims.

E. Government Reports on RHCs

The GAO report, ''Rural Health Clinics: Rising Program Expenditures Not Focused on Improving Care in Isolated Areas'' (GAO/HHS–97–24, November 22, 1996), and the HHS/IG report ''Rural Health Clinics: Growth, Access and Payment'' (OEI–05–94–00040, July 1996), both 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, critical access hospital (CAH), skilled nursing facility (SNF), or home health agency (HHA), and is operated with other departments of the provider under common governance, professional supervision, and usually licensure. All other RHCs are considered to be independent.)

In August 2005, the OIG issued a followup report, ''Status of the Rural Health Clinic Program'' (OEI–05–03–00170), which recommended that HRSA review shortage designations within the requisite 3-year period and publish regulations to revise its shortage designation criteria. The report also suggested that CMS issue regulations to: (1) Ensure that RHCs determined to be essential providers remain certified as RHCs; and (2) require prospective RHCs to document need on access to health care in rural underserved areas.

II. Provisions of This Proposed Rule

A. RHC Location Requirements and Exceptions

1. RHC Location Requirements

In sections 4205(d)(1) and (2) of the BBA, the Congress amended section 1861(aa)(2) of the Act. As revised, the statute states that RHCs may include only a facility which is located in: (1) A nonurbanized area, as defined by the U.S. Census Bureau; (2) an area in which there are an insufficient number of needed health care practitioners as determined by the Secretary; and (3) an area that has been designated or certified by the Secretary within the previous 3 years as having an insufficient number of needed health care practitioners.

Section 4205(d)(3)(A) of the BBA, which amended the third sentence of section 1861(aa)(2) of the Act, 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 specified that an exception was available only if the RHC was 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 CMS to issue by January 1, 1999. The BBA requirement that every RHC must have a current shortage area designation (made or updated within the previous 3-year period), has been implemented for new RHCs through administrative instructions.

To determine if a facility is in a nonurbanized area, we propose that the most recently available U.S. Census Bureau list of Urbanized Areas (UA) be used. An area that is not in a UA would be considered a nonurbanized area. Information on whether an area is urbanized can be found at *http://factfinder.census.gov* or by contacting the appropriate CMS Regional Office (RO) at *http://www.cms.hhs.gov/RegionalOffices*.

To determine if a facility is in an area that has a current designation as an underserved or shortage area, the most current HRSA list of these designations would be used. Information on designation status, including the date of the most recent designation or update, is available on the HRSA Web site at *http://hpsafind.hrsa.gov/* and *http://muafind.hrsa.gov* or by contacting the appropriate CMS RO.

Health professional shortage area (HPSA) and MUA designations establish initial eligibility for Federal and State programs to improve access to health care services. They are based on established criteria (42 CFR part 5) to identify geographic areas or population groups with a shortage of primary health care services. HPSA designations are based primarily on the population to provider ratio in a defined service area. MUA designations utilize an Index of Medical Underserviced which calculates a score for each area based on a weighted combination of the ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of the population with incomes below the poverty level, and percentage of the population age 65 or over.

(**Note:** HRSA has proposed a revision of the methodology used for determining HPSA and MUA designations. If necessary, this description of the designations will be updated in the final rule. Any change that HRSA makes to the methodology used to determine designations will not alter the requirements for the RHC program.)

Any of the following types of designations are acceptable for the purpose of RHC certification and compliance with this proposed requirement:

- Geographic Primary Care HPSAs (section 332(a)(1)(A) of the PHS Act)
- Population-group Primary Care HPSAs (section 332(a)(1)(B) of the PHS Act)
- MUAs (This does not include population group Medically Underserved Population designations) (Section 330(b)(3) of the PHS Act)
- Governor-designated and Secretary-certified shortage areas. (section 6213(c) of OBRA '89 (Pub. L. 101–239))

In section 302(a)(1)(A) of the Health Care Safety Amendments of 2002 (Pub. L. 107–251, October 26, 2002), the Congress amended section 332 of the PHS Act to create a new type of HPSA designation for FQHCs and RHCs referred to as an ''automatic'' HPSA designation. This type of designation is available to any RHC or FQHC irrespective of its physical location that utilizes sliding scale fees consistent with section 330 of the PHS Act for the purpose of National Health Service Corps eligibility. Facilities with these automatic HPSA designations are sometimes referred to as ''safety net facilities.'' However, we are proposing not to include the automatic HPSA designations as an eligible shortage area for purposes of Medicare qualifications as an RHC. Section 1861(aa)(2) of the Act specifically requires RHCs to be located in one of four specified designation types in which the Secretary has determined that there are

insufficient numbers of needed practitioners. Consequently, we would not recognize automatic HPSA designations for purposes of RHC certification or protecting a currently participating clinic from RHC decertification.

New and existing RHCs would have to be in a rural area that is currently designated as one of the four types of shortage areas listed previously. A designation is considered current for not more than 3 years after the date of the original designation or the date of the most recent update to the designation. An existing RHC that no longer meets would not be decertified based on the loss of its shortage area designation if: (1) A complete designation application has been received by HRSA before the end of the 3-year period since the shortage area designation date or most recent update; or (2) we have determined that the RHC is an essential provider. If either of these conditions is not met, the clinic would be terminated from participation in the Medicare program as an RHC 180 days after the date that the RHC no longer meets the location requirements, effective the last day of the month. States are encouraged to submit designation applications and updates to HRSA in a timely manner and may apply or reapply for a designation at any time.

2. Essential Provider Requirements

The RHC program was established for the purpose of improving and maintaining access to primary care for rural underserved communities. RHCs that apply to CMS for an exception to the location requirements must be able to show that they satisfy this program objective.

In accordance with section 1861(aa)(2) of the Act, an existing RHC may be considered essential to the delivery of primary care (a so-called ''essential provider'') if the care otherwise would be unavailable in the geographic area served by the clinic. The Secretary is directed by the Act to set the criteria by which ''essential provider'' status is to be determined. The Secretary has determined that an RHC may be considered an essential provider and be granted an exception to the location requirements if the clinic is no longer in a nonurbanized area or it is no longer in a currently designated shortage area, and it meets the criteria of an essential provider. An RHC that is neither in a rural area nor a designated area would not be considered an essential provider. Proposed criteria for essential provider status were published in the February 2000 proposed rule and have been revised based on comments that were received and other relevant information.

Under this authority, we are proposing the following requirements for essential provider status:

If an RHC is located in an area that has been classified as a UA by the U.S. Census Bureau, it would have to be in a level 4 or higher Rural Urban Commuting Area (RUCA) to assure that it is in a rural area. Under section 330A of the PHS Act, HRSA's Office of Rural Health Policy determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, any census tract that is in a RUCA level 4 or higher is determined to be a rural census tract. For the purposes of an exception to the RHC nonurbanized area location requirement, we would use the RUCA level 4 as the minimum level of rurality to meet this requirement.

Additionally, an RHC that is located in an area that has been classified as a UA by the U.S. Census Bureau would have to demonstrate that at least 51 percent of its patients reside in an adjacent nonurban area in order to be considered essential for the purposes of an exception to the location requirements. We prefer to give RHCs flexibility in establishing that at least 51 percent of their patients reside in an adjacent nonurban area; however, this could generally include the identification of the nonurban area(s) and a retrospective review of patient visits to determine residence, or other factors to support that the requirement has been met.

3. Location Exception Criteria

We are proposing to revise § 491.5 to specify that an RHC that meets the previously stated requirements may apply for an exception if it meets any one of the following criteria:

• *Sole Community Provider (proposed § 491.5(c)(1)):* The RHC is the only participating primary care provider that meets either of the following requirements:

++ The RHC is at least 25 miles from the nearest participating primary care provider; or

++ The RHC is at least 15 miles but less than 25 miles from the nearest participating primary care provider and can demonstrate that it is more than 30 minutes from the nearest primary care provider based on local topography, predictable weather conditions, or posted speed limits. (These criteria are based on the criteria established for sole community hospitals in § 412.92.) For purposes of this exception, a participating primary care provider would mean another RHC, FQHC, or primary care provider that is actively accepting and treating Medicare beneficiaries, Medicaid recipients, low-income patients, and the uninsured (regardless of their ability to pay).

• *Major Community Provider (proposed § 491.5 (c)(2)):* The RHC meets the following requirements:

++ Has a Medicare, Medicaid, low-income, and uninsured patient utilization rate greater than or equal to 51 percent, or a low-income patient utilization rate greater than or equal to 31 percent; and

++ Is actively accepting and treating a major share of Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC.

• *Specialty Clinic: Obstetrics/Gynecology (Ob/Gyn) or Pediatrics (proposed § 491.5(c)(3)):* The RHC meets the following requirements:

++ Exclusively provides ob/gyn or pediatric health services (as applicable).

++ Is the sole or major source of ob/gyn or pediatrics for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is either of the following:

—At least 25 miles from the nearest participating provider of ob/gyn or pediatric services.

—At least 15 miles but less than 25 miles from the nearest participating provider of ob/gyn or pediatric services, and can demonstrate that it is more than 30 minutes from the nearest participating primary care provider providing these services based on local topography, predictable weather conditions, or posted speed limits.

++ Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients.

++ Has a Medicare, Medicaid, low-income patient and uninsured utilization rate greater than or equal to 31 percent.

++ Provides ob/gyn (including prenatal care) or pediatric services onsite to clinic patients.

• *Extremely Rural Community Provider (Proposed § 491.5(c)(4)):* The RHC meets the following requirements:

++ Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay).

++ Is located in a frontier county (a county with 6 or less persons per square mile) or in census tract or zip code with a RUCA code 10.

In the December 2003 final rule, we included RHC's that are mental health

specialty clinics as an acceptable category for an exception to the location requirements. However, section 1861(aa)(2)(iv) of the Act prohibits RHC status from being applied to clinics which are ''primarily for the care and treatment of mental diseases.'' We interpret ''primarily'' to mean that mental health services provided by the RHC cannot constitute more than 50 percent of the total services provided by the RHC.

In order to assure that the regulation and statue are consistent, we are asking for comments on—(1) whether it is appropriate to allow an exception to the location requirements for RHCs based on the provision of mental health services in light of the fact that RHC status cannot be granted to a facility providing more than 50 percent of its total services in mental health; and (2) if so, what should be the minimum level of mental health services provided in order to qualify for an exception. This would apply only to existing an RHC that no longer meet the location requirements, either because it is no longer in a non-urbanized area, or because it is no longer designated by HRSA as an underserved or shortage area. Existing RHCs that are in compliance with the location requirements may continue to provide mental health services as long as the mental health services provided do not exceed 50 percent of the total clinic services.

