GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

RE: RURAL HEALTH CLINICS

This packet of information is in response to your request for information regarding **Medicare approval as a Rural Health Clinic (RHC) or information regarding a Change of Ownership (CHOW)**. This Office is responsible for assisting the Centers for Medicare and Medicaid Services (CMS), formally known as HCFA, in performing the certification functions for those suppliers wishing to participate in the Medicare program. Approval for participation in the Medicare Program is prerequisite to qualifying to participate in the State Medicaid program.

CRITERIA FOR ELIGIBILITY: To be approved as a supplier of rural health clinic services, a clinic **must be located** in an area designated by the Bureau of the Census as non-urbanized and by the Secretary of Health and Human Services as a shortage area, where a shortage of personal health services or primary medical care manpower exists. Under the law***, the clinic must employ a physician's assistant, a nurse practitioner, or a nurse mid-wife; must make arrangements with a physician for medical direction, guidance, and supervision; and must make arrangements with a Medicare certified hospital for referral and admission of patients by the clinic.*** Regulations of the Department of Health and Human Services specify the minimal health and safety standards rural health clinics must meet to qualify for reimbursement under this law.

In those instances where a central organization supplies rural health services at more than one clinic site, **each site is considered a separate clinic** and the location of the clinic site determines its location eligibility (i.e. rural shortage area) rather than the location of the central organization. A separate "Request to Establish Eligibility", is required for each clinic site and each site will be required to obtain a Medicare provider number.

COMPLETING THE FORMS: Online you will find the Conditions of Coverage governing Rural Health Clinics and other HCFA forms that must be completed if you desire to be approved as a Medicare supplier of RHC services. Complete and return the forms with original signatures signed in blue ink. Please note that **TWO** signed originals of the HCFA 1561, Health Insurance Benefit (HIB) Agreement are required. Instructions for completing the HIB are as follows:

- On the first and third line of the HIB form, enter the entrepreneurial name of the facility. If a trade name is used, follow the entrepreneurial name by the d/b/a (trade name). Ordinarily, the entrepreneurial name is the same as the legal name used on all official IRS correspondence concerning payroll withholding taxes, such as the W-3 or 941 forms. For example, Health Services, Inc., owner of Tifton RHC, would enter on the agreement: "Health Services, Inc. d/b/a Tifton RHC." A partnership of several persons would complete the agreement to read: "Robert Johnson, Louis Miller, and Paul Allen, ptr., d/b/a Tifton RHC." A sole proprietorship would complete the agreement to read: "John Smith d/b/a Tifton RHC."

- It is imperative that the PERSON WHO SIGNS the agreement is AUTHORIZED BY THE LEGAL OWNERS to sign and enter into this supplier agreement with CMS. Original signature, title, and date of signature are required following the words "accepted for the provider of services by."

  As of November 1, 2001, your carrier will supply all HCFA 855 provider/supplier enrollment forms to you. Please contact your carrier for the 855 Form and for answers to questions related to completion of the 855 forms. The carrier for RHCs is Riverbend Government Benefits Administration (423) 763-3823 and the CMS web site is **www.cms.gov/medicare/enrollment,** where you can download the 855A form**.** The carrier will notify this Office of its recommendation for approval or denial for enrollment or change of ownership (CHOW) within 30 calendar days of receipt of the completed 855 application. Once this Office is notified that the initial Medicare enrollment or CHOW has been approved and all other required forms have been submitted, the Medicare survey process **will be initiated or the CHOW will be processed.**

  THE MEDICARE SURVEY PROCESS: You must be supplying services, (i.e., have patients) before this Office can survey or recommend certification to CMS; therefore, please indicate on the enclosed "Request for Medicare Survey Form", the date you anticipate being fully operational and ready for a survey. Please indicate the days and hours of operation. If the date you anticipate being fully operational changes, please notify this Office immediately. By CMS policy, all certification surveys must be **unannounced**. The Health Care Section will conduct the unannounced federal survey generally within 21 days from the date our Office receives your notice in writing that you are fully operational and ready for the Medicare survey, all the required HCFA forms are complete, and the carrier has approved your provider enrollment (855A form). Our surveyors will inspect your facility, conduct interviews, review documents, and undertake other procedures necessary to evaluate the extent to which your facility meets the Conditions of Coverage for RHCs.

  If your agency is found to be in full compliance (no deficiencies) with the Medicare Conditions of Coverage, then this Office will recommend to CMS that your facility be certified for participation in the Medicare program effective the date of the survey.

  If condition level deficiencies are identified during the course of the survey, this Office will recommend to CMS that your application to participate in the Medicare program be denied. If CMS accepts this recommendation, CMS will send a notice giving the reasons for denial and inform you of your right to appeal.

  If deficiencies below the "condition level" are identified during the course of the survey, you will be given an opportunity to submit an acceptable plan of correction. This Office will recommend to CMS that your rural health clinic be certified effective the date you submit an acceptable plan of correction.

  LABORATORY SERVICES: If you anticipate that your facility will be performing any clinical laboratory testing or specimen collection, you need to contact the Diagnostic Services Unit at (404) 657-5450. This Unit will assist you in determining whether there are additional federal and state laboratory requirements that your facility will have to meet.

ISSUANCE OF PROVIDER NUMBER: After CMS determines that all requirements for participation in the Medicare program are met, the Health Insurance Benefit Agreement (HIB) will be signed by CMS, who will return one copy of the approval agreement to you along with your assigned SUPPLIER NUMBER for participation in the Medicare program. You **cannot claim supplier reimbursement for services furnished to Medicare patients prior to approval from CMS.**

PROVIDER BASED STATUS: Determination of provider-based status is a function of your carrier. If you wish to seek provider-based status as outlined at 42 CFR 413.65, please contact your carrier.

CHANGES IN OWNERSHIP, ETC.: If operation of the clinic is later transferred to another owner, ownership group, or to a lessee, the Medicare agreement (provider number) will be assigned automatically to the successor, unless a specific request for a new provider number is made to CMS in writing. However, you are required to notify this Office, as CMS's representative, of the change in ownership, by filling out an 855A and submitting the form to your fiscal intermediary. You also need to fill out the Change of Ownership (CHOW) packet on this website and mail it to 2 Peachtree Street, 31-447, Specialized Unit, Atlanta, GA 30303. The CHOW packet consists of all the forms that are required in an "initial" packet with the exception of the Conditions of Coverage.

Again, your rural health clinic cannot claim reimbursement for services rendered to Medicare patients prior to CMS approval. Once you have received CMS approval and received the supplier number, you should contact Medicaid and provide them with a copy of the letter indicating that you have been approved to be a Medicare supplier of RHC services. The Medicaid office should then supply your facility with appropriate papers needed to apply to be Medicaid approved.

Should you have any questions concerning this information or completion of enclosed forms, (with the exception of the HCFA 855 form); please do not hesitate to call our Office at (404) 657-5411.

Enclosures
Medicare Conditions of Coverage
Request for Medicare Survey memo
HCFA 29- Request for Certification
HCFA 1561A Health Insurance Benefit Agreement (**2 signed originals**)
HHS 690 – Title VI form (1)

STATE OF GEORGIA)
) AFFIDAVIT RE: PERSONAL IDENTIFICATION
COUNTY OF_____) FOR LICENSURE/REGISTRATION

PERSONALLY APPEARED before the undersigned officer, duly authorized to administer oaths, came the undersigned, who after having been duly sworn, states under oath, the following:

1. That my name is _____ and that I am who I say I am;
2. That my address is_____;
3. That I have presented sufficient personal identification to the notary that is true and accurate;
4. That I am legally in the United States of America;
5. That I am applying to the Georgia Department of Community Health, Healthcare Facility Regulation Division, to operate a business activity that is subject to regulation by the Department of Community Health; and that this affidavit is a material part of the application; and
6. That if the Department subsequently determines that the material information contained in this affidavit is false, I will in violation of licensing/registration requirements, which may result in revocation of my license or registration.

Sworn to and subscribed before me)
This _____ day of _____,___.)
)
)
)_____
_____) Affiant
NOTARY PUBLIC)
STATE OF GEORGIA)

My commission expires:_____.

Documents That Establish Identity

For individuals 18 years of age or older:

- Driver's license or ID card issued by a state or outlying possession of United States provided it contains a photograph or information such as name, date of birth, sex, height, eye color, and address

- ID card issued by federal, state, or local government Agencies or entities provided it contains a photograph or Information such as name, date of birth, sex, height, eye color, and address (including U.S. Citizen ID Card [INS Form I-197] and ID Card for use of Resident Citizen in the U.S. [INS Form I-179])

- School identification card with a photograph

- Voter's registration card

- United States Military card of draft record

- Military dependent's identification card

- United States Coast Guard Merchant Mariner Card

- Native American tribal document

- Driver's license issued by a Canadian government authority

Source:http://uscis.gov//graphics/lawregs/handbook/hand_emp.pdf US Handbook for Employers, page 23

APPENDIX G

INTERPRETIVE GUIDELINES

RURAL HEALTH CLINICS

APPENDIX G

Interpretive Guidelines - Rural Health Clinics

Conditions of Coverage

Condition I	COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS 491.4
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Conditions for Certification

EXPLANATION OF CONDITIONS FOR CERTIFICATION FOR RURAL HEALTH CLINICS (RHCs)

I. COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS (42 CFR 491.4)

The RHC and its staff are in compliance with applicable Federal, State, and local laws and regulations.

A. Federal Laws and Regulations.--The Federal regulations governing the certification of RHCs were published in the Federal Register on July 14, 1978, 43 FR 136. Conditions for certification under those regulations are the subject of these guidelines.

