because of the culture practices in those state. Residue chemistry data supporting this regulatory action were limited to data from the Pacific Northwestern states mentioned above.

An adequate analytical method, high performance liquid chromatography with photo-conductivity detection, is available for enforcement purposes.

There are presently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerances are being sought.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR 180.451 will protect the public health. Therefore the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register,file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines tht the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP–4F4322/R2217] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 22, 1996.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
Authority: 21 U.S.C. 346a and 371

2. In § 180.451 by revising the section heading to read as set forth below, designating the existing text as paragraph (a), and by adding a new paragraph (b), to read as follows:

§ 180.451 Tribenuron methyl; tolerances for residues.

(a) * * *

(b) Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the herbicide tribenuron methyl (methyl-2-[[[[*N*-(4-methoxy-6-methyl-1,3,5- triazin-2-yl) methylamino] carbonyl]amino]sulfonyl]benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass forage, fodder and hay group (except Bermudagrass); forage	0.10
Grass forage, fodder and hay group (except Bermudagrass); hay	0.10

[FR Doc. 96–8145 Filed 4–2–96; 8:45 am]
BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 491

[BPD–728–F]

RIN 0938–AF14

Medicare Program; Payment for Federally Qualified Health Center Services

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

ACTION: Final rule.

SUMMARY: These regulations establish, as a Medicare benefit, outpatient services furnished by a Federally Qualified Health Center (FQHC) and establish requirements for coverage and payment of FQHC services. An FQHC is one of the following: An entity that is receiving a grant under section 329, 330, or 340 of the Public Health Service (PHS) Act; a non-grant receiving entity that is determined by the Secretary to meet the PHS Act requirements for receiving a grant; certain native American health centers; and certain facilities that have previously been identified as Federally funded health centers.

These regulations implement certain provisions of the Omnibus Budget Reconciliation Act of 1990 and the Omnibus Budget Reconciliation Act of 1993.

EFFECTIVE DATE: These regulations are effective on May 3, 1996.

FOR FURTHER INFORMATION CONTACT: Helen Klein, (410) 786–4641 (FQHC coverage issues) Randy Ricktor, (410) 786–5650 (FQHC payment issues)

SUPPLEMENTARY INFORMATION:

I. Background

On June 12, 1992, we published in the Federal Register, at 57 FR 24961, a final rule with a comment period, which established a new Medicare benefit, outpatient services furnished by FQHCs. This benefit is authorized by section 4161(a) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), which amends section 1861(aa) of the Social Security Act (the Act). The statutory provisions are effective on October 1, 1991.

OBRA '90 defines an FQHC as an entity that is receiving a grant under section 329, 330, or 340 of the PHS Act; is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330, or 340 of the PHS Act; based on the recommendation of the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services, is determined by the Secretary to meet the requirements for receiving such a grant; or was treated by the Secretary, for purposes of Medicare Part B, as a Federally funded health center (FFHC) as of January 1, 1990.

Subsequent to the June 12, 1992 regulations, the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) further amended section 1861(aa) of the Act relating to the definition of FQHCs. Section 13556 of OBRA '93 expanded the definition of FQHCs to include outpatient programs operated by tribes, tribal organizations under the Indian Self-Determination Act, or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act. This provision was effective as if it had been included in the OBRA '90 legislation. Thus, such organizations may qualify for FQHC status, and under certain circumstances, as early as October 1, 1991. We are implementing this provision in a separate Federal Register rule.

The Act defines FQHC services as the same type of services provided by rural health clinics (RHCs) under the Medicare program, plus preventive primary health services.

II. Provisions of the Final Rule With Comment Period

The rule described in considerable detail the requirements an entity must meet to qualify as an FQHC, what services the FQHC must furnish, and the methodology we will use to determine how much we pay an FQHC. We provided that an entity that meets the requirements must enter into a signed agreement with us and must terminate any other Medicare provider agreement.

Under provisions of our final rule, services that are payable under the Medicare program when furnished by an FQHC are the same outpatient services that are currently covered as RHC services, plus preventive services. FQHC services do not include services furnished to hospital patients. RHC services include services furnished by physicians, physician assistants, nurse practitioners, nurse-midwives, qualified clinical psychologists, clinical social workers, and services and supplies furnished incident to professional services of these practitioners. In certain home health agency shortage areas, RHC services may also include visiting nurses' services.

Preventive services include medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, well child care, including periodic screening, immunizations, voluntary family planning services, and services outlined in the recommendations of the U.S. Preventive Services Task Force for patients age 65 and older. Preventive services do not include eyeglasses, hearing aids, group or mass information programs or health education classes, or preventive dental services. Preventive services covered under special provisions of Medicare, such as screening mammography, may be provided by an FQHC only if the center meets the special provisions that govern those benefits.