4. Process for Essential Provider Status and Timeline

An RHC that is located in (a) an area that has not been designated or its designation was not been updated for more than 3 years, or (b) an urbanized area that is defined by the Census Bureau, would have 90 calendar days from the effective date of the final rule to apply to CMS RO for an exception to the location requirement. The RHC may continue to operate as an RHC for an additional 90 days, for a total of 180 calendar days after the end of the 3-year period. To assist with the cost reporting and payment reconciliation process, decertification would be effective on the last day of the month in which the 180-day limit was met.

An RHC would have 180 days after the date that it does not meet the location requirements to continue operating as an RHC. We expect that most RHCs that do not meet the location requirements would want to know as soon as possible if they would receive an exception to the location requirements and would want as much time as possible to make other arrangement for the provision of services after the 180 days, so it is in the interest of the RHC to apply for an exception to the location requirements as soon as possible.

An RHC which is located in an area which has been found by HRSA to no longer qualify for one of the 4 types of eligible designations would have 90 calendar days from the date HRSA determined that the area no longer qualified for one of the eligible designations to apply to CMS RO for an exception from decertification. This would include designations that are proposed for withdrawal, as well as areas whose designations type has changed to one that does not meet the RHC criteria.

For example, if HRSA determines on April 1, 2009, that the area no longer qualifies for one of the designations required for RHC purposes, the RHC would have until June 30, 2009 to submit an application to the appropriate RO for a location exception, and would be protected until September 30, 2009 from decertification based on not meeting the location requirements.

An RHC which is located in an area whose designation has not been updated in a timely manner and which does not apply for a location exception may continue to operate as an RHC for 180 calendar days after the 3 years from the date of the last designation, effective the last day of the month.

An RHC may be decertified 180 days after the 3-year date of the area's designation if it does not provide a complete application for a location exception within 90 days from the date it no longer meets the location requirements, or if the application for a location exception is not approved. In rare circumstances, the RO may request an extension from the CMS Central Office if it has not been possible to process the location exception request before the RHC would be decertified.

For example, (see accompanying sample timeline) if an area was designated (either a new designation or an update) on January 2, 2006 (#1 on sample timeline), the designation would be considered valid for RHC purposes for 3 years, which would be January 2, 2009 (#2). If an application to update the designation is submitted to HRSA by January 2, 2009 (#3), the RHC would be protected from decertification while the HPSA application is under review (#3.1). If the area qualifies as a HPSA and is updated (#3.2), then no further action would be needed for purposes of the RHC designation for 3 years from the date of the designation update (#3.3). If a HPSA application is submitted by January 2, 2009 (#3), but is determined to not qualify as a HPSA (#3.1.1), then the RHC would have 90 days from the date of that determination to submit an application for an exception (#3.1.2).

If an application to update the designation is not submitted to HRSA by January 2, 2009 (#4), the RHC would have until April 3, 2009 (#4.1), to submit an application for a location exception. If the RHC does not submit an application for a location exception to CMS by April 3, 2009 (#4.2), it would be decertified on July 31, 2009 (#4.3). (Decertification is effective the final day of the month.)

An RHC that submits an application for a location exception would be protected from decertification while the application is under review (#5). If the application is approved (#5.1), then no further action would be needed for purposes of the RHC recertification for 3 years from the date of the exception (#5.1.1). If the application is not approved (#5.2), the RHC would be decertified 90 days from the date of notification that the application was not approved (#5.2.1).

The process to appeal a denial of certification is described in § 498.3(b)(5). For the purpose of an appeal, RHCs and FQHCs are considered suppliers, not providers.

In the December 24, 2003 final rule, we stated that an RHC would have 120 days from the date of notification that it was no longer in a designated area and therefore not compliant with the RHC requirements to submit an application to update its MUA or HPSA designation. Although HRSA regulations do not preclude RHCs from submitting a designation application, it is usually the State not the RHC that submits the designation application. The State should not wait until a designation is more than 3 years old to prepare and submit an update for RHC purposes. As noted previously, an existing RHC is protected from decertification based on its designation status as long as an application has been submitted for an updated designation. We encourage RHC to work with the applicable State Primary Care Office to assure that any necessary information is provided to HRSA in a timely manner. A list of the State Primary Care Offices is available online at *http://hrsa.gov/grants* and then by selecting ''HRSA Grantees by Program or State'' and then by selecting ''State Primary Care Offices'', or by contacting the State's Department of Health.

An RHC that chooses to apply for an exception to the location requirements would send its application with the necessary documentation to the appropriate RO. An RHC that applied for an exception would not be

disqualified as an RHC based on not meeting the location requirements while its application is under review. If approved, the exception would be for a period of 3 years. Every 3 years, an RHC may reapply for an exception to the location requirements to continue its RHC eligibility.

Some provider-based RHCs that do not meet the location requirements and do not qualify for an exception may want to continue to operate as another type of Medicare provider. In some cases, these entities will need to go through the standard Medicare application process, which includes an application and, for entities wishing to enroll as a ''provider of services'' under 1861(u), a state survey. We have been informed that the waiting time for a state survey can be several months, so we are proposing that provider-based RHCs that do not meet the location requirements and do not qualify for an exception and have submitted an application to CMS to be another type of Medicare provider that requires a State survey for certification may receive an additional 120-day extension of their status as an RHCs while their application is being processed.

We propose to revise § 491.2 to redefine ''shortage areas'' as geographic and population group HPSAs, MUAs, and areas designated by the Governor of the State and certified by the Secretary.

We propose to amend § 491.3 as follows by adding paragraphs (a)(1) through (a)(3) to specify general certification requirements, and (b)(1) to specify permanent and mobile unit requirements.

We propose to amend § 491.5 as follows:

- Adding paragraphs (a)(1) through (a)(3) to specify the location requirements for RHCs and FQHCs.
- Adding paragraph (a)(4) to specify when a clinic would be terminated from the RHC program.
- Adding paragraphs (a)(5) and (a)(6) to specify the requirements for being considered an essential provider.
- Adding paragraph (a)(7) to specify the time period for a clinic's essential provider status.
- Adding paragraph (a)(8) to specify the time period that a decertified RHC may continue to operate.
- Adding paragraph (a)(9) to specify that conditions for an extension of RHC status when the location requirements are not met and the clinic does not qualify for an exception.
- Adding paragraphs (b)(1) through (b)(4) to specify the criteria for an exception from the location requirements.
- Adding paragraphs (c)(1) and (c)(2) to specify the conditions for termination.
- Adding paragraphs (d)(1) through (d)(8) to set forth the circumstances and timeline for submitting a request for an exception to the location requirements.

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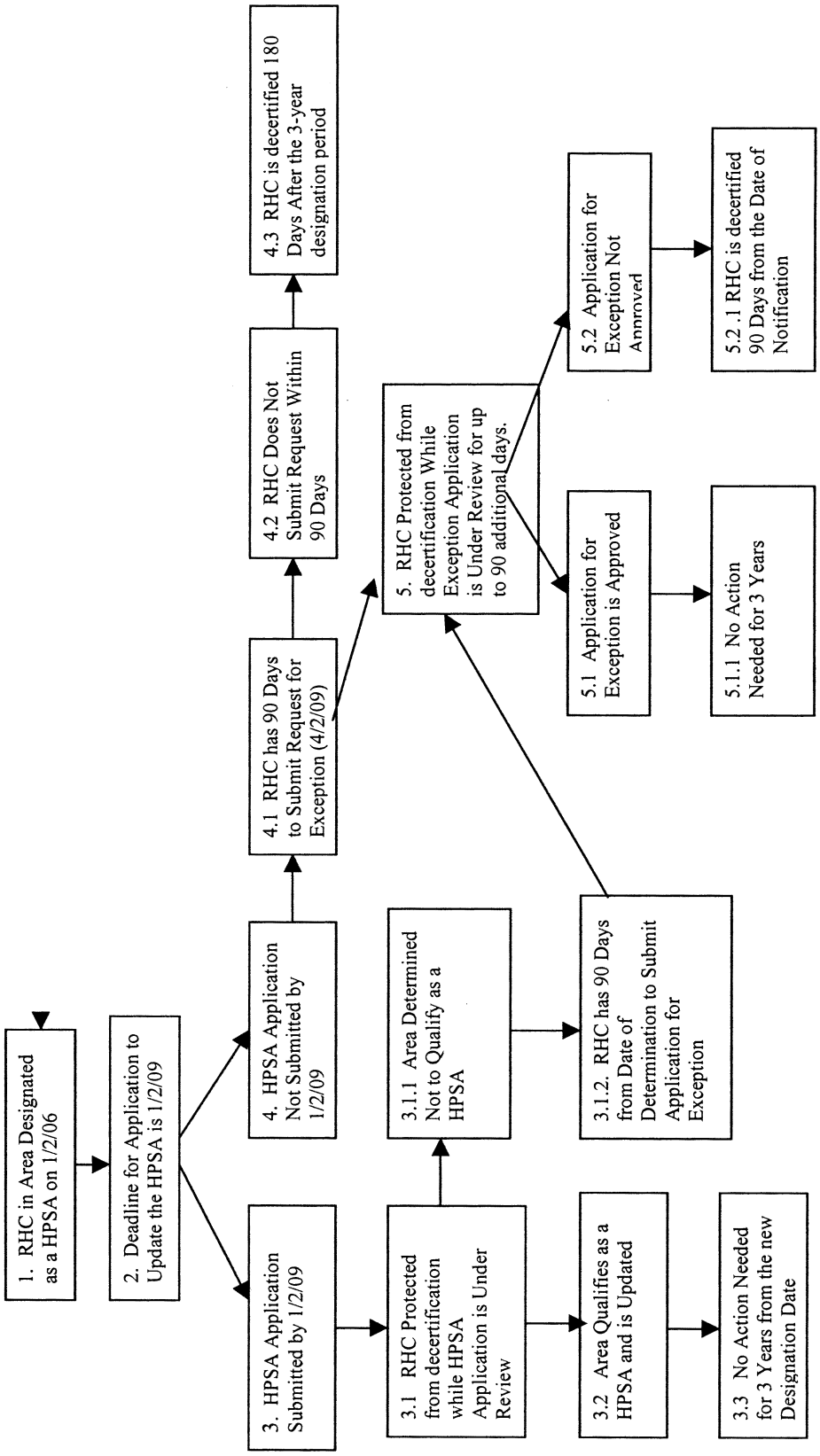
Sample Timeline



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B. Staffing Requirements, Waivers, and Contracts

1. Staffing Requirements

One of the goals of the RHC program is to encourage the use of nonphysician practitioners to provide quality health care in rural areas. We propose to amend § 491.8(a)(6) to conform with section 6213(a)(3) of OBRA '89 (Pub. L. 101–239) which requires that an NP, PA, or CNM be available to furnish patient care at least 50 percent of the time the RHC operates. An RHC that opens its premises solely to address administrative matters or to allow patients shelter from inclement weather would not be considered to be in operation as an RHC during that period.