B. State Laws and Regulations.--All States have practice acts that govern the activities of health professionals. While there is considerable variation in the States' practice acts concerning physician assistants, nurse practitioners and certified nurse-midwives, there is a broad mandate in the medical practice acts of all States giving physicians authority to diagnose and treat medical conditions. The extent to which the physician may delegate these responsibilities and to whom, and under what conditions, varies in the States. Some States have updated their practice acts since the advent of the physician assistant, nurse practitioner and certified nurse-midwife health care professionals. In some instances, these updated practice acts have included definitions and specific references to permitted/prohibited activities, supervision/guidance required by a physician, and location/situations in which nurse practitioners, certified nurse-midwives and physician assistants may function. In some States where nurse practice acts have not been significantly updated, some functions of the nurse practitioner are viewed as an extension of the traditional nursing role as being covered by the existing nurse practice act.

Rural health clinics can be certified only if the State permits--that is, does not explicitly prohibit--the delivery of primary health care by a nurse practitioner, certified nurse-midwife or a physician assistant. The surveyor will encounter wide variations in the wording, interpretation, and application of States' practice acts as they affect the physician assistant, nurse practitioner and certified nurse-midwife in the RHC setting.

In situations where the State law is silent, or where the State law does not specifically prohibit the functioning of a physician assistant, nurse practitioner or certified nurse-midwife with medical direction by a physician and with the degree of supervision, guidance, and consultation required by the RHC regulations, the surveyor may consider this condition as being met. Interpretations needed on specific aspects of the State's practice act should be sought through the State regulatory agency or board(s) dealing with the practice and profession.

II. LOCATION OF CLINIC (42 CFR 491.5)

Consult with the RO to preliminarily ascertain that a clinic meets the basic requirement of location prior to scheduling a survey. The clinic must be located in a rural area that is designated as a shortage area. Applicants determined not qualified under this requirement should be sent a letter (see Exhibit 27) with the appropriate notation.

A. Rural Area Location.--The law requires the clinic to be located in an area "that is not an urbanized area as defined by the Bureau of the Census." The Bureau has published both a narrative definition of an urbanized area and maps displaying the land area of urbanized areas. Lists and maps of the urbanized areas are contained in the "number of inhabitants" census volume for that State (census of population series PC-80-1-A). Note that this definition is different from that of a metropolitan statistical area (MSA). The area. Contact the Bureau of the Census ROs or the HCFA ROs for a determination on whether the clinic is located in a nonurbanized area.

B. Shortage Area Designation.--After it has been ascertained that the clinic is located in a nonurbanized area, the HCFA RO will certify whether or not the clinic is located in a designated shortage area. The HCFA RO, after consulting with PHS RO staff, promptly responds in writing to the request for a determination. This information may be given by telephone as long as it is followed by a written response. This consultation explores designation:

- As an area with a shortage of personal health services under §330(b)(3) or 1302(7) of the PHS Act;
- As a health manpower shortage area described in §332(a)(1)(A) of the PHS Act;
- As an area which includes a population group which the Secretary determines has a health manpower shortage under §332(a)(1)(B) of the PHS Act;
- As a high migrant impact area described in §329(a)(5) of the PHS Act; or
- As an area designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

These designations are published periodically in the Federal Register by the PHS Bureau of Health Care Delivery and Assistance. Designation under any section qualifies a RHC location. The designation process is a continuing process, with additions of newly designated areas and deletions of previously designated areas occurring daily.

C. Mobile Units.--The Conditions for Certification must be met by a mobile unit for it to qualify as a RHC. In addition, it should be ascertained that the mobile unit has fixed scheduled locations, each of which meet the rural and shortage area requirements.

Since the mobile unit is a clinic, it is expected that the RHC services are provided in the unit and not in a permanent structure, with the unit serving only as a mobile repository for the equipment, supplies, and records. The only exception would be if the RHC services are furnished off the clinic's premises (away from the unit) to homebound patients.

Where a facility offers RHC services at a permanent structure as well as in a mobile unit, each facility must be certified separately as a RHC. This is differentiated from the situation where a permanent structure provides RHC services off the premises, e.g., to homebound patients, with the use of a vehicle to transport supplies, equipment, records, and staff.

D. Exceptions to the Location Requirement.--There are two grandfather provisions applicable to the certification process.

1. Loss of Location Eligibility.--This grandfather provision applies to the annual recertification process. It should be used as a "yes" response to item J11 and on the HCFA-30 when a facility which was previously certified as being located in a nonurbanized and designated shortage area subsequently loses either or both of these characteristics. When this occurs, the facility does not lose its eligibility for continued participation in the program because it does not meet the location requirement. If J11 is marked yes, mark J17 and J18 N/A.

2. Clinics Operating on July 1, 1977.--Potential applicants under this grandfather provision still have to meet the rural location requirement. The other requirement under this provision is that the Secretary has determined that the area served has an insufficient supply of primary care physicians. Facilities providing services on July 1, 1977, in a nonurbanized area which is determined to have unmet needs for primary health care but which is not a designated shortage area are potential applicants. Therefore, the facility may be primarily serving a designated area but not located in a designated shortage area. It must be determined whether the location of the clinic is an appropriate part of a service area which includes areas or populations which have been designated either as having a health manpower shortage, or as being medically underserved. Aiding this determination will be previous PHS decisions made on behalf of the Secretary. The answer to question V on HCFA-29 is an important indicator. Several PHS programs provide or have provided grant support to enable the facility to provide health care to designated areas. These programs do not require that the facility be located in a designated shortage area. Many of these facilities were operating with PHS grant support prior to enactment of the Rural Health Clinic Services Act of 1977 (P.L. 95-210) and may constitute certifiable RHC applicants. Some examples of these PHS programs are National Health Service Corps (NHSC), Migrant Health, Health Underserved Rural Areas (HURA), and Rural Health Initiative (RHI).

Prior to P.L. 95-210, a number of States had programs to assist their rural areas with greater access to primary care. The location of the facilities developed by these programs was determined by valid criteria established by the State, although location in a designated shortage area may not have been one of them. These facilities are also potential applicants under this grandfather provision.

When it is determined that an applicant clinic not located in a designated shortage area may be a potential applicant under this grandfather provision, develop the following information and submit it to the HCFA RO for a determination as to whether the facility meets the requirements of this grandfather provision:

- A description of the geographic boundaries of the facility's service area;

o Information developed through consultation with the PHS RO staff about whether the area, or any portion of the area, had ever been reviewed for designation under any of the applicable sections of the PHS Act;

o Identification of any designated population group or institution in the facility's service area;

o Information secured from the appropriate Health Systems Agency and the State Health Planning and Development Agency about the primary care resources available in the facility's service area;

o Information about any planning, developmental, or operating funds awarded to the facility by the county, State, or Federal Government to assist in providing greater access to health care in the area;

o Information about the factors considered in determining where the facility was to be located; and

o Any additional information the SA or RO feels is relevant.

III. PHYSICAL PLANT AND ENVIRONMENT (42 CFR 491.6)

A. Physical Plant Safety.--To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review. Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.

B. Preventive Maintenance.--A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)) and inspection of the facility to assure that services are rendered in a clean and orderly environment. Inspection schedules and reports should be available for review by the surveyor.

C. Non-medical Emergencies.--Review written documentation and interview clinic personnel to determine what instructions for non-medical emergency procedures have been provided and whether clinic personnel are familiar with appropriate procedures. Non-medical emergency procedures may not necessarily be the same for each clinic.

IV. ORGANIZATIONAL STRUCTURE (42 CFR 491.7)

A. Basic Requirements.--Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of §491.8, and has adequate written material covering organization policies, including lines of authority and responsibilities.

B. Written Policies.--Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic's operation.

C. Disclosure of Names and Addresses.--The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction.

Any entity may organize itself as an owner of a RHC. The types of organizations being referred to are described in answers to question IV on the Request to Establish Eligibility. These range from:

o A physician in a private general practice located in a shortage area who employs either a nurse practitioner, certified nurse-midwife or a physician assistant;

o A nurse practitioner, certified nurse-midwife or a physician assistant in solo practice in a shortage area who develops the required relationship with a physician for medical direction; to

o Organizations either for profit or not for profit who own primary care clinics located in shortage areas.

Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the State.

V. STAFFING AND STAFF RESPONSIBILITIES (42 CFR 491.8)

A. Sufficient Staffing.--The staffing described in 42 CFR 491.8(a) is the minimum staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When item J42 on the SRF is marked no, explain, with reasonable detail, the circumstances (and efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician, physician assistant, certified nurse-midwife or nurse practitioner member of the staff reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide some type of documentation showing the its good faith effort to obtain staff. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. The loss of a physician assistant or nurse practitioner staff member may require a temporary adjustment of the clinic's operating hours or services and an adjustment in the scheduled visits by the physician(s)

providing medical direction. The loss of the physician member will require the clinic to make temporary arrangements for medical direction with another physician(s), and this might alter the scheduled times the physician is present in the clinic. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification. It is the responsibility of the clinic to promptly advise you of any changes in staffing which would affect its certification status.

B. Staffing Availability.--A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)(10)) or physician assistant must be available to furnish patient care services at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant must be available to furnish patient care services at least 50 percent of the scheduled operating hours during which RHC services are offered, even though a physician is present in the clinic on a full-time basis during the time RHC services are offered. The phrase "available to furnish patient care services" means (1) providing RHC services in the clinic; (2) being physically present in the clinic even though not providing RHC services; or (3) providing RHC services to clinic patients outside the clinic. These services must be RHC services. Items (1) and (2) indicate that a physician, physician assistant, certified nurse-midwife or nurse practitioner is present on the premises, not on call, during the scheduled operating hours when RHC services are offered at the facility. Item (3) refers to that part of the clinic's operating schedule utilized in providing RHC services outside the clinic.