Our regulations state that qualified clinical psychologists and clinical social workers who furnish FQHC services must be legally authorized to perform those services under State law. We clarified that nurse-midwives, clinical social workers, and clinical psychologists are employees of the FQHC.

Payment provisions for FQHCs parallel the provisions for payment of RHCs. We pay freestanding FQHCs on an all-inclusive rate basis, subject to a test of reasonableness. We apply payment limits to the all-inclusive rate per visit. We pay provider-based FQHCs in accordance with 42 CFR parts 405 and 413 of the Medicare regulations. For additional description, see the June 12, 1992 final rule (57 FR 24961). Issues regarding the interaction between managed care and Medicare entities, such as FQHCs, are under consideration by us, and therefore, not addressed in this final rule.

III. Analysis of and Responses to Public Comments

In response to the publication of the final rule with a comment period in the Federal Register on June 12, 1992, we received 48 public comments. The comments were submitted by a wide variety of health care centers, consultants and local and national organizations. We reviewed all the comments, and the comments and our responses are in the order that the issues appeared in the June 12, 1992 rule.

Qualification Requirements

Comment: A few commenters objected to application of the conditions for coverage requirements in 42 CFR part 491 to FQHCs and believed it is without legal basis. They noted that the language in the Medicaid law is nearly identical, and Medicaid does not place health and safety requirements on FQHCs. The commenters argued that by virtue of receiving grants under the PHS Act, these centers already must meet

stringent standards established by HRSA and further standards are unnecessary.

Response: When the Congress created the FQHC benefit, it envisioned that FQHC services would be provided under the same conditions as RHCs services are furnished. Thus, FQHC services are defined in section 1861(aa)(3)(A) of the Act as ''services of the type described in subparagraphs (A) through (C) of paragraph 1 of section 1861(aa).'' As a result, the services of FQHCs are to be identical to those of RHCs.

Similarly, section 1861(aa)(3)(B) of the Act provides that ''any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center, respectively.'' This means that physician-directed FQHCs are to be treated identically to their RHC counterparts. Finally, section 1861(aa)(5) of the Act provides the same definitions of physician assistants, nurse practitioners and clinical nurse specialists for RHCs and FQHCs.

These provisions of the Act indicate that the Congress built upon the statutory and regulatory provisions for coverage and payment of RHCs and intended that we use those provisions as a model for the FQHC program. Therefore, we believe that the Congress expected us to apply the same rules to FQHCs that we apply to RHC services and to professionals providing RHC services.

Based on the above, we believe there is a rationale for applying all or part of the RHC requirements to the services furnished in FQHCs. While HRSA may monitor the health and safety standards for a subset of FQHCs that are grantees, for some FQHCs (in other words, ''look-alikes,'' which are entities that are not receiving grants under the PHS Act but meet grant requirements, and some former FFHCs), there is no other alternative for monitoring the quality of the service furnished. Without our oversight, there would be no assurance that facilities furnish safe services.

In addition, the Congress has given us the responsibility to establish standards to ensure the health and safety of beneficiaries in all other statutorily-created types of facilities, and it would be extraordinary to interpret the law as preventing application of such standards in regard to FQHCs. There is nothing in the law that would support the view that the Congress intended for us to be without the power to assure the safety and efficacy of FQHC services.

We believe the health and safety requirements we established are minimal and are not a burden on the vast majority of centers that want to provide high quality care. In fact, we informally surveyed RHCs and FQHCs regarding the difficulties involved in participating in the Medicare program, and no one noted concerns with the health and safety requirements we extended to FQHCs. Likewise, no commenters on this document raised concerns with any particular requirement. However, should further correspondence indicate documented difficulties with a specific condition, we will be open to considering refinement, as appropriate.

Finally, we note that we are implementing the requirements in a fashion that is as administratively simple as possible. That is, we are not surveying potential FQHCs prior to participation or on a routine basis. Rather, centers merely attest to meeting the requirements. The standards thus establish a set of expectations for FQHCs to monitor themselves and provide an enforcement mechanism for those very few centers that do not take adequate health and safety precautions. In the absence of such health and safety standards, we would have no means to protect beneficiaries from potentially serious health and safety threats that have materialized with other types of providers and suppliers over time. Given the statutory provision referencing RHC procedures, we are confident that the Congress intended that we place health and safety requirements on FQHCs.