2. Temporary Staffing Waivers

We propose to amend § 491.8(d) to conform with section 1861(aa)(7) of the Act, which authorizes us to grant a 1-year waiver of staffing requirements for nonphysician primary care providers (NPs, PAs, or CNMs) upon request from the RHC. The requesting RHC would have to demonstrate that it made a good faith effort to recruit and retain an adequate number of nonphysician primary care providers, and that it has been unable in the 90-day period prior to the request to hire one of these providers to meet the staffing requirement. This could include activities such as advertising in a newspaper, advertising in a professional journal, conducting outreach to an NP, PA, or CNM school, or other activities that would demonstrate a good faith effort to recruit and retain a nonphysician primary care provider. In accordance with section 1861(aa)(7)(B) of the Act, this waiver would be available only to existing RHCs that meet the nonphysician primary care requirement before seeking the waiver.

Section 1861(aa)(7) of the Act also specifies that an additional waiver cannot be granted until a minimum of 6 months has passed since the expiration of the previous waiver.

We are proposing that an RHC that has not complied with staffing requirements for one or more nonphysician primary care providers and has not submitted a request for a waiver of this requirement would be decertified from the RHC program. The decertification would be mandatory, since the noncompliant facility would fail to meet the statutory definition of an RHC. An RHC that has submitted a waiver request would not be decertified based on this requirement while its request was under review. A waiver would be deemed granted after 60 days, unless written notification is provided that the request has been denied. An RHC that is decertified from the RHC program due to failure to meet the staffing requirements would no longer be eligible to operate as an RHC. However, the RHC could apply to become a physician-directed clinic, group practice, or a group of individual practitioners who would then bill Medicare using the Part B fee-for-service system.

3. Contractual Arrangements

Due to the difficulty in recruiting and retaining physicians in rural areas, RHCs have had the option of hiring physicians either as RHC employees or as contractors. However, in order to promote stability and continuity of care, the Rural Health Clinic Services Act of 1977 required RHCs to ''employ a physician assistant or nurse practitioner'' (section 1861(aa)(2)(iii) of the Act). We note that the term ''employee'' is defined in section 3121(d)(2) of the Internal Revenue Code of 1986 and is usually evidence by the employer's provision of a W–2 form to the employee. Our current regulations at § 405.2468(b)(1) state that '' * * * (RHCs are not paid for services furnished by contracted individuals other than physicians).''

In the more than 30 years since this legislation was enacted, the health care environment has changed dramatically, and RHCs have requested that they be allowed to enter into contractual agreements with PAs and NPs as well as physicians. To provide RHCs with greater flexibility in meeting their staffing requirements, we propose to revise § 405.2468(b)(1) by removing the parenthetical ''RHCs are not paid for services furnished by contracted individuals other than physicians.'' Also, we propose to revise § 491.8(a)(3) to state that nonphysician practitioners may furnish services under contract to an RHC within the statutory limits.

RHCs would still be required, under section 1861(aa)(2)(iii) of the Act, to employ a PA or NP. However, as long as there is at least one PA or NP employed at all times (subject to the waiver provision set forth at section 1861(aa)(7) of the Act), an RHC would be free to enter into employment contracts with other PAs, NPs, or other nonphysician staff.

FQHCs already have the option to contract with PAs and NPs. Authority to allow contracting for clinical services is provided for in the PHS Act. The authority to allow Medicare participating FQHCs to contract with any necessary health professional for the purpose of treating their patients is further clarified by section 5114 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) which amended section 1842(b)(6) of the Act to require consolidated billing of contracted professional services by adding new subsection (H) with the following language: ''in the case of services described in section 1861(aa)(3) of the Act that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center.'' Similar language regarding contracted medical professionals was also added to section 1861(aa)(3) of the Act. FQHCs and RHCs also have authority to claim the costs of such contracted practitioners' services on the Medicare cost report to receive Medicare payment.

A practitioner providing services under contract to the RHC or FQHC should have a signed contract that includes his or her responsibilities and requirements. All practitioners should be familiar with the clinic or center's policies and procedures, and comply with the staffing requirements in § 491.8. Practitioners should be employed or contracted to the RHC in a manner that enhances continuity and quality of care.

We propose to remove the parenthetical statement at § 405.2468(b)(1) which states that RHCs are not paid for services furnished by contracted individuals other than physicians. We also propose to revise § 491.8(a)(3) to state that nonphysician practitioners may furnish services under contract to an RHC.

C. Payment Issues

1. Payment Methodology for RHCs and FQHCs

Payment to RHCs and FQHCs for covered services furnished to Medicare beneficiaries is made on the basis of an all-inclusive rate per visit, subject to a payment limit. The Medicare Administrative Contractor (MAC) or FI determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

With the exception of services provided under Medicare Advantage plans to RHCs and FQHCs, the statutory payment requirements for RHC and FQHC services are set forth at section 1833(a)(3) of the Act, (as amended by the MMA), which states that RHCs and FQHCs are paid reasonable costs ''* * * less the amount a provider may charge as described in clause of section 1866(a)(2)(A), but in no case may the payment exceed 80 percent of such costs[.]'' The beneficiary is responsible for the Medicare Part B deductible

(except for services provided in FQHCs, where there is no Part B deductible) and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

Section 237(c) of the MMA which pertains to cost sharing permitted under MA organizations, revised section 1857(e) of the Act. These changes were addressed in § 405.2469 as part of the CY 2006 Physician Fee Schedule final rule with comment period (70 FR 70116).

In general, the statutory payment methodology requires that except for services provided under MA plans to FQHCs in accordance with section 1833(a)(3)(B) of the Act, RHCs and FQHCs subtract beneficiary coinsurance and deductible amounts, as applicable (based on reasonable charges) from reasonable costs to determine the Medicare payment. The statute further stipulates that Medicare reimbursement may not exceed 80 percent of reasonable costs.

Until now, Medicare has been paying RHCs and FQHCs 80 percent of the facility's reasonable costs, regardless of deductible and coinsurance amounts billed to Medicare beneficiaries. This allowed RHCs and FQHCs to receive, in some instances, payment in excess of 100 percent of reasonable costs.

Therefore, to conform existing regulations to the statutory payment methodology described above, we propose to revise § 405.2410 and § 405.2466(b)(1)(iii) by stipulating that, except for services provided under MA plans to FQHCs, Medicare payment is equal to reasonable costs less aggregate coinsurance and deductible amounts billed, but in no case may total Medicare payment exceed 80 percent of reasonable costs.

Note: Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in § 410.155

2. Exceptions to the Per Visit Payment Limit

Prior to 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 FI in accordance with our regulations at 42 CFR 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 42 CFR part 405, subpart X. Payment to independent RHCs also was 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. Under the BBA, the independent RHC all-inclusive payment methodology and payment limit were applied to provider-based RHCs. This BBA provision also provided an exception to the RHC payment limit for those RHCs based in small, rural hospitals to help them remain financially viable.

Section 224 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) enacted on December 21, 2000, expanded to RHCs based in small, urban hospitals the eligibility criteria for receiving an exception to the RHC payment limit, effective July 1, 2001. This was implemented through a program memorandum on December 6, 2001.

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:

- The determination of the number of beds at § 412.105(b); or
- The hospital's average daily patient census count of those beds described in § 412.105(b), and the hospital meets all of the following conditions:

++ It is a sole community hospital as determined in accordance with § 412.92 or § 412.109(a).

++ It is located in a level 9 or 10 RUCA.

++ It has an average daily patient census that does not exceed 40.

The December 24, 2003 final RHC rule used the 1993 Urban Influence Codes (UICs), then a 9-category measure developed by the U.S. Department of Agriculture (USDA), to identify hospitals which are located in sparsely populated rural areas. Hospitals with a level 8 or 9-level UIC and which have an average daily census of less than 50 patients would qualify for an exception to the RHC per visit payment limit. The USDA has since changed the UICs to a 12-category measure, with levels 9 through 12 comparable to the 1993 levels 8 and 9.

The UICs are a county-level measurement. Since many counties encompass large geographical areas with significant variations in population density, demographics, economics, and health care services, the UICs do not always provide an accurate assessment of a local area's degree of rurality.

The RUCA system is another method for identifying rural areas. RUCA codes classify U.S. census tracts using measures of population density, urbanization, and daily commuting. This classification uses 10 numbers with subdivisions to reflect commuting flows.

RUCAs are used by CMS for purposes of determining rurality in the hospital and ambulance payment systems. To target the needs of rural populations more accurately and to be consistent with other CMS programs, we propose to utilize the RUCA methodology instead of the UIC methodology. We also propose that RUCA codes 9 and 10 be used for the purpose of approving an exception to the per visit payment limit.

We propose to amend § 405.2462 to provide payment to all RHCs and FQHCs on the basis of an all-inclusive rate per visit, subject to the per-visit payment limit. For a hospital-based RHC that is the primary source of health care in its rural community as defined at § 412.92(a) or § 412.109(a), we propose to utilize the hospital's average daily census rather than bed count in determining whether RHC services are subject to the per-visit payment limit. We also propose to utilize RUCAs 9 and 10 to determine eligibility for an exception to the per visit payment limit.

3. Commingling

Commingling refers to the sharing of RHC space, staff (employees or contractors), supplies, records, and other resources with an onsite Medicare Part B or Medicaid fee-for-service practice operated by the same RHC physician(s) or nonphysician practitioner(s) or both. Commingling is prohibited when it results in duplicate Medicare or Medicaid reimbursement, either due to the inability of the RHC to distinguish its actual costs from those that are reimbursed on a fee-for-service basis, or due to other reasons.

An RHC and a Medicare fee-for-service practice may not operate simultaneously in order to prohibit these shared practices from selecting patient encounters for enhanced Medicare Part B billing.

However, an RHC that is part of a multipurpose clinic may house other entities (such as private medical practices, x-ray and lab clinics, dental clinics, emergency room) in the non-RHC space. The entities occupying the non-RHC space may bill the assigned Medicare Administrative Contractor (MAC), Fiscal Intermediary (FI), or carrier as appropriate; authority is delegated to the MAC, FI, or carrier to

determine acceptable accounting methods for allocation of staff costs between the RHC and other entities to be used in documenting allocation of costs. Since in a multipurpose clinic the RHC may share some resources in common with the non-RHC entity (for example, waiting room or receptionist), the RHC must maintain accurate records to assure that the RHC costs that it claims for Medicare reimbursement are only for the staff, space, or other resources that are used for RHC purposes. Any shared staff, space, or other resources must be allocated appropriately between the RHC and non-RHC usage to avoid duplicate reimbursement.

This commingling policy does not prohibit a hospital-based RHC from sharing its health care practitioners with the hospital emergency department in an emergency, or prohibit an RHC physician from providing on-call services for an emergency room, as long as the RHC continues to meet the RHC conditions for certification (CfCs) in the absence of the practitioner(s) and the RHC is able to allocate appropriately the practitioner's salary between RHC and non-RHC time.