A RHC's total operating schedule, therefore, consists of offering RHC services at the clinic, as well as providing RHC services to patients outside the clinic. Determinants of how a clinic schedules its operating time include the size of the required staff, patient population, and where the services need to be provided. Some clinics, within their scheduled hours, may be able to concurrently offer RHC services both on and off the clinic's premises, whereas other clinics may have to schedule separate hours for offering the services on and off the clinic's premises (e.g., a clinic's total operating schedule may be from 9 a.m. to 5 p.m. daily, with on-premises services offered from 9 a.m. to 3 p.m., and off-premises services offered from 3 p.m. to 5 p.m.).

Section 1861(aa)(2)(J) of the Act requires that a physician assistant, certified nurse-midwife or nurse practitioner must be available to provide patient care services during at least 50 percent of the RHC's total operating schedule. Therefore, a physician must provide needed services at other times during the clinic's scheduled operating hours. A RHC which does not have a physician, physician assistant, certified nurse-midwife or nurse practitioner on the premises to render services during the scheduled operating hours of the clinic does not meet the requirements of §1861(aa)(2) of the Act, even though the 50 percent requirement may be met.

The following are examples of how determinations regarding these requirements may be made. A clinic has a total operating schedule of from 9 to 5 Monday through Friday, and from 9 to 1 on Saturday (44 hours a week). RHC services are offered from 10 to 5 Tuesday through Friday (28 hours a week, which satisfies the 51 percent requirement). A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services from 10 to 5 Tuesday through Friday (28 hours a week). Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 14 hours (50 percent of 28 hours) to furnish patient care services.

In some cases, the clinic's weekly schedule may not be a logical period of time on which to base these determinations, and consideration of the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when a clinic has a very limited total operating schedule and the schedule offering RHC services is concentrated in a specified period of the biweekly or monthly total schedule. An example would be a clinic that is open only every other Tuesday and Friday from 10 to 4 (24 hours a month), and RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). In this situation, it is appropriate to consider the clinic's total monthly operating schedule for determining whether RHC services are offered during at least 51 percent of the schedule. A physician, a nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services every other Tuesday from 10 to 4, and one Friday from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 9.18 hours to furnish patient care services.

C. Staff Responsibilities.--The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

1. Physician Responsibilities.--Ascertain through written documentation, such as dates and signatures, that the physician staff member satisfactorily meets the requirement of periodically reviewing the clinic's patient records, provides medical orders, and provides medical care services to the patients.

A physician member is required to be present in the clinic for sufficient periods of time to perform the duties and responsibilities described in 42 CFR 491.8(b)(i), (ii), and (iii). The term "sufficient periods of time" requires relative evaluations. There are a number of elements to consider in weighing what would constitute a reasonable time sufficient to discharge the physician member's responsibilities. These elements include: patient case load and mix (type), number of patient care records which must be reviewed in order to establish a good overview for adherence to policies and principles of quality patient care, number of patient care records which require review and discussion of specific health problems and regimens of therapy; need for consultative time with other members of the clinic's staff; need for revision to the clinic's patient care guidelines; and need for time to provide medical care to patients. Time required to accomplish these activities will fluctuate. Thus, the "sufficient time" the physician must spend in the clinic will vary. The survey should verify the time spent in the clinic by the physician for consulting records, etc.

Extraordinary circumstances which constitute exceptions to the requirement that the physician member be present in the clinic at least once every 2 weeks for "sufficient time" to discharge the physician's responsibilities are

primarily nonrecurring circumstances beyond the control of the physician and which postpone (not cancel) the visit. These circumstances include illness, extreme weather or driving conditions of short duration, or those emergencies which occur in the physician's practice and require his presence elsewhere. When nonrecurring circumstances cause postponement of the physician's visit, they should be documented in the clinic's records.

In some instances, recurring extraordinary circumstances may constitute reasonable exception to the physician's presence requirement. This type of exception requires specific approval from the HCFA RO for certification purposes, and must be documented by the surveyor. The essential areas for consideration of this exception would include:

o The remoteness of the clinic (due to extraordinary distance and inaccessibility of the terrain) make frequent travel impossible or unreasonable;

o The remoteness of the physician member's location has already placed the physician in an extraordinary extended practice and/or designated shortage area and required visits at least once in every 2 week period to a clinic located at a great distance would severely detract from the physician's practice; or

o It is clearly established in advance that continuing conditions are known to be expected (snow, flood, bridge repair, etc.) which will make reasonable access to the clinic not possible for extended periods of time.

2. Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities.--The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is periodically performing the necessary responsibilities listed under J51, HCFA 30.

VI. PROVISION OF SERVICES (42 CFR 491.9)

A. Basic Requirements

1. State and Local Laws.--Know the State's position, generally, with respect to implementing the Federal RHC requirements vis-a-vis the State's Medical Practice Act, Nurse Practice Act, the Pharmacy Act, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91- 513) and the general scope of practice permitted for nurse practitioners, certified nurse-midwives and physician assistants.

Some States may have legal impediments because applicable practice acts prohibit nurse practitioners, certified nurse-midwives and/or physician assistants from independent acts of medical diagnosis and treatment precluding the fullest implementation of the Federal RHC requirements.

This does not necessarily preclude participation by a RHC that provides RHC services (physician-type services) furnished by nurse practitioners, certified nurse-midwives and/or physician assistants under the direct supervision (as distinguished from indirect supervision) of a physician.

Therefore, inquiries to State authorities about compliance with the Federal RHC requirements, as well as decisions concerning applicant RHCs, must be weighed against several determinations, including:

o The medical direction and supervision described in the regulations is the minimum requirement; many participating RHCs operate with greater medical direction and supervision than these minimums.

o The word "supervision" does not automatically equate with direct, over the shoulder supervision. Many States requiring physician supervision of medical acts performed by a nurse practitioner or a physician assistant have held that performances of such medical acts under written patient care guidelines developed and/or approved by a licensed physician satisfy the requirement of supervision.

2. Providing Rural Health Clinic Services.--The law describes a RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services; usually, related health care services such as the "other ambulatory services" covered by Medicaid State plans. Certification as a RHC applies to the facility as a whole and the total operating schedule of the facility (the hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services. If onsite observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician's office), then the clinic may satisfy the "primarily engaged" requirement providing that RHC services are offered at least 51 percent of the total operating schedule. The time RHC services are offered may differ from the total operating schedule of the facility, but may not be less than 51 percent of this total operating schedule.

If there is a question about this condition, review a sample of patient health records covering a reasonable period of time to determine the majority of specific services actually furnished.

An example of a clinic schedule that combines RHC services and "other ambulatory services" would be a clinic in which primary medical care is offered from 9 to 4 Monday through Thursday, and dental services are offered from 9 to 4 on Friday.

B. Patient Care Polices Requirements.--Review the clinic's policies and ascertain who developed them. Where changes in clinic personnel and/or clinic administration make it impossible or not relevant to ascertain who developed the policies, it is necessary to ascertain that the current physician member(s) and the nurse practitioner, certified nurse-midwife, and/or physician assistant member(s) of the staff have an indepth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed- to written changes in them. If a clinic's organizational structure includes a governing body, ascertain whether the governing body has ultimate authority in approving the patient care policies and, if so, when such approval was last given. While clinics frequently seek the participation of other health care

professionals in developing patient care policies (particularly the written guidelines for the medical management of health problems) the term "a group of professional personnel" is not restricted to health care professionals. In some cases, the clinic will have involved health care professionals representatives to a hospital with which the clinic has an agreement for patient referral. In any event, one member of the group of three or more may not be a member of the clinic's staff, and professions which are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.

The requirements concerning written policies address four areas:

1. Description of Services.--A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. The services furnished by the clinic should be described in a manner than informs potential patients of the types of health care available at the clinic, as well as setting the parameters of the scope of what services are furnished through referral. Such statements as the following sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning, complete dental care, emergency medical care. Statements such as "complete management of common acute and chronic health problems" standing alone, do not sufficiently describe services.

Additional services, furnished through referral, are sufficiently described in such statements as: Arrangements have been made with X hospital for clinic patients to receive the following services if required: specialized diagnostic and laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.

2. Guidelines for Medical Management.--The clinic's written guidelines for the medical management of health problems include a description of the scope of medical acts which may be undertaken by the physician assistant, certified nurse-midwife, and/or nurse practitioner. They represent an agreement between the physician providing the clinic's medical direction and the clinic's physician assistant, certified nurse-midwife, and/or nurse practitioner on the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken without direct, over the shoulder physician supervision. They describe the regimens to be followed and stipulate the conditions in the illness or health care management at which consultation or referral is required.

Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies.

The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition, its etiology, its clinical features, recommended laboratory studies, differential diagnosis, treatment procedures, complications, consultation/referral required, and follow-up.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements. They:

o Are comprehensive enough to cover most health problems that patients usually see a physician about;

o Describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant;

o Describe the medical conditions, signs, or developments that require consultation or referral; and

o Are compatible with applicable State laws.

A number of patient care guidelines have been published by members of the medical profession. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the essential elements described above.

3. Drugs and Biologicals.--Written policies cover at least the following elements:

o Requirements dealing with the storage of drugs and biologicals in original manufacturer's containers to assure that they maintain their proper labeling and packaging;

o Requirements dealing with outdated, deteriorated, or adulterated drugs and biologicals being stored separately so that they are not mistakenly used in patient care prior to their disposal in compliance with applicable laws;

o Requirements dealing with storage in a space that provides proper humidity, temperature, and light to maintain the quality of drugs and biologicals;

o Requirements for a securely constructed locked compartment for storing drugs classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970;

o Requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV, and V; with Schedule II drugs being accounted for separately;

o Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;

o Requirements dealing with the complete and legible labeling of containers used to dispense drugs and biologicals to patients;

o Requirements concerning the availability of current drug references and antidote information; and

o Requirements dealing with prescribing and dispensing drugs in compliance with applicable State laws.

4. Review of Policies.--The group of professional personnel, which can be the governing body acting as the group, is responsible for an annual review of patient care policies.

C. Direct Services.--The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services which must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.

The clinic's laboratory is to be treated as a physician's office for the purpose of licensure and meeting health and safety standards. The listed laboratory services are considered essential for the immediate diagnosis and treatment of the patient. To the extent they can be provided under State and local law, the nine services listed in J61, HCFA-30, are considered the minimum the clinic should make available through use of its own resources.

If any of these laboratory services cannot be provided at the clinic under State or local law, that laboratory service is not required for certification.
Some clinics are not able to furnish the nine services, even though they may be allowed to do so under State and local law, without involving an arrangement with a Medicare approved laboratory.

Those clinics unable to furnish all nine services directly when allowed to by State and local law should be given deficiencies. Such deficiencies should not be considered sufficiently significant to warrant termination if the clinic has an agreement or arrangement with an approved laboratory to furnish the basic laboratory service it does not furnish directly, especially if the clinic is making an effort to meet this requirement.

VII. PATIENT HEALTH RECORDS (42 CFR 491.10)

A. Records System.--The clinic is to maintain patient health records in accordance with its written policies and procedures. These records are the responsibility of a designated member of the clinic's professional staff and should be maintained for each person receiving health care services. All records should be kept at the clinic site so that they are available when patients may need unscheduled medical care.

Examine a randomly selected sample of health records to determine if appropriate information, as related in J70 of the SRF and 42 CFR 491.10(a)(3), is included. This listing is the minimum requirement for record maintenance. If deficiencies are found while reviewing the records, review additional records to determine the prevalence of these deficiencies.

Record on the SRF the number of records reviewed and deficiencies found, if any, and as questions arise concerning the records, discuss them with the person responsible for record maintenance.

B. Protection of Record Information.--The clinic must ensure the confidentiality of the patient's health records and provide safeguards against loss, destruction, or unauthorized use of record information. Ascertain that information regarding the use and removal of records from the clinic and the conditions for release of record information is in the clinic's written policies and procedures. The patient's written consent is necessary before any information not authorized by law may be released.

C. Retention of Records.--Review the clinic policy pertaining to the retention of patient health records. This policy reflects the necessity of retaining records at least 6 years from the last entry date or longer if required by State statute.

VIII. PROGRAM EVALUATION (42 CFR 491.11)

An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other appropriate professionals. The surveyor clarifies for the clinic that the State survey does not constitute any part of this program evaluation.

The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same personnel. However, if the evaluation is not done all at once, no more than a year should elapse between evaluating the same parts. For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of each fiscal year; and its utilization of clinic services, clinic records, and health care policies evaluated 6 months later by a group of health care professionals.

If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.

A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered in the evaluation. What will be covered should be consistent with the requirements of 42 CFR 491.11. Record this information under the explanatory statements on the SRF.

Review dated reports of recent program evaluations to verify that such items are included in these evaluations. When corrective action has been recommended to the clinic, verify that such action has been taken or that there is sufficient evidence indicating the clinic has initiated corrective action.

TAB A

The following publications of the Bureau of the Census include maps displaying urbanized areas:

- Bureau of Census publication series (PC(1)A entitled "Characteristics of the Population 1970 Census." This series is consecutively numbered paperback volumes dealing with individual States. the volumes may be purchased individually, and the following index shows the volume number relating to a specific State:

Parts 1-53 are bound separately; parts 54-58 are bound together in on book.

1 U.S. Summary
2 Alabama
3 Alaska
4 Arizona
5 Arkansas
6 California
7 Colorado
8 Connecticut
9 Delaware
10 District of Columbia
11 Florida
12 Georgia
13 Hawaii
14 Idaho
15 Ilinois
16 Indiana
17 Iowa
18 Kansas
19 Kentucky
20 Louisana
21 Maine
22 Maryland
23 Massachusetts
24 Michigan
25 Minnesota
26 Mississippi
27 Missouri
28 Montana
29 Nebraska
30 Nevada
31 New Hampshire
32 New Jersey
33 New Mexico
34 New York
35 North Carolina
36 North Dakota
37 Ohio
38 Oklahoma
39 Oregon
40 Pennsylvania
41 Rhode Island
42 South Carolina
43 South Dakota
44 Tennessee
45 Texas
46 Utah
47 Vermont
48 Virginia
49 Washington
50 West Virginia
51 Wisconsin
52 Wyoming
53 Puerto Rico
54 Guam
55 Virgin Islands
56 American Samoa
57 Canal Zone
58 Trust Territory of the Pacific Islands

- Bureau of the Census publication PC(S1)-106. This is a supplement to the above series. It includes the current definition of an urbanized area and displays maps of 27 additional urbanized areas that were identified under the current definition.

TAB A (Cont.)

- Bureau of the Census publication PC(SI) -108 entitled "Population and Land Area of Urbanized Areas for the United States 1970 and 1960." This new publication lists all urbanized areas and displays the geographic boundaries of each urbanized area in shaded maps. The cost is $6.00.

These publications may be ordered from the Subscriber Services Division, Bureau of the Census, Room 1121, Building 4, Washington, D.C. 20233.

TAB B

Contacts in the Bureau of the Census Regional Offices:

Atlanta	Wayne Hall	404-881-2274
Boston	Judith Cohen	617-223-0668
Charlotte, N.C.	Lawrence McNutt	704-372-0711 ext. 438
Chicago	Thomas Moss	312-353-0980
Dallas	Valerie McFarland	214-749-2394
Denver	Jerry O'Donnell	303-234-5825
Detroit	Timothy Jones	313-226-4675
Kansas City	Kenneth Wright	816-374-4601
Los Angeles	E. J. Steinfeld	213-824-7291
New York	James Hsiung	212-264-4730
Philadelphia	David Lewis	215-597-8314
Seattle	Lyle Larson	206-442-7080

TAB C

The Bureau of the Census has determined that the boundaries of some cities are so extended that they include areas having rural populations. These cities have been identified as "extended cities" and the rural portion of them meets the definition of non-urbanized areas. The following is a listing of extended cities.

I. Boston

Maine	-	Auburn City
Massachusetts	-	Fall River city

II. New York

New York	-	Rome city
New Jersey	-	Millville city
		Ringwood borough
		Vineland city

III. Philadelphia

Pennsylvania	-	Archbald borough
Virginia	-	Chesapeake city
		Virginia Beach city

IV. Atlanta

Alabama	-	Madison town
Florida	-	Jacksonville city
		Miramar city
		West Palm Beach city
South Carolina	-	Columbia city
Tennessee	-	Memphis city
Nashville	-	Davidson city

V. Chicago

Indiana	-	Indianapolis city
Minnesota	-	Apple Valley village
		Blane city
		Cottage Grove village
		Eden Prairie village
		Inver Grove Heights village
		Lake Elmo village
		Lakeville village
		Lino Lakes village
		Maple Grove village
		Medina village
		Minnestrista village

			Savage village Woodbury village
	Wisconsin	-	Mequon city Muskego city
VI.	Dallas		
	Louisiana	-	New Orleans city
	Oklahoma	-	Broken Arrow city Edmond city Jones town Moore city Norman city Oklahoma City city Tulsa city
	Texas	-	Houston city League city Texas City city Euless village
VII.	Kansas City		
	Iowa	-	Davenport city Waterloo city
	Kansas	-	Leawood city Overland Park city
	Missouri	-	Kansas City city Lee's Summit city Liberty city
VIII.	Denver		
	None		
IX.	San Francisco		
	Arizona	-	Scottsdale city
	California	-	Fremont city Hayward city Palo Alto city Roseville city San Diego city San Jose city Union City city
X.	Seattle		
	None		

B. J. Walker, Commissioner

Georgia Department of Human Resources · Office of Regulatory Services · Specialized Care Unit · Sharon E. Dougherty, Director
Health Care Section · Two Peachtree Street, NW · Suite 31-447 · Atlanta, Georgia 30303-3142 ·
(404) 657-5850 · FAX (404) 657-8935

Date: _____

MEMORANDUM

TO: Health Care Section
Office of Regulatory Services
2 Peachtree St., SW, Suite 33.250
Atlanta, GA 30303-3142

FROM: _____(administrator's name)
_____(facility name)
_____(facility address)
_____(additional space)
_____(type of program)

RE: Request for Medicare Survey

Our facility will be ready for survey on or after: _____

I understand that our facility must be fully operational, i.e., have provided services to patients, and in compliance with all Medicare conditions as of the date set forth immediately above. If I determine that the facility will not be fully operational and ready for inspection on the "original" date listed above, I will immediately advise the Health Care Section orally and in writing of the changed date.

I further understand that surveyors for the Health Care Section will make an UNANNOUNCED visit (FOLLOWING THE RECEIPT OF THE CMS FORM 855 APPROVED FROM THE INTERMEDIARY/SUPPLIER) and on the date that I have stated above the facility is fully operational or on the date that the Section received this written notification, whichever events occurs last. The purpose of the surveyors' visit will be to inspect the facility and determine whether the facility can be recommended for participation in the Medicare program. If the facility is not in compliance with the Medicare conditions at the time of the inspection, then the Health Care Section will send forward a recommendation to the Center for Medicare and Medicaid Services (CMS) that our facility not be certified.