Facilities are encouraged to work with their MAC, FI, or carrier and RO in determining permissible resource-sharing situations and proper cost reporting methods.

4. Payment for Services to Hospital Patients

The hospital inpatient bundling provision was enacted on April 20, 1983 in section 602(e)(3) of the Social Security Act Amendments of 1983 (Pub. L. 98–21), by adding paragraph (a)(14) to section 1862 of the Act. The hospital outpatient bundling provision was enacted in section 9343(c) of OBRA '86, Public Law 99–509. Taken together, these two provisions require bundling of the costs for all nonprofessional services furnished to hospital patients. Consequently, section 1862(a)(14) of the Act now requires hospitals and CAHs to bundle all costs, other than those for the professional services specified in the statute.

Only professionals exempt from the hospital bundling provisions are permitted to bill for services furnished to hospital patients. RHCs and FQHCs cannot bill for services furnished by RHC practitioners to hospital patients because RHC and FQHC services are not exempt from the hospital bundling provisions.

Accordingly, any costs incurred by an RHC or FQHC associated with the provision of services to hospital patients must be excluded from RHC or FQHC allowable costs on their Medicare cost report. However, a practitioner who provides services in an RHC or FQHC may, in some cases, also have a private practice and be enrolled and qualified to bill Medicare under that practice as a Part B practitioner. In these situations, the practitioner may be able to bill Medicare Part B under their private practice for covered services provided to hospital patients.

Section 1862(a)(14) of the Act places restrictions on the payment for services furnished to hospital and CAH patients. We propose to revise § 405.2411(b) and (c) to specify that RHC services are covered when furnished in an RHC setting or other outpatient setting, but are not covered when furnished in a hospital or CAH.

5. Payment for Services to Skilled Nursing Facility (SNF) Patients

Section 4432(b) of the BBA amended the statute to add a consolidated billing provision for SNFs in section 1862(a)(18) of the Act. Similar to the hospital bundling provision in section 1862(a)(14) of the Act, this provision bundled all Part B services furnished to SNF residents during a covered Part A stay into the SNF Prospective Payment System (PPS) rates, except those services specifically excluded under statute. RHC services were not among the excluded services. Although the Congress excluded physician services and several other services from the SNF bundle of services, RHC and FQHC services were not among the services on the excluded under section 1888(e)(2)(A)(ii) of the Act. Consequently, through program instructions to Medicare contractors (PM A–99–8, March 1999), we announced that under the statute, RHC and FQHC services furnished to SNF residents were subject to the SNF consolidated billing provision and could not be billed to Medicare by the RHC or FQHC.

However, section 410 of the MMA amended section 1888(e)(2)(A) of the Act by adding a new paragraph (iv) to exclude RHC and FQHC services from the SNF consolidated billing provision. This MMA change was effective for services furnished on or after January 1, 2005. In accordance with this section of the MMA, services included within the scope of RHC and FQHC services described at section 1888(e)(2)(A)(ii) of the Act are excluded from the SNF consolidated billing provision. These services are limited to physician, PA, NP, CP, and CNM services. Only this subset of RHC and FQHC services may be covered and paid through the RHC and FQHC benefit when furnished to RHC and FQHC patients in a Medicare Part A covered SNF stay. Payment for this subset of services is made in the usual manner under the RHC and FQHC all-inclusive payment methodology. All services other than physician, PA, NP, CP, and CNM services that an RHC or an FQHC may furnish to a patient in a Medicare covered Part A SNF stay are subject to the SNF consolidated billing provision. This means any costs associated with these other services are excluded from coverage and payment under the RHC and FQHC benefit when furnished to a Part A SNF patient.

We propose to require in § 405.2411(b) and (c) that payment for RHC services furnished to patients at the RHC, at the patient's place of residence, or at another facility other than a hospital or CAH, be made to the RHC. As a result of the provisions in section 1862(a)(14) of the Act, RHCs and FQHCs cannot bill for RHC or FQHC services furnished by their practitioners to hospital or CAH inpatients.

6. 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 NPs, CNSs, and PAs. This provision also expanded the professional services benefits for NPs and CNSs 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 PA services can be made only to the PA's employer regardless of whether the PA is employed directly or is 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 PA services may be made directly to a PA under certain circumstances. This provision permits Medicare to directly pay a PA who is the owner of an RHC, as described in section 1861(aa)(2) of the Act, 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 services furnished before January 1, 2003.

Section 222 of the BIPA amended section 1842(b)(6)(C) of the Act, which permits PAs who owned RHCs and subsequently lost RHC status to receive direct Medicare payment for their services, effective December 21, 2000. This BIPA provision eliminated the January 1, 2003 sunset date. We propose

to revise § 410.150(h)(15) and add § 410.150(b)(20) to allow PAs to receive direct Medicare payment for services provided by the RHC, as long as the RHC continues to meet the requirements of section 1861(aa)(2) of the Act.

7. Screening Mammography

In June 2000 we released Program Memorandum A–00–30, which stated that preventive physician and nonphysician services, such as screening mammography, were covered when performed in an RHC/FQHC to the same extent as other RHC/FQHC services. We propose to revise § 405.2448 by removing paragraph (d), which states that screening mammography is not considered a covered FQHC service.

8. Payment for High Cost Drugs

RHCs are reimbursed based on an all-inclusive payment methodology, subject to an upper payment limit, which includes the cost of drugs provided incident to a patient visit. We are aware that many RHCs would like to provide services such as outpatient cancer treatments to their patients, and that the patients would benefit from this service by not having to travel greater distances to receive treatment elsewhere. However, because drugs are included in the all-inclusive rate per visit, it may not be financially viable for an RHC to provide treatments that require high cost drugs for their patients.

We recognize the dilemma that RHCs may face in deciding whether to provide certain treatments in the RHC that would benefit their patients but may put their financial viability at risk. Therefore, we are soliciting comments on this situation and possible solutions that can be addressed through regulation or program guidance. Any possible solution would need to take into account our legislative authority, which does not generally allow reimbursement to RHCs for drugs, our policy on commingling, and the need for administrative accountability.

D. Health and Safety, and Quality

1. Quality Assessment and Performance Improvement Program (QAPI)

Currently, each RHC is required to evaluate its total program annually. The evaluation must include reviewing the utilization of the clinic's services using a representative sample of both active and closed clinical records, as well as reviewing 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 if 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 (QAPI). Therefore, RHCs are required by statute to have a QAPI program and it is a requirement for certification as an RHC. Upon an initial or subsequent survey, an RHC would be required to develop a plan of correction where a viable QAPI program is not in effect.

A QAPI program enables the organization to systematically review its operating systems and processes of care to identify and implement opportunities for improvement.

Some RHCs have already incorporated a QAPI program into normal RHC operating activities. For those which are starting to develop an appropriate QAPI program, guidance and examples of QAPI-related activities are available from professional and governmental organizations, including some State offices of rural health.

HHS previously has contracted with the National Association of RHCs (*http://www.narhc.org*) to develop technical assistance materials which provide guidance for RHCs in complying with QAPI requirements. These and other materials are available through HRSA's Office of Rural Health Policy (*http://www.ruralhealth.hrsa.gov*). Information is also available from the Rural Assistance Center (*http://www.raconline.org*), the National Rural Health Association (*http://www.nrharural.org*), and the Rural Policy Research Center (*http://www.rupri.org*). As it develops its QAPI program, an RHC may find additional guidance through the information contained in the Institute of Medicine report, ''Quality Through Collaboration: The Future of Rural Health Care'', as well as that contained at the database and Web site sponsored by the agency for Healthcare Research and Quality, the National Quality Measures Clearinghouse (*http://www.qualitymeasures.ahrq.gov/*). RHCs are encouraged to take advantage of the resources available.

We would deem an RHC that chose to utilize a QAPI model program provided by the Department (or other on-line resources mentioned in this regulation) to have met the QAPI CfC, provided that the model program chosen was one that was in compliance with the substantive provisions of § 491.11.

We propose to revise § 491.11 to set forth explicit requirements for a QAPI program. An RHC would set its own priorities for performance improvement based on the prevalence and severity of identified problems. The QAPI program would contain three standards that would address: (1) Program components; (2) program activities; and (3) program responsibilities.

The first standard, § 491.11(a), would require that an RHC use objective measures to evaluate organizational processes, functions and services and the use of clinic services, including at least the number of patients served and the volume of services.

The second standard, § 491.11(b), would require RHCs to adopt or develop performance measures that reflected processes of care and RHC operation and were shown to be predictive of desired patient outcomes or were the outcomes themselves. The RHC would have to use the measures to analyze and track its performance. The RHC would set priorities for performance improvement, considering 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. Also, the RHC would have to conduct distinct improvement projects and maintain records on its QAPI program for each of the areas listed under the standard in § 491.11(a). Additionally, a project to develop and implement an information technology (IT) system explicitly designed to improve patient safety and quality of care would be considered as meeting the requirement for a QAPI project under this section. We are proposing this IT provision because we believe that it is critically important that RHCs identify opportunities to improve and expand the use of information technology 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 IT (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 would allow RHCs to receive QAPI recognition for undertaking 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 other performance improvement projects (see § 491.11(b)(4)). In recognition of the time and resources required to implement these IT programs, we would not require associated activities to have a demonstrable benefit in the initial stages, but would expect that the quality improvement goals and the associated achievements would be incorporated in the plans for these programs.

The third proposed standard, § 491.11(c), would require that the RHCs professional staff, administrative officials, and governing body (if applicable) ensure that there is an effective QAPI plan that addresses identified priorities.

2. Infection Control

While the physical plant and environment standard in § 491.6(a)(3) requires that RHCs and FQHCs keep the premises clean and orderly, there is no current Medicare standard addressing infection control in RHCs and FQHCs. We believe that RHCs and FQHCs should be required to have infection control guidelines and an implementation plan. The value of infection control measures in reducing infectious and communicable diseases long has been recognized, and we realize that a large number of clinics and centers may be implementing some aspects of an infection control program. However, because of the real and potential hazards which infectious and communicable diseases present, we believe that it would be prudent to add a formal standard requiring adherence to infection control guidelines that have been recognized by industry standards and regulatory bodies as being appropriate for facilities such as RHCs and FQHCs. The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA), in their October 1999 Consensus Panel Report, stated that infection prevention and control issues are important throughout a continuum of care, including physicians' offices, clinics, ambulatory surgical centers, and in individuals' homes through home health agencies. Likewise, a Centers for Disease Control (CDC) article, entitled ''Health-Care Quality Promotion, through Infection Prevention: Beyond 2000''; Vol. 7, No. 2, March–April 2001, by Julie Louise Gerberding, reported that the urgent need for enhanced infection prevention programs in nonhospital settings has been acknowledged for more than a decade. However, programs designed to effectively address this need have been slow to evolve. One contributing factor offered in the article was a lack of regulatory and accreditation standards to ensure that truly effective program components are in place.