To assist the Health Care Section in scheduling the unannounced survey, I am providing the following schedule of the facility's hours of operation for 21 days following the date I have stated that the facility will be ready for the Medicare survey.

The regular business days and hours of our facility are as follows:

_____

_____

NOTE: This memo must be returned so that a Medicare survey can be conducted at your facility. PLEASE return either with your application or as soon as you know that you are ready for survey.

FORM APPROVED
OMB No. 0938-0832

HEALTH INSURANCE BENEFITS AGREEMENT

(Agreement with Rural Health Clinic Pursuant to Section 1861(aa)(2)(K)(ii) of the Social Security Act)

For the purpose of establishing eligibility for payment under Title XVIII of the Social Security Act,

_____

(Insert name of clinic)

hereafter referred to as the Rural Health Clinic, hereby agrees:

(A) to maintain compliance with the conditions for certification set forth in part 491 of chapter IV, title 42 of the Code of Federal Regulations, and to report promptly to the Centers for Medicare & Medicaid Services any failure to do so;

(B) not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of part 405 of chapter IV, title 42 of the Code of Federal Regulations (or for which the beneficiary would have been entitled if the Rural Health Clinic had filed a request for payment in accordance with §410.165 of chapter IV), except for any deductible or coinsurance amounts for which the beneficiary is liable under §405.2410;

(C) to refund as promptly as possible any money incorrectly collected from a beneficiary or from someone on his or her behalf;

(D) to accept beneficiaries for care and treatment without limitations, except as it may impose on all other persons;

(E) to accept any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

This agreement, upon submission by the Rural Health Clinic and upon acceptance for filing by the Secretary of Health and Human Services, shall be binding on the Rural Health Clinic and the Secretary. The agreement may be terminated by either party in accordance with regulations. In the event of termination, payment will not be available for Rural Health Clinic services furnished on or after the effective date of termination.

This agreement shall become effective on the date specified below by the Secretary or the Secretary's delegate, and shall remain in effect unless terminated.

In the event of a transfer of ownership, the agreement is automatically assigned to the new owner subject to the conditions specified in this agreement and 42 CFR 489, to include existing plans of correction and the duration of this agreement, if the agreement is time limited.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or make any false, fictitious or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement, or entry, shall be fined not more than $10,000 or imprisoned not more than 5 years or both (18 U.S.C. section 1001).

Accepted for Rural Health Clinic by:	Accepted for the Secretary of Health and Human Services by:
NAME (SIGNATURE)	NAME (SIGNATURE)
TITLE	TITLE
DATE	DATE

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0832. The time required to complete this information collection is estimated to average 5 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-08

DATE: **November 12, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Survey Agency Responsibilities in Obtaining Information For Civil Rights Clearances For Initial Certifications And Changes of Ownership (CHOW)

Letter Summary

- The purpose of this letter is to remind state survey agencies (SAs) of their role in the Office for Civil Rights (OCR) clearance process
- SAs are to include the OCR questionnaires and attestation forms with their initial enrollment package that is sent to a new provider or to a provider undergoing a CHOW.
- The role of the SA and the Centers for Medicare & Medicaid Services (CMS) is limited to obtaining the forms for OCR.

Section 2010 of the State Operations Manual (SOM) requires CMS to obtain information from new providers and those who have undergone CHOWs related to their compliance with civil rights requirements. The HHS Office for Civil Rights must make a determination that the provider is in compliance with the Civil Rights Act and other relevant statutes. In practice, CMS Regional Offices (ROs) will approve a provider's initial certification or a CHOW pending clearance from OCR. On rare occasions, OCR informs CMS that clearance has been denied or that the required assurances have not been submitted.

The SOM at section 2010 states: "The SA provides potential providers with required forms for OCR clearance and forwards the completed forms to the RO upon receipt."

- SAs are to include the OCR questionnaires and attestation forms with their initial enrollment package that is sent to a new provider or to a provider undergoing a CHOW.
- Completed forms must be returned by the provider to the SA with the rest of the application package.

- SAs should ascertain that completed OCR forms are included in the package before forwarding it to their CMS RO.
- If the provider does not include the OCR forms, inform the provider that the application will not be forwarded to CMS until the forms have been completed and returned to the SA.

Upon receipt of the OCR forms, the CMS RO forwards them to the Office for Civil Rights for processing and clearance. **The role of the SA and CMS is limited to obtaining the forms for OCR.**

Copies of the current version of the OCR forms are included with this transmittal. Effective immediately, SAs must include these forms with their initial certification and CHOW packages. Questions concerning the forms should be referred to your regional HHS Office for Civil Rights.

Effective Date: Immediately. The state agency should disseminate this information within 30 days of the date of this letter.

Training: The information contained in this announcement should be shared with all survey and certification staff and with managers who have responsibility for processing initial Medicare certifications and CHOW.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments

Office for Civil Rights

Medicare Certification

Nondiscrimination Policies and Notices

Please note that documents in PDF format require Adobe's Acrobat Reader.

The regulations implementing Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 require health and human service providers that receive Federal financial assistance from the Department of Health and Human Services to provide notice to patients/residents, employees, and others of the availability of programs and services to all persons without regard to race, color, national origin, disability, or age.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.6(d) Information to beneficiaries and participants. Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation.

Go to 45 CFR Part 80 for the full regulation.

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§ 84.8 Notice. (a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to **§**84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in

recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

Go to 45 CFR Part 84 for the full regulation.

Age Discrimination Act: 45 CFR Part 91

§ 91.32 Notice to subrecipients and beneficiaries. (b) Each recipient shall make necessary information about the Act and these regulations available to its program beneficiaries in order to inform them about the protections against discrimination provided by the Act and these regulations.

Go to 45 CFR Part 91 for the full regulation.

Policy Examples

Example One (for posting in the facility and inserting in advertising or admissions packages):

NONDISCRIMINATION POLICY

As a recipient of Federal financial assistance, (insert name of provider) does not exclude, deny benefits to, or otherwise discriminate against any person on the ground of race, color, or national origin, or on the basis of disability or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by (insert name of provider) directly or through a contractor or any other entity with which (insert name of provider) arranges to carry out its programs and activities.

This statement is in accordance with the provisions of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Regulations of the U.S. Department of Health and Human Services issued pursuant to these statutes at Title 45 Code of Federal Regulations Parts 80, 84, and 91.

In case of questions, please contact:

Provider Name:

Contact Person/Section 504 Coordinator:

Telephone number:

TDD or State Relay number:

Example Two (for use in brochures, pamphlets, publications, etc.):

(Insert name of provider) does not discriminate against any person on the basis of race, color, national origin, disability, or age in admission, treatment, or participation in its programs, services and activities, or in employment. For further information about this policy, contact: (insert name of Section 504 Coordinator, phone number, TDD/State Relay).

Medicare Certification

Communication with Persons Who Are Limited English Proficient

Please note that documents in PDF format require Adobe's Acrobat Reader.

In certain circumstances, the failure to ensure that Limited English Proficient (LEP) persons can effectively participate in, or benefit from, federally-assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, and the Title VI regulations against national origin discrimination. Specifically, the failure of a recipient of Federal financial assistance from HHS to take reasonable steps to provide LEP persons with a meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS's implementing regulations. It is therefore important for recipients of Federal financial assistance, including Part A Medicare providers, to understand and be familiar with the requirements.

Applicable Regulatory Citations:

Title VI of the Civil Rights Act of 1964: 45 CFR Part 80

§80.3 Discrimination prohibited.

(a) General. No person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this part applies.
(b) Specific discriminatory actions prohibited. (1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit under the program;
(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;
(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;
(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;
(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;
(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as

an employee but only to the extent set forth in paragraph (c) of this section).
(vii) Deny a person the opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.

Go to 45 CFR Part 80 for the full regulation.

Resources

For further guidance on the obligation to take reasonable steps to provide meaningful access to LEP persons, see HHS' "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.hhs.gov/ocr/lep/. This guidance is also available at http://www.lep.gov/, along with other helpful information pertaining to language services for LEP persons.

"I Speak" Language Identification Flashcard (PDF) From the Department of Commerce, Bureau of the Census, the "I Speak" Language Identification Flashcard is written in 38 languages and can be used to identify the language spoken by an individual accessing services provided by federally assisted programs or activities.

Technical Assistance for Medicare and Medicare+Choice organizations from the Centers for Medicare and Medicaid for Designing, Conducting, and Implementing the 2003 National Quality Assessment and Performance Improvement (QAPI) Program Project on Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services-
http://www.cms.hhs.gov/healthplans/quality/project03.asp

Examples of Vital Written Materials

Vital written materials could include, for example:

- Consent and complaint forms.
- Intake forms with the potential for important consequences.
- Written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services, actions affecting parental custody or child support, and other hearings.

- Notices advising LEP persons of free language assistance.
- Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required.
- Applications to participate in a recipient's program or activity or to receive recipient benefits or services.

Nonvital written materials could include:

- Hospital menus.
- Third party documents, forms, or pamphlets distributed by a recipient as a public service.
- For a non-governmental recipient, government documents and forms.
- Large documents such as enrollment handbooks (although vital information contained in large documents may need to be translated).
- General information about the program intended for informational purposes only.

Medicare Certification

Auxiliary Aids and Services for Persons With Disabilities

Please note that documents in PDF format require Adobe's Acrobat Reader.

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973: 45 CFR Part 84

§84.3 Definitions

(h) Federal financial assistance – means any grant, loan … or any other arrangement by which [DHHS] makes available … funds; services …

(j) Handicapped person – means any person who has a physical or mental impairment which substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.