We agree with the CDC's findings as well as with the intent of the article, and are proposing that the new infection control standard place accountability on RHCs and FQHCs to prevent and control infectious and communicable diseases, and to take actions that result in improvements to infection control practices.

We are proposing to add, under § 491.6, a new paragraph (d) that would require RHCs and FQHCs to have infection control guidelines and an implementation plan. Model guidelines are available from various professional organizations, and RHCs and FQHCs would have flexibility in determining how best to meet these objectives. For example, RHCs and FQHCs would determine how much staff training in infection control would be necessary, the method of oversight, and the appropriate level of documentation that would be required. However, we do expect that RHC and FQHC staff engaged in direct patient care would follow current accepted standards of infection control practice (for example, wearing gloves when handling blood or blood products, and following hand hygiene guidelines). We believe that if a clinic or center currently complies with the infection control standards of the industry for outpatient health care facilities, then they would most likely meet or exceed this proposed standard. The infection control activities should be an integral part of the RHCs or FQHCs overall QAPI program and the FQHCs quality improvement program as also required by section 330(k)(3)(C) of the PHS Act, and should be addressed in these programs on an ongoing basis.

3. Hours of Operation

a. Posting of Hours

RHCs and FQHCs have varying hours and days of operation based on staff and anticipated patient load. Beneficiaries in rural areas often travel long distances to obtain services. Therefore, we are proposing to require under § 491.6(e) that an RHC or FQHC must post at or near the entrance to the facility a sign that states the days of the week and hours when RHC or FQHC services are furnished. This information would have to be displayed in a manner so that it can be viewed easily by persons who have vision problems and who are in wheelchairs.

b. Use of the RHC Facility

Section 491.8(a)(6) states that a RHC must have a physician, NP, PA, CNM, CSW, or CP available to furnish patient care services at all times the RHC operates, and that an NP, PA, or CNM must be available to furnish patient care services at least 50 percent of the time the RHC operates.

To provide RHCs with flexibility to allow access patients to enter the RHC for purposes other than patient care while complying with the requirements of § 491.8(a)(6), we are clarifying that RHCs may allow patients to enter the waiting room or other areas not utilized for patient care when the premises are opened solely to address administrative matters, or to allow patients entry into the building to get out of inclement weather. The RHC would not be considered ''in operation'' as an RHC during these periods. No health care services would be provided until a physician, NP, PA, CNM, CSW, or CP was present to provide such services. RHCs that choose to exercise this flexibility should post the hours they offer administrative services only versus the hours they offer RHC health care services. The signage which would be required by § 491.6(e) should clearly delineate the times the NP, PA, CNM, CSW, CP, or physician was present and the RHC would be in operation and providing health care services. If State law does not allow access to the RHC premises when the RHC is not in operation as an RHC, the facility must adhere to State law.

4. Emergency Services and Training

We propose to revise § 491.9(c)(3) to reflect current industry standards and procedures for first responses to common life-threatening injuries and acute illnesses. We would expect that clinical personnel responding to emergencies would assess and stabilize sick or injured persons and administer emergency medical treatment while waiting for emergency transport to arrive or until such time that the patient could receive an advanced level of care.

RHCs and FQHCs would continue to be required to provide medical emergency procedures as a first response to common life-threatening injuries and acute illness and to have available the drugs and biologicals commonly used in lifesaving procedures. Even though we are proposing to retain the language in the requirement regarding the availability of drugs and biologicals, we propose to eliminate the prescriptive list of those drugs and biologicals that is currently required. In addition to the drugs and

biologicals that currently are required, we propose that a clinic or center also have available commonly used equipment and supplies for emergency first response procedures that are appropriate for its patient population. Since the proposed conditions are outcome-oriented, we do not believe that we need to specify all the equipment and supplies that a facility should have to accommodate the emergency medical needs of a clinic or center's patients. However, we would expect a clinic or center to have the emergency equipment and supplies that are commonly found in a physician's office or a clinic. Appropriate drugs, biologicals, equipment, and supplies that one would expect to find in a clinic providing emergency first response procedures might include those items that are normally found in an emergency medical crash cart. We believe that most, if not all, clinics and centers would already have these types of supplies in order to provide the emergency services required under the current regulations.

Although we are not specifically proposing to require defibrillators at this time, studies have shown that the appropriate use of defibrillators can save lives. In particular, automated external defibrillators (AEDs) have been shown to save lives in a variety of settings. The key to saving a life is getting the defibrillator on the patient as soon as possible. According to the American College of Emergency Physicians article entitled ''Automatic External Defibrillators,'' June 2003 (*http://www.acep.org/12891.0.html*), when a person suffers a sudden cardiac arrest, the chance of survival decreases by 7 to 10 percent for each minute that passes without defibrillation. The potential for saved lives supports the financial investment in an AED. Currently, the cost of an AED is approximately $2,000 to $3,000. We are soliciting comments on whether AEDs should be made a regulatory requirement in the future, since RHCs and FQHCs can be located in remote and frontier areas where advanced emergency care might not be available in time to prevent cardiac complications or death.

We also are proposing that staff receive training in the provision of the RHCs or FQHCs emergency procedures. The current requirement does not address this issue. Primary care providers such as physicians, nurse practitioners, physician assistants, nurses, and other allied health personnel often do not frequently receive opportunities to participate in a wide range of emergency care procedures, and, therefore, can benefit from training. At a minimum, we would expect that these professionals are trained in basic life support (BLS). The American Heart Association's (AHA's) guidelines for health care provider courses state that its BLS course teaches the skills of cardiopulmonary resuscitation (CPR) (including ventilation with a barrier device, a bag-mask device, and oxygen) for victims of all ages, and the use of an AED. The course is designed for health care providers that care for patients in a wide variety of settings, both in and out of a hospital.

This basic training may also be augmented by the clinic or center through a variety of means. For example, a facility may elect to provide its own in-service training in emergency procedures or it may choose to use outside resources such as basic trauma life support (BTLS), advanced cardiac life support (ACLS), and pediatric advanced life support (PALS) courses. We encourage clinics and centers to take advantage of these and other existing resources as they determine training needs of personnel providing care to patients.

Additionally, as proposed in § 491.9(c)(3)(iii), a clinic or center would be required to provide training for staff. Because a midlevel practitioner is required to be available to furnish patient care at all times the RHC or FQHC operates, we do not expect the nonprofessional staff to be responsible for providing first response emergency care. However, these individuals would need to be trained in accordance with the facility's policies and procedures related to their roles during the provision of emergency medical services by professional staff. We would expect facilities to determine the best way to train these personnel according to the facilities' individual needs. Facilities may elect to use outside resources such as the AHA's Heartsaver First Aid course, which combines first aid, adult CPR, and AED training, in-service training through the clinic or center's professional staff, or a combination of both. Each facility would be expected to develop its own emergency strategies which are consistent with commonly accepted practice and to document such plans in its written policies.

5. Patient Health Records

RHCs and FQHCs are required to maintain a medical record for each patient receiving health care services. To update patient health record requirements to reflect technological advances in how physicians or other health care professionals sign and authenticate their signatures, we are proposing to update the medical records requirement at § 491.10(a)(3) for RHCs and FQHCs to reflect our requirements and guidelines for other participating providers regarding electronic medical records and electronic signatures.

We propose at § 491.10(a)(3)(v) that all entries (electronic or manual) in the medical record must be legible, complete, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service furnished. We are also proposing that any entry in the patient health record must be identified and authenticated promptly by the person making the entry. In addition, we are proposing that all entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

The identification may include signatures, written initials, or computer entry. If rubber stamp signatures are authorized, the individual whose signature the stamp represents must place in the administrative offices of the RHC or FQHC a signed statement to the effect that he or she is the only individual authorized to use the stamp and may not delegate the stamp to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. When rubber stamps or electronic authorizations are used for identification, the RHC must have policies and procedures in place to ensure that stamps or authorizations are used only by the individuals whose signature they represent.

Inherent in these proposed requirements is the idea that there be a specific action by the author to indicate that entries are verified and accurate. Examples of such authentication of entries include: a computerized system that requires the physician to review the document on-line and indicate that it has been approved by entering a computer code; a system in which the physician signs off against a list of entries that must be verified in the individual record; or a mail system in which transcripts are sent to the physician for review, after which he or she signs and returns a postcard identifying the record and verifying its accuracy.

A system of auto-authentication in which a physician or other practitioner authenticates a report before transcription is not consistent with these proposed requirements. There

must be a method of determining that the practitioner in fact did authenticate the document after it was transcribed.

E. Other Proposed Changes

1. General

In addition to the regulatory changes previously described, we propose the following:

- Adding the definition of ''nurse practitioner (NP)'' and ''physician assistant (PA)'' to § 405.2401(b) and removing the definitions from § 491.2 so that RHC/FQHC-related provider definitions are located in the same regulatory section (with the exception of clinical psychologist, which continues to be defined in § 405.2450.)
- Adding the word ''certified'' to the definition of ''nurse-midwife'' in § 405.2401(b) and § 405.2414 to conform to statutory language in sections 1861(aa) and (gg)(2) of the Act.
- Adding the definition of ''clinical social worker'' (CSW) to § 405.2401(b). The definition of ''covered RHC services'' was extended to include the services of a CSW but the definition of a CSW has not been added to the regulations.
- Revising the definition of ''Federally qualified health center'' (FQHC) in § 405.2401(b) to conform the regulations to current statutory requirements.
- Revising the definition of ''rural health clinic'' to § 405.2401(b) and removing the definition from § 491.2 so that it conforms with statutory language in section 1861(aa)(2) of the Act.
- Revising references to the ''Secretary'' in § 405.2404 and § 491.2 to incorporate gender-neutral language.
- Adding the phrase ''CNM, CP, CSW services and supplies'' to § 405.2411 and § 405.2415 to conform to statutory changes in section 1861(aa)(1)(B) and section 1861(aa)(2)(J) of the Act.
- Making additional revisions to § 491.3 to implement proposed certification procedures, in conjunction with the proposed changes to the designation process previously described.
- Revising the heading and introductory text of § 491.4 to make it consistent with the comparable CoP provisions for hospitals and most other providers and to emphasize that the requirements of primary concern are State licensure laws.

2. FQHCs

Section 5114 of the DRA makes a technical correction to section 1861(aa)(4)(A) of the Act by striking the phrase ''(other than subsection (h))'' from that clause. This section of the statute identifies the types of health centers receiving funding under section 330 of the PHS Act that are eligible for Medicare FQHC status. Section 330(h) of the PHS Act, to which the clause refers, addresses Healthcare for the Homeless Health Centers. We are conforming our regulations at § 405.2401 to recognize Healthcare for the Homeless Health Centers as Medicare FQHCs. We also are taking this opportunity to delete obsolete references to sections 329 and 340 of the PHS Act.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-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 evaluate fairly whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA 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 (ICRs) discussed below.