(k) Qualified handicapped person means - (4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

§84.4 Discrimination prohibited

(1) General. No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

Discriminatory actions prohibited –

(1) A recipient, in providing any aid, benefits, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded other;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any

class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

Subpart F – Health, Welfare and Social Services

§84.51 Application of this subpart

Subpart F applies to health, welfare, or other social service programs and activities that receive or benefit from Federal financial assistance …

§84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered non-handicapped persons;

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in **§** 84.4(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) Notice. A recipient that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) ***Auxiliary aids.*** (1) A recipient with fifteen or more employees "shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such person an equal opportunity to benefit from the service in question." (2) Pursuant to the Department's discretion, recipients with fewer than fifteen employees may be required "to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services." (3) "Auxiliary aids may include brailed and taped material, interpreters, and other aids for persons with impaired hearing or vision."

Go to 45 CFR Part 84 for the full regulation.

504 Notice

The regulation implementing Section 504 requires that an agency/facility "that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified disabled persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their disability." **(45 CFR §84.52(b))**

Note that it is necessary to note each area of the consent, such as:

1. Medical Consent

2. Authorization to Disclose Medical Information

3. Personal Valuables

4. Financial Agreement

5. Assignment of Insurance Benefits

6. Medicare Patient Certification and Payment Request

Resources:

U.S. Department of Justice Document:

ADA Business Brief: Communicating with People Who are Deaf or Hard of Hearing in Hospital Settings

ADA Document Portal
A new on-line library of ADA documents is now available on the Internet. Developed by Meeting the Challenge, Inc., of Colorado Springs with funding from the National Institute on Disability and Rehabilitation Research, this website makes available more than 3,400 documents related to the ADA, including those issued by Federal agencies with responsibilities

under the law. It also offers extensive document collections on other disability rights laws and issues. By clicking on one of the general categories in the left column, for example, you will go to a catalogue of documents that are specific to the topic.

Last revised: February 12, 2004

Medicare Certification

Requirements for Facilities with 15 or More Employees

Please note that documents in PDF format require Adobe's Acrobat Reader.

Applicable Regulatory Citations:

Section 504 of the Rehabilitation Act of 1973:

45 CFR Part 84§84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

Go to 45 CFR Part 84 for the full regulation.

Policy Example

The following procedure incorporates appropriate minimum due process standards and may serve as a model or be adapted for use by recipients in accordance with the Departmental regulation implementing Section 504 of the Rehabilitation Act of 1973.

SECTION 504 GRIEVANCE PROCEDURE

It is the policy of (**insert name of facility/agency**) not to discriminate on the basis of disability. (**Insert name of facility/agency**) has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) or the U.S. Department of Health and Human Services regulations implementing the Act. Section 504 states, in part, that "no otherwise qualified handicapped individual...shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance..." The Law and Regulations may be examined in the office of (**insert name, title, tel. no. of Section 504 Coordinator**), who has been designated to coordinate the efforts of (**insert name of facility/agency**) to comply with Section 504.

Any person who believes she or he has been subjected to discrimination on the basis of disability may file a grievance under this procedure. It is against the law for (**insert name of facility/agency**) to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.

Procedure:

- Grievances must be submitted to the Section 504 Coordinator within (**insert time frame**) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
- A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
- The Section 504 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it must be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 504 Coordinator will maintain the files and records of (**insert name of facility/agency**)

relating to such grievances.

- The Section 504 Coordinator will issue a written decision on the grievance no later than 30 days after its filing.
- The person filing the grievance may appeal the decision of the Section 504 Coordinator by writing to the (**Administrator/Chief Executive Officer/Board of Directors/etc.**) within 15 days of receiving the Section 504 Coordinator's decision.
- The (**Administrator/Chief Executive Officer/Board of Directors/etc.**) shall issue a written decision in response to the appeal no later than 30 days after its filing.
- The availability and use of this grievance procedure does not prevent a person from filing a complaint of discrimination on the basis of disability with the U. S. Department of Health and Human Services, Office for Civil Rights.

(**Insert name of facility/agency**) will make appropriate arrangements to ensure that disabled persons are provided other accommodations if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing interpreters for the deaf, providing taped cassettes of material for the blind, or assuring a barrier-free location for the proceedings. The Section 504 Coordinator will be responsible for such arrangements.

Medicare Certification

Age Discrimination Act Requirements

Please note that documents in PDF format require Adobe's Acrobat Reader.

The Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) has the responsibility for the Age Discrimination Act as it applies to Federally funded health and human services programs. The general regulation implementing the Age Discrimination Act requires that age discrimination complaints be referred to a mediation agency to attempt a voluntary settlement within sixty **(60)** days. If mediation is not successful, the complaint is returned to the responsible Federal agency, in this case the Office for Civil Rights, for action. OCR next attempts to resolve the complaint through informal procedures. If these fail, a formal investigation is conducted. When a violation is found and OCR cannot negotiate voluntary compliance, enforcement action may be taken against the recipient institution or agency that violated the law.

The Age Discrimination Act permits certain exceptions to the prohibition against discrimination based on age. These exceptions recognize that some age distinctions in programs may be necessary to the normal operation of a program or activity or to the achievement of any statutory objective expressly stated in a Federal, State, or local statute adopted by an elected legislative body.

Applicable Regulatory Citations:

45 CFR Part 91: Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance From HHS

§ 91.3 To what programs do these regulations apply?

(a) The Act and these regulations apply to each HHS recipient and to each program or activity operated by the recipient which receives or benefits from Federal financial assistance provided by HHS.
(b) The Act and these regulations do not apply to:
(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:
(i) Provides any benefits or assistance to persons based on age; or
(ii) Establishes criteria for participation in age-related terms; or
(iii) Describes intended beneficiaries or target groups in age-related terms.

Subpart B-Standards for Determining Age Discrimination

§ 91.11 Rule against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§91.13 and 91.14 of these regulations.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.
(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of:
(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance.
(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.
(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 91.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and
(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and
(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and
(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 91.11 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 91.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions

outlined in §§ 91.13 and 91.14 is on the recipient of Federal financial assistance.

For the full regulation, go to 45 CFR Part 91.

Last revised: June 15, 2004

OMB Number: 0990-0243
Expiration Date: 06/30/2007

Medicare Certification Civil Rights Information Request Form

Please return the completed, signed Civil Rights Information Request form and the required attachments with your other Medicare Provider Application Materials.

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT THE FACILITY:

a. **CMS Medicare Provider Number:**_____

b. **Name and Address of Facility:** _____

_____

_____

c. **Administrator's Name** _____

d. **Contact Person** _____
(If different from Administrator)

e. **Telephone** _____ **TDD** _____

f. **E-mail** _____ **FAX** _____

g. **Type of Facility** _____
(e.g., Home Health Agency, Hospital, Skilled Nursing Facility, etc.)

h. **Number of employees:** _____

i. **Corporate Affiliation** _____ (if the facility is now or will be owned and operated by a corporate chain or multi-site business entity, identify the entity.)

j. **Reason for Application** _____
(Initial Medicare Certification, change of ownership, etc.)

PLEASE RETURN THE FOLLOWING MATERIALS WITH THIS FORM.

To ensure accuracy, please consult the technical assistance materials (www.hhs.gov/ocr/crclearance.html) **in developing your responses.**

√	No.	REQUIRED ATTACHMENTS
	1.	Two original signed copies of the form HHS-690, Assurance of Compliance (www.hhs.gov/ocr/ps690.pdf). *A copy should be kept by your facility.*
Nondiscrimination Policies and Notices Please see Nondiscrimination Policies and Notices (www.hhs.gov/ocr/nondiscriminpol.html) for the regulations and technical assistance.		
	2.	A copy of your written notice(s) of nondiscrimination, *that provide for admission and services without regard to race, color, national origin, disability, or age, as required by Federal law. Generally, an EEO policy is not sufficient to address admission and services.*
	3.	A description of the methods used by your facility to disseminate your nondiscrimination notice(s) or policy. *If published, also identify the extent to which and to whom such policies/notices are published (e.g., general public, employees, patients/residents, community organizations, and referral sources) consistent with requirements of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.*
	4.	Copies of brochures or newspaper articles. *If publication is one of the methods used to disseminate the policies/notices, these copies must be attached.*
	5.	A copy of facility admissions policy or policies.
Communication with Persons Who Are Limited English Proficient (LEP) Please see Communication with Persons Who Are Limited English Proficient (LEP) (www.hhs.gov/ocr/commune.html) for technical assistance. For information on the obligation to take reasonable steps to provide meaningful access to LEP persons, including guidance on what constitutes vital written materials, and HHS' "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at www.hhs.gov/ocr/lep . This guidance is also available at http://www.lep.gov/ , along with other helpful information pertaining to language services for LEP persons.		
	6.	A description (or copy) of procedures used by your facility to effectively communicate with persons who have limited English proficiency, including: 1. *How you identify individuals who are LEP and in need of language assistance.* 2. *How language assistance measures are provided (for both oral and written communication) to persons who are LEP, consistent with Title VI requirements.* 3. *How LEP persons are informed that language assistance services are available.*
	7.	A list of all vital written materials provided by your facility, and the languages for which they are available. *Examples of such materials may include consent and complaint forms; intake forms with the potential for important consequences; written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services; applications to participate in a recipient's program or activity or to receive recipient benefits or service; and notices advising LEP persons of free language assistance.*