A. ICRs Regarding Location of Clinic (§ 491.5)

Proposed § 491.5(b) states that an RHC may be granted an exception to the location requirement specified in § 491.5(a)(1) if the clinic meets the requirements listed in § 491.5(b)(1) through (3). Section 491.5(b)(3) states that an RHC may be granted an exception to the location requirements if it meets the essential provider criteria that are outlined in § 491.5(c). As stated in § 491.5(c), CMS grants essential provider status for a period of 3-years. However, a clinic may reapply for essential provider status if it still needed the exception. An RHC must furnish documentation to demonstrate its compliance with one of the conditions listed in § 491.5(c)(1) through (4).

The burden associated with these proposed requirements is the time and effort necessary for an RHC to submit an application to CMS for an exception to the location requirement. As part of the application, the RHC must collect and submit to CMS the necessary information to support its claim that it meets one of the essential provider criteria listed in § 491.5(c)(1) through (4). We estimate that it would take each RHC 10 hours to collect and submit the necessary information to CMS. The total estimated annual burden associated with this requirement is 5000 hours.

Section 491.5(e)(7) states that at the conclusion of the 3-year exception period, an RHC may renew its essential provider status. The RHC must submit written assurances to the appropriate CMS regional office that it continues to meet the conditions specified in § 491.5. The burden associated with this proposed requirement would be the time and effort necessary to submit written assurances to the appropriate CMS regional office.

We estimate that a total of 500 RHCs would be subject to the requirements contained in § 491.5(e)(7). We estimate that it would take each of the 500 RHCs 1 hour to submit the necessary information to CMS. The estimated annual burden is 500 hours.

B. ICRs Regarding Physical Plant and Environment (§ 491.6)

Proposed § 491.6(d) states that RHCs and FQHCs must protect their patients and staff members by maintaining and documenting an infection control process. The burden associated with this proposed requirement is the time and effort necessary to establish, maintain, and document the infection control process that meets the requirements listed in § 491.6(d)(1) and (2). While these requirements are subject to the PRA, the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Establishing, maintaining and documenting an infection control program and processes are usual and customary business practices. In addition, maintenance of a documented infection control program is required as part of quality assessment and performance improvement (QAPI) program. The total burden associated with QAPI program requirements is discussed later in Section III.E of the collection of information section of this regulation.

Section 491.6(e) would require clinics or centers to post signs that are noticeable and can be viewed by those with vision problems and those in wheelchairs. The signs must be located at or near the front of the facility. The purpose of the signs is to advise the public of the hours of operation for the center or clinic. The burden associated

with this reporting requirement is the time and effort necessary to create signs and post the signs for the public. While this requirement is subject to the PRA, we believe that the associated burden is exempt as stated in 5 CFR 1320.3(b)(2); posting the signs containing the hours of operation is a usual and customary business practice.

C. ICRs Regarding Staffing and Staff Responsibilities (§ 491.8)

Proposed § 491.8(d) states that a qualified RHC can request a temporary staffing waiver. If the request is approved, the waiver is in effect for a 1-year period. As stated in § 491.8(d)(1), to request a waiver the RHC must demonstrate that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a certified nurse-midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC provides clinical services. The burden associated with this proposed requirement is the time and effort necessary for an RHC to demonstrate to CMS it has been unable to meet the RHC staffing requirements. We estimate that 100 RHCs would apply for waivers on an annual basis. We believe that it would take 3 hours for each RHC to draft its waiver request and demonstrate its inability to meet the staffing requirements. We estimate the total annual burden to be 300 hours.

Proposed § 491.8(d)(3) states that an RHC may submit a request for an additional waiver of staffing requirements no earlier than 6 months after the expiration of the previous waiver. The burden associated with this proposed requirement is the time and effort necessary to submit an additional waiver request. The burden associated with this requirement is explained in our discussion of proposed § 491.8(d)(1).

D. ICRs Regarding Patient Health Records (§ 491.10)

Proposed § 491.10 states that an RHC or an FQHC must maintain a record for each patient receiving health care services. The record must include legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service. All entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

The burden associated with these proposed requirements is the time and effort necessary to maintain a patient record. This burden includes the time necessary to record complete, legible entries and to authenticate the record. While these requirements are subject to the PRA, the associated burden is exempt under 5 CFR 1320.3(b)(2). Maintaining and authenticating patient health records is part of usual and customary business practices. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities is exempt from the PRA.

E. ICRs Regarding Quality Assessment and Performance Improvement (§ 491.11)

Section 491.11 would require an RHC to develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. As part of the QAPI program, § 491.11(b)(1)(i) requires an RHC to adopt or develop performance measures that reflect processes of care and RHC operations. Section 491.11(b)(1)(ii) further requires that the RHC use the measures to analyze and track its performance.

Proposed § 491.11(b)(3) states that an RHC must conduct distinct improvement projects. The number and frequency of the distinct improvement projects must reflect the scope and complexity of the clinic's services and available resources. In addition, § 491.11(b)(5) states that an RHC must maintain records on its QAPI program and quality improvement projects.

The burden associated with this proposed requirement would be the time and effort necessary for the RHC to maintain records on its QAPI and quality projects. We estimate that it will take each clinic 1 hour per year to meet this requirement. Since there are an estimated 3,700 facilities, the total burden associated with this requirement would be 3,700 annual hours. The burden associated with this requirement is currently approved under OMB# 0938–0334.

The burden associated with all of the proposed requirements in § 491.11 is the time and effort necessary for an RHC to develop, implement, evaluate, and maintain a QAPI program. We estimate that it would take each of the 3,700 facilities 40 hours to comply with the requirements in § 491.11. We estimate a one-time annual burden of 148,000 to develop a QAPI program.

TABLE 1.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Total annual burden (hours)
§ 491.5(c)	0938–New	*500	500	5,000
§ 491.5(e)(7)	0938–New	*500	500	500
§ 491.8(d)	0938–New	100	100	300
§ 491.11	0938–0334	3,700	3,700	**148,000
Total		4,300	4,300	153,800

*The same 500 respondents are subject to the requirements in both § 491.5(c) and § 491.5(e)(7). They are only counted once in our burden estimate.

**Estimated one-time annual burden.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William N. Parham, III (Attn: CMS–1910–P2) Room C4–26–05, 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: Carolyn Lovett, CMS Desk Officer, CMS–1910–P2, *Carolyn_Lovett@omb.eop.gov*. Fax (202) 395–6947.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million or less annually (see 65 FR 69432). For purposes of the RFA, all RHCs and FQHCs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act, because we have determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year of $120 million in the aggregate by State, local, or tribal government, or by the private sector. This proposed rule would not mandate any new requirements for State, local or tribal governments, and private sector costs are expected to be less than the $120 million threshold.

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

Although we view the anticipated results of these regulations as beneficial to the Medicare and Medicaid programs as well as to Medicare beneficiaries and Medicaid recipients, 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 be anticipated definitely, especially in view of the 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 meaningfully quantify a projection of the future effect of all of these provisions on RHCs' and FQHCs' operating costs or on the frequency of substantial noncompliance and termination procedures.

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

B. Anticipated Effects

1. Effects of the Location Requirements on Rural Health Clinics

There are approximately 3,705 participating RHCs. Of these, approximately 500 no longer meet the location requirements for either because they are not in an area designated by the U.S. Census Bureau as nonurban, or they are not designated by the Health Resources and Services Administration as an eligible shortage area. Participating RHCs that no longer are located in rural, underserved areas could lose RHC status and related cost-based reimbursement, potentially causing them to reduce services or discontinue serving Medicare beneficiaries. The estimated Medicare savings associated with the decertification of certain RHCs from the Medicare program are not considered significant.

To minimize the impact of this provision on rural health care, however, the Congress has authorized us to grant, if needed, an exception to clinics determined to be essential to the delivery of primary care in these affected areas. Section 491.5 proposes criteria to determine if an RHC qualifies for an exception to the location requirements. An RHC that is no longer in a valid shortage or is in an urban area may apply for exception from RHC location requirements. Most, but not all, RHCs that apply for an exception are expected to qualify, and would not be decertified based on the location requirements.

Section 4205 of the BBA amended section 1833(f) of the Act to require that provider-based RHCs are subject to the same payment methodology as independent RHCs. 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. This already has been implemented through manual instructions and has helped to establish payment equity and consistency within the RHC program. We have codified the statutory requirement to pay all RHCs under an all-inclusive rate per visit, which avoids allocation of excessive administration costs to RHCs, and allow exceptions to the per-visit payment limit for qualifying RHCs.

We believe the fiscal impact of limiting the provider-based RHC payment to the independent RHC rate per visit has resulted in program savings. Provider-based RHCs that have costs above the all-inclusive cost-per-visit limit required by the law may have experienced some decrease in current reasonable cost basis payments. To reduce detrimental impacts of this decrease, section 4205 of the BBA permits an exception to the upper payment limit for RHCs based in small hospitals of less than 50 beds. The number of beds is determined according to the definitions established in § 412.105(b), or an alternative definition established in a Program Memorandum issued September 30, 1998, and updated on December 6, 2001. The alternative bed definition states that a hospital-based RHC can receive an exception to the per visit payment limit if its hospital has fewer than 50 beds as determined by the hospital's average daily census count, is a sole community hospital

located in a level 9–12 UIC, and has an average daily census that does not exceed 40.

There are currently 909 provider-based RHCs whose parent hospital has fewer than 50 beds. Of these, 354 are in UICs 9–12 and are therefore eligible for the exception to the per visit payment limit. By changing to the more accurate RUCAs, approximately 100 of these RHCs would no longer be eligible for the exception to the per-visit payment limit, but 251 previously ineligible RHCs would be eligible. This would result in a net total of 505 RHCs eligible for the exception to the per visit payment limit, a gain of 151. We expect that the RHCs that would gain eligibility to the payment limit exception would be in more rural areas that have greater financial challenges. Therefore, the fiscal impact of this change is expected to be minimal.

The QAPI requirement may increase burden in the short term because resources currently used for the required evaluation of the clinic's programs would need to be directed to the development of a QAPI program that covers the complexity and scope of the particular clinic. Although the requirements may result in some immediate costs to an individual clinic, we believe that the QAPI program would 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 may lead to increased patient visits for the clinic).

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

2. Impact of the QAPI Provisions

We estimate that the additional one-time impact for the initial development of the QAPI provisions would be as Shown in Table 2.

TABLE 2

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	.....
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	3,630,000	646,800

To develop our estimates, we used information on the salaries and wage estimation obtained 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 overall staffing needs.

3. Effects on Other Providers

We are aware of situations in which an RHC and a physician's private practice occupy the same space and bill Medicare for services either as an RHC or as a physician, depending upon which payment method produces the greater payment. Our revision would require an RHC to be a distinct entity that is not used simultaneously as a private physician office or the private office of any other health care professional. As a result, 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.