√	No.	REQUIRED ATTACHMENTS
Auxiliary Aids and Services for Persons with Disabilities Please see Auxiliary Aids and Services for Persons with Disabilities (www.hhs.gov/ocr/auxaids.html) for technical assistance.		
	8.	A description (or copy) of the procedures used to communicate effectively with individuals who are deaf, hearing impaired, blind, visually impaired or who have impaired sensory, manual or speaking skills, including: 1. *How you identify such persons and how you determine whether interpreters or other assistive services are needed.* 2. *Methods of providing interpreter and other services during all hours of operation as necessary for effective communication with such persons.* 3. *A list of available auxiliary aids and services, and how persons are informed that interpreters or other assistive services are available.* 4. *The procedures used to communicate with deaf or hearing impaired persons over the telephone, including TTY/TDD or access to your State Relay System, and the telephone number of your TTY/TDD or your State Relay System.*
	9.	Procedures used by your facility to disseminate information to patients/residents and potential patients/residents about the existence and location of services and facilities that are accessible to persons with disabilities.
Requirements for Facilities with 15 or More Employees Please see Requirements for Facilities with 15 or More Employees (www.hhs.gov/ocr/reqfacilities.html) for technical assistance.		
	10.	For recipients with 15 or more employees: the name/title and telephone number of the Section 504 coordinator.
	11.	For recipients with 15 or more employees: A copy or description of your facility's procedure for handling disability discrimination grievances.
Age Discrimination Act Requirements Please see Age Discrimination Act Requirements (www.hhs.gov/ocr/agediscrim.html) for technical assistance, and for information on permitted exceptions.		
	12.	A description or copy of any policy (ies) or practice(s) restricting or limiting admissions or services provided by your facility on the basis of age. *If such a policy or practice exists, please submit an explanation of any exception/exemption that may apply. In certain narrowly defined circumstances, age restrictions are permitted.*

After review, an authorized official must sign and date the certification below. Please ensure that complete responses to all information/data requests are provided. Failure to provide the information/data requested may delay your facility's certification for funding.

***Certification*: I certify that the information provided to the Office for Civil Rights is true and correct to the best of my knowledge.**

Signature of Authorized Official: _____

Title of Authorized Official: _____

Date: _____

ASSURANCE OF COMPLIANCE

ASSURANCE OF COMPLIANCE WITH TITLE VI OF THE CIVIL RIGHTS ACT OF 1964, SECTION 504 OF THE REHABILITATION ACT OF 1973, TITLE IX OF THE EDUCATION AMENDMENTS OF 1972, AND THE AGE DISCRIMINATION ACT OF 1975

The Applicant provides this assurance in consideration of and for the purpose of obtaining Federal grants, loans, contracts, property, discounts or other Federal financial assistance from the Department of Health and Human Services.

THE APPLICANT HEREBY AGREES THAT IT WILL COMPLY WITH:

1. Title VI of the Civil Rights Act of 1964 (Pub. L. 88-352), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 80), to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

2. Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 84), to the end that, in accordance with Section 504 of that Act and the Regulation, no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

3. Title IX of the Educational Amendments of 1972 (Pub. L. 92-318), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 86), to the end that, in accordance with Title IX and the Regulation, no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any education program or activity for which the Applicant receives Federal financial assistance from the Department.

4. The Age Discrimination Act of 1975 (Pub. L. 94-135), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 91), to the end that, in accordance with the Act and the Regulation, no person in the United States shall, on the basis of age, be denied the benefits of, be excluded from participation in, or be subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department.

The Applicant agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the Applicant, its successors, transferees and assignees for the period during which such assistance is provided. If any real property or structure thereon is provided or improved with the aid of Federal financial assistance extended to the Applicant by the Department, this assurance shall obligate the Applicant, or in the case of any transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. If any personal property is so provided, this assurance shall obligate the Applicant for the period during which it retains ownership or possession of the property. The Applicant further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the Applicant to the above provisions.

_____
Date

_____
Signature and Title of Authorized Official

_____
Name of Applicant or Recipient

_____
Street

_____
City, State, Zip Code

Mail Form to:
DHHS/Office for Civil Rights
Office of Program Operations
Humphrey Building, Room 509F
200 Independence Ave., S.W.
Washington, D.C. 20201

Form HHS-690
5/97

Federal Register

Wednesday,
December 24, 2003

Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 491
Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405 and 491

[CMS–1910–F]

RIN 0938–AJ17

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

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

ACTION: Final rule.

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

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

FOR FURTHER INFORMATION CONTACT: David Worgo (payment and certification policy), (410) 786–5919.

Mary Collins (quality policy issues), (410) 786–3189.

SUPPLEMENTARY INFORMATION: *Copies.* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is *http://www.access.gpo.gov/nara/index.html.*

I. Background

A. General

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

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

Qualifying clinics, among other criteria, had to be located in a nonurbanized area as defined by the Census Bureau and in a health professional shortage area or medically underserved area as designated by the Health Resources and Services Administration or (since the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, Pub. L. 101–239, enacted on December 19, 1989), section 6213(c)) by the chief executive officer of the State. (*See* section 1861(aa)(2) of the Act, following subparagraph (K).) There are three types of shortage area designations applicable to RHC qualification: health professional shortage areas, medically underserved areas, and governor-designated shortage areas. The clinic's service area must have, in addition to being located in a nonurbanized area, one of these shortage area designations if the clinic is to qualify to receive RHC status.

Qualifying clinics also must employ a nonphysician practitioner and, to meet requirements of the OBRA '89, must have a nurse practitioner, a physician assistant, or a certified nurse midwife available to furnish patient care services at least 50 percent of the time the RHC operates.

Growth of RHCs in the Medicare Program

After a slow start, the program has recently grown at a rapid rate—from less than 1,000 Medicare-approved RHCs in 1992 to more than 3,300 in early 2001. While part of this increase has improved access to primary care services in rural areas for Medicare and Medicaid beneficiaries, there are instances in which these additional RHCs have not expanded access.

Continuing Participation

A significant factor in the growth of RHCs stems from the original (pre-BBA) RHC legislation, which included a "grandfather clause" to promote the development of RHCs. (See section 1(e) of Pub. L. 95–210, 42 U.S.C. 1395x *note.* Also see 42 CFR 491.5(b)(2).) Specifically, the third sentence of section 1861(aa)(2) of the Act stated that:

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

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

The Congress established this protection to encourage clinics to attract needed health care professionals to underserved rural areas and to retain them without being concerned about losing the shortage area designation, which would make the clinics ineligible for RHC status and its reimbursement

incentives. Once the clinic successfully attracted the needed health care professionals to the area, the Congress wanted to ensure that the service area did not return to its previous underserved status because we removed the clinic's RHC status and reimbursement incentives.

Although the grandfather provision was based on justifiable policy considerations, we are now confronted with RHC participation in some service areas with extensive health care delivery systems where Medicare and Medicaid beneficiaries are not having difficulty obtaining primary care. Both the General Accounting Office (GAO) and the Department of Health and Human Services' Inspector General (DHHS/IG) recommended the establishment of a mechanism, under the survey and certification process for Medicare facilities, to discontinue RHC status and its payment incentives in those service areas where they are no longer justified. (See the next paragraph.) In section 4205(d)(3) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 05, 1997), the Congress responded to these recommendations by amending the grandfather provision to provide protection only to clinics essential to the delivery of primary care.

Medically Underserved Designations

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

Commingling

The growth of RHCs has also been stimulated by industry practices that are designed to maximize Medicare payment by obtaining RHC status for an integrated practice that submits both RHC and non-RHC Medicare claims. We define the term "commingling" to mean the simultaneous operation of an RHC and another physician practice, thereby mixing the two practices. The two practices share hours of operation, staff, space, supplies, and other resources. Commingling occurs in RHCs that are an integral part of another provider, such as a hospital, as well as in RHCs that are independent.

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

Government Reports

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

B. Legislation

Refinement of Shortage Area Requirements

Refinement of the shortage area requirements involves two phases.

1. *Phase I.* Section 4205(d)(1) and (2) of the BBA pertain to the requirements in the second sentence of section 1861(aa)(2) of the Act that RHCs must be located in a nonurbanized area as defined by the Bureau of the Census, as well as in a health professional shortage area (HPSA), an MUA, or in a shortage area designated by a State governor. The Congress amended those provisions to state that the rural area must also be one in which there are insufficient numbers of needed health care practitioners as determined by the Secretary. This BBA change will be addressed by our sister agency, the Health Resources and Services Administration (HRSA), under separate rules. The Congress also amended that sentence to specify that, to be used in RHC certification, shortage area designations made by the Department or by a State governor must have been made within the previous 3-year period.

2. *Phase II.* Section 4205(d)(3)(A) of the BBA, which amended the third sentence of section 1861(aa)(2) of the Act, the Congress revised the "grandfather clause" that permitted an exception to the termination of RHC status for a clinic located in an area that is no longer a rural area or a shortage area. This revision amended the grandfather clause to specify that an exception is available only if the RHC is determined to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the RHC. These amendments were made effective upon issuance of implementing regulations that the Congress directed us to issue by January 1, 1999.