4. Effects on the Medicare and Medicaid Programs

As a result of this proposed rule, some existing RHCs would be at risk of losing their RHC status. We believe that any aggregate changes to overall spending would be negligible. This proposed rule would also result in some RHCs losing their exception to the per visit payment limit, while other RHCs would become eligible for the exception to the per visit payment limit. We cannot estimate accurately the payment differential since the clinics vary in terms of size and patient visits.

However, we believe that since total expenditures for this program represent a small fraction of the Medicare and Medicaid total budget and less than 20 percent of all RHCs would experience changes to payment rates, any aggregate savings would be insignificant. We also believe an insignificant amount of Medicare and Medicaid program savings would result from the provision that would terminate RHC status for certain providers. An RHC that loses its eligibility to participate in the RHC program likely would choose to participate in the Medicare and Medicaid programs in a non-RHC capacity such as a physician-directed clinic or a group of individual practitioners who would then bill Medicare using the Part B fee-for-service system.

C. Alternatives Considered

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

1. ''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 in comparison 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, an applicant would have to demonstrate that its 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 determine accurately

''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, we considered the establishment of tests narrowly focused on a few extreme cases, such as an exception test for only sole community providers. We rejected this option because of concern that the decertification of a clinic from the RHC program could decrease access to primary care for the entire community. We believe several options should be available to reflect the variability of communities in providing access to care for rural areas.

2. 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, 2000, proposed rule, we described alternative ways of satisfying the ''minimum level requirement'' for the QAPI program and requested public comment. We considered the following alternatives:

- Require RHCs to engage in an improvement project in three specified domains annually.
- Require a minimum number of improvement projects in any combination of the specified 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 State 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. As we noted in the December 24, 2003, final rule, we did consider alternatives for the rule. One alternative was to take a more rigid approach, whereby the final rule would be more prescriptive in the process that RHCs must follow to develop the QAPI program, to include setting forth specific performance measures to be used, the frequency and number of QAPI ''interventions'' that must be done, and 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 RHC's individualized QAPI program than in specific steps the RHC takes to achieve the improvement. A more moderate QAPI requirement would allow an RHC the flexibility to use staff and other resources in ways that more directly support 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 would allow each RHC the flexibility to fulfill this requirement based on its resources.

D. Conclusion

We do not expect a significant change in the operations of RHCs or FQHCs generally, nor do we believe a substantial number of small entities in the community, including RHCs, FQHCs, and a substantial number of small rural hospitals, would be affected adversely by these changes.

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

List of Subjects

42 CFR Part 405

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

42 CFR Part 410

Health facilities, health professions, Kidney diseases, Laboratories, 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 proposes to amend 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 subpart X continues to read as follows:

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

2. Section 405.2401(b) is amended by—

A. Adding the definitions of ''clinical social worker'' and ''employee'' in alphabetical order.

B. Republishing the introductory text of the definition of ''Federally qualified health center'' and revising paragraph (1) of that definition.

C. Adding the word ''Certified'' before ''Nurse-midwife'' in the definition of ''Nurse-midwife,'' changing the ''N'' of ''Nurse-midwife'' to lower case, and putting the definition in alphabetical order.

D. Removing the definition of ''nurse practitioner and physician assistant''.

E. Adding the definitions of ''nurse practitioner'' and ''physician assistant'' in alphabetical order.

F. Revising the definition of ''rural health clinic.''

The revisions and additions read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Clinical social worker (CSW) means an individual who has the following qualifications:

(1) Possesses a doctoral or master's degree in social work.

(2) After obtaining a doctoral or master's degree in social work, has performed at least 2 years of supervised clinical social work.

(3) Either is licensed or certified as a CSW by the State in which the individual practices or, in the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post-master's degree clinical social work practice under the supervision of a qualified master's degree social worker in an appropriate setting such as a hospital, clinic, or SNF.

(4) Is employed by or under contract with the RHC or FQHC to furnish diagnostic and therapeutic mental health services.

* * * * *

Employee means any individual who, under the common law rules that apply

in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

(1) Is receiving a grant under section 330 of the Public Health Service (PHS) Act, or is receiving funding from such a grant under a contract with a recipient of such a grant and meets the requirements to receive a grant under section 330 of the PHS Act;

* * * * *

Nurse practitioner (NP) means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has satisfactorily completed a formal academic 1-year educational program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

* * * * *

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that meets all of the following requirements:

(i) Was at least 1 academic year in length.

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care.

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

* * * * *

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

(1) The requirements specified in 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.

* * * * *

§ 405.2402 [Amended]

3. Amend § 405.2402(d) by removing ''he'' and adding ''the Secretary'' in its place.

§ 405.2404 [Amended]

4. Amend § 405.2404(a)(2)(ii) by removing ''he'' and adding ''the Secretary'' in its place.

5. 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.* The beneficiary is responsible for the coinsurance amount.

(1) For any one service provided by an RHC—

(i) If the deductible has already been met, beneficiary coinsurance liability must not exceed 20 percent of the clinic's reasonable customary charge for the covered service;

(ii) If the deductible has not already been met, the beneficiary coinsurance liability must not exceed 20 percent of any remainder amount after deducting the unmet deductible from 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 20 percent of the reasonable amount customarily charged by the RHC for that particular service.

(3) Except for services provided under Medicare Advantage plans to FQHCs in accordance with section 1833(a)(3)(B) of the Act, the coinsurance liability may not exceed 20 percent of the reasonable amount customarily charged by the FQHC for the particular service.

6. Section 405.2411 is amended by—

A. Revising paragraph (a) introductory text.

B. Amending paragraphs (a)(1) through (a)(3) by removing the ''; '' at the end of each paragraph and adding a ''.'' in its place.

C. Amending paragraph (a)(4) by removing the ''; and'' at the end of the paragraph and adding ''.'' in its place.

D. Adding new paragraphs (a)(6) through (a)(8).

E. Revising paragraph (b).

F. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this part are as follows:

* * * * *

(6) Certified nurse-midwife (CNM) services.

(7) Clinical psychologists (CP) and clinical social worker (CSW) services specified in § 405.2450 of this subpart.

(8) Service and supplies furnished as an incident to CP or CSW services, as specified in § 405.2452 of this subpart.

(b) RHC services are covered when furnished in an RHC setting or other

outpatient setting, including a patient's place of residence or a skilled nursing facility.

(c) RHC services are not covered in a hospital, as defined in section 1861(e)(1) of the Act, or a critical access hospital.

7. Section 405.2414 is amended by—

A. Revising the section heading.

B. Revising paragraph (a)(1).

C. Adding the word ''certified'' before ''nurse-midwife'' in paragraph (a)(4).

D. Adding the word ''certified'' before ''nurse-midwives'' in paragraph (c).

The revisions read as follows:

§ 405.2414 Nurse practitioner (NP), physician assistant (PA), and certified nurse-midwife (CNM) services.

(a) * * *

(1) Furnished by a nurse practitioner, physician assistant or certified nurse-midwife, who is employed by, or receives compensation from, the rural health clinic;

* * * * *

8. Amend § 405.2415 by—

A. Revising the section heading.

B. Revising the introductory text of paragraph (a).

C. Revising paragraph (a)(4).

D. Revising paragraph (b).

The revisions read as follows:

§ 405.2415 Services and supplies incident to a clinical psychologist (CP), clinical social worker (CSW), nurse practitioner (NP), physician assistant (PA), or certified nurse mid-wife (CNM) services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's, nurse practitioner's, physician assistant's, or certified nurse-midwife's services are reimbursable under this subpart if the service or supply is—

* * * * *

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, or physician; and

* * * * *

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, certified nurse-midwife, nurse practitioner, clinical psychologist, or clinical social worker only if the person is permitted to supervise those services under the written policies governing the RHC.

* * * * *

§ 405.2448 [Amended]

9. Amend § 405.2448 by removing and reserving paragraph (d).

10. Section 405.2462 is revised to read as follows:

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

(a) *General rules.* (1) RHCs and FQHCs are paid on the basis of an all-inclusive rate per visit, subject to a payment limit.

(2) The Medicare Administrative Contractor or fiscal intermediary determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

(b) *Rules for RHCs.* RHCs must meet the following requirements:

(1) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid approved or certified practice owned, controlled or operated by the same physicians and nonphysician practitioners that staff the RHC as employees or contractors; and

(2) If sharing a multipurpose clinic with other types of health providers or suppliers, appropriately allocates and excludes from the RHC cost report the net non-RHC costs associated with the sharing of common space, medical support staff, or other physical resources.

(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 essential access community hospital as determined in accordance with § 412.109(a) of this chapter.

(B) It is located in a level 9 or 10 Rural-Urban Commuting Area (RUCA).

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

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

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

11. In § 405.2466 paragraph (b)(1)(iii) is revised to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iii) Medicare payment to the RHC or FQHC is equal to its reasonable costs less aggregate coinsurance and deductible amounts billable, but in no case may total Medicare payment exceed 80 percent of reasonable costs.

* * * * *

§ 405.2468 [Amended]

12. In § 405.2468 paragraph (b)(1) is revised by removing the parenthetical statement ''(RHCs are not paid for services furnished by contracted individuals other than physicians.)''

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

13. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

14. Section 410.150 is amended by—

A. Revising the first sentence of paragraph (b)(15).

B. Adding a new paragraph (b)(20).

The revision and addition read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(15) Except for certain physician assistant services provided in a rural health clinic owned by a physician assistant, as specified in paragraph (b)(20) of this section, to the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies furnished incident to his or her services. * * *

* * * * *

(20) To a physician assistant who was the owner of a rural health clinic as described § 405.2401(b) of this subchapter. Payment is made to such physician assistant for services and supplies furnished incident to his or her services only if—

(i) No facility, other provider charges, or other amount has been paid for services furnished by such physician assistant; and

(ii) The physician assistant owned the rural health clinic for a continuous period beginning on or before August 4, 1997 and ending on the date that the Secretary determines that the clinic no longer meets the requirements of section 1861(aa)(2) of the Act.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

15. 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).

16. Section 491.2 is revised to read as follows:

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Certified nurse-midwife (CNM), clinical social worker (CSW), nurse practitioner (NP), physician, and physician assistant (PA) mean an individual who has the qualifications for such practitioner set forth in § 405.2401 of this chapter.

Clinical psychologist (CP) means an individual who has qualifications as defined in § 405.2450 of this chapter.

Nonurban area means an area that is not delineated as an urbanized area by the U.S. Census Bureau.

Rural area means an area that is not delineated as an urbanized area by the U.S. Census Bureau.

Rural health clinic means a facility as defined in § 405.2401(b).

Shortage area means a geographic area that meets one of the following criteria:

(1) Designated by the Secretary as a geographic primary care health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (PHS Act);

(2) Designated by the Secretary as a population group primary care HPSA under section 332(a)(1)(B) of the PHS Act;

(3) Designated by the Secretary as a medically underserved area (but not as a medically underserved population group) under section 330(b)(3) of the PHS Act; or

(4) Designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services under section 6213(c) of the Omnibus Budget Reconciliation Act of 1989.

17. Section 491.3 is revised to read as follows:

§ 491.3 General certification requirements.

(a) *General.* (1) RHCs participate in Medicare in accordance with an agreement as specified in § 405.2402 through § 405.2404 of this chapter.

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

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

(b) *Permanent and mobile units.* An RHC and an FQHC may be located in a permanent or a mobile unit.

(1) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of services furnished directly by the clinic or center are housed in a permanent structure.

(2) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled locations.

(3) *Permanent unit in more than one location.* If the RHC or FQHC services are furnished at permanent units in more than one location, each unit is independently considered for certification as an RHC or FQHC and must meet the location requirements based on the physical location of the clinic or center.

18. Section 491.4 is revised to read as follows:

§ 491.4 Compliance with State licensure laws.

The RHC or FQHC and its staff meet applicable Federal laws related to the health and safety of patients as well as State licensure requirements.

19. Section 491.5 is amended by revising paragraphs (a) through (e) to read as follows:

§ 491.5 Location of clinic.

(a) *General location requirements.*

(1) An existing RHC or an applicant requesting entrance into the Medicare program as an RHC—

(i) Is located in a rural area that is currently designated as a shortage area as defined in § 491.2; and

(ii) The designation of such shortage area has been made or updated during the past 3 years.

(2) An FQHC is located in a rural or urban area that is designated as either a medically underserved area or includes a medically underserved population group.

(b) *Location exception requirements.* An RHC may be considered for an exception to the location requirements specified in § 491.5(a)(1) if the clinic—

(1)(i) Is in an area currently classified by the U.S. Census Bureau as an urbanized area; or

(ii) Is in an area not currently designated as a shortage area.

(2)(i) Is located in an area that has been classified as an Urbanized Area by the U.S. Census Bureau and is in a level 4 or higher RUCA; and

(ii) Demonstrates that at least 51 percent of the clinic's patients reside in an adjacent nonurbanized area.

(3) Meets the essential provider criteria specified in paragraph (c) of this section.

(c) *Essential provider criteria.* CMS grants essential provider status is for a period of 3 years. At the end of the 3-year period, the clinic may reapply for continued essential provider status if an exception is still needed. To receive an exception to the location requirements, an RHC must provide documentation to support that it meets one of the following conditions:

(1) *Sole community provider.* The RHC is the only participating primary care provider that meets either of the following criteria:

(i) Is at least 25 miles from the nearest participating primary care provider.

(ii) Is at least 15 miles but less than 25 miles from the nearest participating primary care provider and demonstrates that it is more than 30 minutes from the nearest primary care provider based on local topography, predictable weather conditions, or posted speed limits. For purposes of this exception, a participating primary care provider means another RHC, FQHC, or other primary care provider that actively is accepting and treating Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay).

(2) *Major community provider.* The RHC must meet the following conditions to be considered a major community provider:

(i) Has a Medicare, Medicaid, low-income and uninsured patient utilization rate greater than or equal to 51 percent or a low-income patient utilization rate greater than or equal to 31 percent.

(ii) Is actively accepting and treating a major share of the Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC.

(3) *Specialty clinic: Obstetrics/gynecology (ob/gyn) or pediatrics.* The RHC must meet all the following conditions to be considered a specialty clinic:

(i) Exclusively provides ob/gyn or pediatric health services.

(ii) Is the sole provider or major source of ob/gyn or pediatrics health services for Medicare (when applicable), Medicaid, low-income, and uninsured patients (regardless of their ability to pay) and that meets either of the following conditions:

(A) Is at least 25 miles from the nearest participating primary care provider of ob/gyn or pediatric services; or

(B) Is at least 15 miles but less than 25 miles from the nearest participating primary care provider of ob/gyn or pediatric services and can demonstrate that it is more than 30 minutes from the nearest primary care provider providing these services based on local

topography, predictable weather conditions, or posted speed limits.

(iii) Is actively accepting and treating Medicare (where applicable), Medicaid, low-income, and uninsured patients;

(iv) Has a Medicare, Medicaid, low-income patient and uninsured patient utilization rate greater than or equal to 31 percent.

(v) Provides ob/gyn or pediatric health services onsite to clinic patients.

(4) *Extremely rural community provider.* The RHC must meet the following conditions to be considered an extremely rural community provider:

(i) Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay).

(ii) Is located in a frontier county (6 or less persons per square mile) or in a Rural-Urban Commuting Area level 10 area.

(d) *Termination.* (1) CMS decertifies a clinic from participation in the Medicare program as an RHC, effective 180 days after the date that the RHC no longer meets the location requirements, unless—

(i) An application to update the shortage area designation has been received by the Health Resources and Services Administration (HRSA) not later than 3 years from the date of the last designation; or

(ii) The RHC has submitted an application for an exception to the location requirement as specified in paragraph (e) of this section and meets the exception standards set forth in paragraphs (b) and (c) of this section.

(2) CMS may terminate RHC status at any time if it determines that the RHC is not in compliance with any certification requirements.

(e) *Process for essential provider status.*

(1) If HRSA has not received an application to update a designation by the end of the 3 years from the date of the previous designation, an RHC in such area has 90 days from the end of the 3-year period to submit its request to CMS for an exception in order to continue to be considered to be an essential provider.

(2) If HRSA has proposed for withdrawal or withdrawn a designation, the RHC in such area must submit its request to CMS for an exception in order to continue to be considered an essential provider 90 days from the date the designation was proposed for withdrawal or withdrawn.

(3) If HRSA has disapproved an application to update a designation, the RHC in such area has 90 days from the date of the disapproval to submit a request for a location exception in order to be considered an essential provider.

(4) An existing RHC may apply for an exception from decertification by submitting to the appropriate CMS regional office a written request with any necessary documentation demonstrating that it meets one of the essential provider criteria specified in paragraph (c) of this section.

(5) CMS does not decertify an RHC that has submitted an application for an exception within 90 days from the date that the RHC no longer meets the location requirements while the application for an exception is under review, for a period not to exceed 180 days from the date the RHC no longer meets the location requirement, or the effective date of the final rule, whichever is later. In rare circumstances, the CMS RO may request an extension from the CMS Central Office if it has not been possible to process the location exception request before the RHC would be decertified.

(6) The CMS regional office may grant a 3-year exception based on its review of an RHC request and other relevant information, if such 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 paragraph (b) of this section.

(7) At the end of the 3-year exception period, a clinic may renew its essential provider status by submitting written assurances to the appropriate CMS regional office that it continues to meet the conditions specified in this section.

(8) An RHC that is located in an area for which an application to update the designation has not been submitted to HRSA or has been found by HRSA to not qualify for an eligible designation, and has not submitted an application for an exception within 90 days of the date that the designation is more than 3 years old, may continue to operate as an RHC for 180 calendar days after the expiration of the applicable 3-year period, effective the last day of the month.

(9) A provider-based RHC that does not meet the location requirements and does not qualify for an exception and has submitted an application to CMS to be another type of Medicare provider that requires a State survey for certification, may receive an additional 120 days extension of their status as an RHC while their application is being processed.

* * * * *

20. Section 491.6 is amended by—

A. Adding paragraph (d).

B. Adding paragraph (e).

The additions read as follows:

§ 491.6 Physical plant and environment.

* * * * *

(d) *Infection control.* The RHC or FQHC must protect patients and staff by maintaining and documenting an infection control process that—

(1) Follows accepted standards of practice, including the use of standard precautions, to prevent the transmission of infectious and communicable diseases; and

(2) Is an integral part of the quality assessment and performance improvement (QAPI) programs.

(e) *Hours of operation.* The clinic or center must post signs that are noticeable and can be viewed by those with vision problems and those in wheelchairs at or near the entrance to the facility to advise the public of the days of the week and hours when services are furnished.

21. Section 491.8 is amended by—

A. Revising paragraphs (a)(1), (a)(3), and (a)(6).

B. Adding paragraph (d).

The revisions and additions read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(1) (i) RHC or FQHC has a health care staff that includes one or more physicians.

(ii) A RHC must employ one or more physician assistants or nurse practitioners.

* * * * *

(3) The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center.

* * * * *

(6) A physician, nurse practitioner, physician assistant, certified 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)(ii) 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 certified nurse-midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC provides clinical services, or to hire a PA or NP as a direct employee.

(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.

22. Section 491.9 is amended by—

A. Revising paragraph (c)(2).

B. Revising paragraph (c)(3).

The revisions and addition read as follows:

§ 491.9 Provision of services.

* * * * *

(c) * * *

(2) *Laboratory*. These requirements apply to RHCs but not to FQHCs. The clinic provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient. See § 405.2462 of this chapter for payment requirements for clinical laboratory services furnished within the RHC setting. These laboratory services include the following:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency*. The clinic or center must—

(i) Provide medical emergency procedures as a first response to common life-threatening injuries and acute illnesses;

(ii) Have available the drugs, biologicals, equipment, and supplies, which are appropriate for the facility's patient population and which are commonly used in emergency first response procedures; and

(iii) Provide training for staff in the provision of these emergency procedures according to the clinic's or center's policies that are consistent with commonly accepted practice as well as in accordance with applicable Federal, State, and local laws.

* * * * *

23. Section 491.10 is amended by—

A. Revising paragraph (a)(3) introductory text.

B. Removing the ''; '' at the end of paragraphs (a)(3)(i) through (a)(3)(iv) and adding a ''.'' in its place.

C. Adding a new paragraph (a)(3)(v).

The revision and addition read as follows:

§ 491.10 Patient health records.

(a) * * *

(3) For each patient receiving RHC or FQHC services at such facility, the RHC or FQHC maintains a record that includes the following, as applicable:

* * * * *

(v) Legible entries that are completed, dated, timed, and authenticated promptly in written or electronic form by the person responsible for ordering, providing, or evaluating the service. Any entry in the patient health record must be identified and authenticated promptly by the person making the entry. All entries in the patient health record must be authenticated within 48 hours unless there is a State law that designates a specific timeframe for the authentication of entries.

* * * * *

24. Revise § 491.11 to read as follows:

§ 491.11 Quality assessment and performance improvement for RHCs.

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 RHCs 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 are shown to be predictive of desired patient outcomes or to 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) An RHC that develops and implements an information technology system explicitly designed to improve patient safety and quality of care meets the requirement for a project under this section.

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

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

(1) Identifying or approving QAPI priorities.

(2) Ensuring that QAPI activities that are developed to address identified priorities are implemented and evaluated.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 11, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 28, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on June 9, 2008.

[FR Doc. E8–13280 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P