Staffing Waiver

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

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

Payment Limits for Provider-Based RHCs

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

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

Expanding Access to Rural Health Clinics

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

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

Payment for Certain Physician Assistant Services

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

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

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

Quality Assessment Program

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

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

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

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

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

II. Provisions of the Proposed Rule

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

Definition of Shortage Area for RHC Certification

Section 6213 of OBRA '89 amended 1861(aa)(2) of the Act to expand the types of shortage areas eligible for RHC certification. Until then, the eligible areas included only those designated by the Secretary as areas having a shortage of personal health services and those designated as geographic health professional shortage areas under section 332(a)(1)(A) of the PHS Act. The OBRA '89 amendment expanded the eligible areas to also include high impact migrant areas designated under section 329(a)(5) of the PHS Act; areas containing a population group HPSA designated under section 332(a)(1)(B) of the PHS Act; and areas designated by

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

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

A. Refinement of Shortage Area Requirements

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

Eligibility for an Exception

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

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

Criteria for Exception

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

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

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

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

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

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

B. Payment Limits for Provider-Based RHCs

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

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

C. Staffing Requirements

Practitioners Available 50 Percent of the Time

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

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

Temporary Staffing Waiver

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

D. Commingling

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

E. Quality Assessment and Performance Improvement Program

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

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

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

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

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

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

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

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

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

Scope and Definitions (§ 405.2401)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comment: Several commenters strongly urged the adoption of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Definition of Shortage Area for RHC Purposes (§ 491.2)

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

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

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

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

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

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

RHC Procedures (§ 491.3)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Location of Clinic (§ 491.5)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sole Community Provider Test

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Traditional Community Provider Test

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

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

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

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

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

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

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

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

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

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

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

Major Community Provider Test

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

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

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

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

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

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

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

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

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

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

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

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

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

Specialty Provider Test

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

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

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

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

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

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

age an opportunity to qualify as an essential provider.

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

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

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

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

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

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

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

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

GME Test

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

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

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

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

Staffing and Staff Responsibilities (§ 491.8)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We anticipate that both large and small RHCs will use a variety of performance measures in their QAPI program. These measures may be designed by the clinic itself or by other sources outside the clinic. We are clarifying proposed § 491.11(b)(3) to state that the RHC will determine the number and frequency of distinct improvement projects it will conduct. The QAPI program could result in some immediate costs to an individual clinic. However, we believe that the QAPI program will result in real, but difficult to estimate, long-term economic benefits to the clinics (such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Provisions of the Final Rule

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

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

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

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

We are revising § 491.3(b)(1) to clarify that both participating RHCs as well as applicants must be located in a current shortage area.

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

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

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

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

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

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

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

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

V. Regulatory Impact Analysis

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually (see 65 FR 69432). For purposes of the RFA, all RHCs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory

impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

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

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

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

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

Anticipated Effects

Effects on Rural Health Clinics

The total number of participating RHCs under Medicare and Medicaid as of February 1, 2001, was 3,341. Using 2000 Census data, there are approximately 100 urban clinics. At least 20 of these urban clinics do "not" have valid shortage area designations and would lose their RHC status.

With regard to the participating clinics that are still located in rural areas (about 3,200), at least 100 of these RHCs no longer have valid shortage area designations. Based on the above estimates, we know that about 180 would be eligible to apply for exception from RHC disqualification, but it is impossible to accurately predict how many will qualify for an exception. However, the estimated Medicare savings associated with the disqualification of certain RHCs from the Medicare program would be less than $10 million. Participating RHCs that are no longer located in rural, underserved areas could lose their RHC status and their cost-based reimbursement, which could cause them to reduce services or discontinue serving our beneficiaries. We believe, based on a recent study by the Maine Rural Health Research Center, that approximately 150 clinics will lose their RHC status. However, to minimize the impact of this provision on rural health care, the Congress has authorized us to grant, if needed, an exception to clinics essential to the delivery of primary care in these affected areas. Our criteria in § 491.5 identify the areas and clinics where RHC status and its payment methodology are still needed despite the fact the service area is no longer considered medically underserved.

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

We believe the fiscal impact of limiting payment to provider-based RHCs to the independent RHC rate per visit will result in program savings. Provider-based RHCs that have costs above the all-inclusive cost-per-visit limit required by the law could experience some decrease in their current reasonable cost basis payments. To reduce detrimental impacts of this decrease, the Congress authorized an exception to the annual payment limit to those clinics affiliated with small hospitals, that is, a hospital with fewer than 50 beds.

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

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

Impact of the QAPI Provisions

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

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

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

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

OBRA '89 reduced the nonphysician staffing requirement for RHC qualification from 60 percent to 50 percent. This reduction should have a positive effect on RHCs by providing them more flexibility in satisfying their overall staffing needs.

Effects on Other Providers

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

Effects on the Medicare and Medicaid Programs

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

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

Alternatives Considered

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

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

Although this test would be administratively feasible, we concluded, based on our analysis of available Medicare and Medicaid RHC data, that it would not accurately determine "essential" clinics at the community level because of the wide variability in the percentage of services furnished to Medicare and Medicaid patients by RHCs. Despite our rejection of a national utilization test, we are open to suggestions on developing a minimum national percentage, which could be integrated with our major community provider test. We also considered the option of establishing less generous tests for identifying RHCs as essential clinics to the delivery of primary care. That is, the establishment of tests narrowly focused on a few extreme cases, such as an exception test for only sole community providers for a very rural community. We rejected this option because of concern that the disqualification of a clinic from the RHC program could harm access to primary care for the entire community. We believe a comprehensive set of tests is needed to avoid harming access to care for rural areas.

• *QAPI Program.* Because the statute mandates that an RHC have a QAPI program, and appropriate procedures for review of utilization of clinic services, no alternatives for the requirement were considered. However, in the preamble of the February 28, 2002 proposed rule, we described alternative ways of satisfying the "minimum level requirement" for the QAPI program and asked for comments. Among the alternatives that we considered were the following:

• Require RHCs to engage in an improvement project in each domain annually.

• Require a minimum number of improvement projects in any combination of the domains annually.

• Require a minimum number of projects annually based on patient population.

• Rather than requiring a minimum number of projects, require RHCs to demonstrate to the survey agency what projects they are doing and what progress is being achieved. After considering the public comments, which were not conclusive, we decided not to establish a minimum requirement. We did consider alternatives for the final rule. One alternative was to take a more rigid approach to QAPI whereby the final rule would be more prescriptive in the process RHCs must follow to develop the QAPI program including setting forth specific performance measures to be utilized, the frequency and number of QAPI "interventions" that must be done, as well as the type and frequency of data to be collected. While a more rigid approach would increase RHC burden, we realize there would be no assurance that it would result in better or more predictable outcomes.

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

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

Conclusion

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

Therefore, we are not preparing analyses for either the regulatory impact analysis or section 1102(b) of the Act since we believe that this rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

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

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the OMB for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

Section 491.3 Rural Health Clinic (RHC) Procedures

Section 491.3(c)(2) states that an existing RHC located in an area no longer considered a shortage area may apply for an exception from disqualification by submitting a written request to our regional offices within 180 days from the date we notify it that it is no longer located in a shortage area. We believe that this information collection requirement is exempt in accordance with 5 CFR 1320.4(a)(2) since this activity is in accordance with the conduct of an investigation or audit against specific individuals or entities.

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

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

Section 491.8 Staffing and Staff Responsibilities

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

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

Section 491.11 Quality Assessment and Performance Improvement

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

Most of the burden of this section is covered by the paperwork requirements of § 491.9(b)(3), patient care policies, which requires the RHCs to have in place a description of services the clinic furnishes, guidelines for management of health problems, and procedures for periodic review and evaluation of clinic services. This burden is approved under 0938–0334 and expires in April, 2003.

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

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

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

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

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

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

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

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

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

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

List of Subjects

42 CFR Part 405

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

42 CFR Part 491

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

■ For the reasons set forth in the preamble, The Centers for Medicare & Medicaid services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

■ 1. The authority citation for part 405 continues to read as follows:

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

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

§ 405.2401 Scope and definitions.

* * * * *

(b) *Definitions.*

* * * * *

Rural health clinic (RHC) means an entity that:

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

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

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

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

* * * * *

■ 3. Revise § 405.2410 to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

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

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

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

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

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

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

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

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

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

■ 4. Revise § 405.2462 to read as follows:

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

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

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

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

(i) The determination of the number of beds at § 412.105(b) of this chapter.

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

(A) It is a sole community hospital as determined in accordance with § 412.92 or 412.109(a) of this chapter.

(B) It is located in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

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

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

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

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

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

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

■ 2. Revise § 491.2 to read as follows:

§ 491.2 Definition of shortage area for RHC purposes.

Shortage area means a geographic area that meets one of the following criteria. It is—

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

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

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

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

■ 3. Revise § 491.3 to read as follows:

§ 491.3 RHC procedures.

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

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

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

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

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

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

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

(2) An existing RHC may apply for an exception from disqualification by submitting a written request to a CMS regional office within 180 days from the date CMS notifies the RHC that it is no longer located in a shortage area. The request must contain all information necessary to establish whether an exception is warranted.

(3) The CMS regional office may grant a 3-year exception based on its review of an RHC request and other relevant information, if the CMS regional office determines that the RHC is essential to the delivery of primary care services that otherwise are not available in the geographic area served by the RHC as specified in § 491.5(b).

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

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

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

§ 491.5 Location of clinic.

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

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

essential provider under this section, CMS will:

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

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

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

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

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

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

(i) *Sole community provider.* The RHC is the only participating primary care provider within 30 minutes travel time. For purposes of this exception, a participating primary care provider means an RHC, an FQHC, or a physician practicing in either general practice, family practice, or general internal medicine that is actively accepting and treating Medicare beneficiaries and low-income patients (Medicaid beneficiaries and the uninsured, regardless of their ability to pay).

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

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

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

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■ 5. In § 491.8, revise paragraph (a)(6) and add a new paragraph (d) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

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

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

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

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

■ 6. Revise § 491.11 to read as follows:

§ 491.11 Quality assessment and performance improvement.

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

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

(1) Organizational processes, functions, and services.

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

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

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

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

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

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

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

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

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

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

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

Dated: February 28, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 28, 2003.

Tommy G. Thompson,

Secretary.

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