We concede that Medicaid currently has no regulations for FQHCs, so it is premature to argue that the Medicaid program does not have health and safety requirements for FQHCs. However, the Medicaid program does require provider agreements between the State agency and an FQHC before the Medicaid program pays the FQHC.

Although the Medicare and Medicaid FQHC legislation is similar in language, the two programs are separate and autonomous. The Medicaid program is a Federal and State partnership and allows more flexibility in determining FQHC approval. Since Medicaid regulations have not yet been issued, we are not in a position to discuss any additional requirements that may be added.

Comment: Several commenters noted that the statutory provisions for FQHC eligibility refer to FQHCs using the term ''entity.'' The regulations require that each site be approved, which the commenters believed exceeds our statutory authority. If site-specific approval is maintained, the commenters suggested that we clarify that an entity may submit combined cost reports and use a combined payment rate for all sites within that entity.

Response: While we independently approve each site for Medicare participation and assign it a unique provider number, each site of a potential FQHC need not independently meet the PHS Act grant requirements. The fact that a site is within the scope of a grant or approved look-alike application is sufficient. However, each site must independently attest to meeting the conditions in part 491 subpart A.

We believe the site specific requirement also has advantages for Medicare beneficiaries and FQHCs and is supported by law. Section 1861(aa)(2)(K) of the Act gives us the authority to establish standards to ensure the health and safety of beneficiaries receiving services at RHCs, and consequently, we believe, at FQHCs. We believe that establishing specific requirements for individual site approval allows us to fulfill this role. If facilities are not independently approved, it is difficult to determine if each site is adequately meeting the required health and safety standards.

There are advantages to the FQHC in this policy. The site-specific approval requirement allows each site in the entity to continue to operate despite individual problems that may arise in other sites under the same corporate entity. Corporate entities are typically large private or public organizations which have, as their organizational components, facilities that must independently meet the conditions established in 42 CFR part 491, subpart A. By requiring individual site approval, all of the sites of an entity are not jeopardized if one site does not meet health and safety requirements. If we were to use entity-based approval, as suggested by the commenter, we would not allow an individual site that continues to meet all of the conditions to provide FQHC services if another site in that parent entity did not meet the Medicare safety standards. In addition, requiring site-specific approval enables us to provide enhanced service to our beneficiaries. Specifically, we are able to respond to beneficiary requests for the names and addresses of approved facilities that are providing Medicare FQHC services.

Although each site within a corporate entity is independently approved and given a unique Medicare provider number, entities have the option to file a single consolidated cost report for the entire entity or individual cost reports for each site within the entity. We provided instructions in the intermediary and RHC/FQHC manuals

that address payment for FQHC network entities.

Finally, we do not believe that the law intended that every site operated by an entity be entitled to FQHC status, especially if the sites are not within the scope of the PHS Act grant, without independently qualifying as ''look-alikes.'' Only by using site-specific approval can we carry out the statutory intent of providing FQHC status to a site that meets the conditions of the law, while excluding a site that is part of an entity, but falls outside the scope of a PHS Act grant or does not otherwise meet the FQHC eligibility criteria.

Comment: One commenter requested clarification of our position regarding provider-based FQHCs, which are not receiving grants under the PHS Act, but meet grant requirements as ''look-alikes.'' The commenter noted that the definition of a provider-based FQHC as an integral and subordinate part of a provider and HRSA governance requirements have prompted some centers to establish independent governance and yet remain located at or near hospital grounds. The commenter requested assurance that such co-location would not result in provider-based designation.

Response: Section 405.2462 defines a provider-based FQHC as a clinic or center that is an integral and subordinate part of a hospital, skilled nursing facility, or home health agency participating in Medicare (that is, a provider of services). The clinic or center is operated with other departments of the provider under common licensure, governance, and professional supervision. These stipulations must be met for us to consider an FQHC as provider-based. Simply being located in or near a hospital does not qualify an entity as a provider-based facility. The converse is also true. An entity may be provider-based despite the fact that it is located outside of the provider. A center with independent governance cannot be considered a provider-based FQHC.

The basis for HRSA governance requirement is to ensure that the services that are provided are responsive to the community. Therefore, HRSA requires that a center approved under sections 329 and 330 of the PHS Act have a governing board, the majority of which are users of the facility.

Comment: One commenter urged that we review the definition and scope of authority of community governing boards in FQHCs. The commenter noted that the requirement for community governing boards excludes from the FQHC benefit clinic facilities that are owned by academic health science centers.

Response: The definition and scope of authority of community governing boards are found in sections 329(f)(3)(G) and 330(e)(3)(G) of the PHS Act. The sections specify that the center has established a governing board which (1) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center, and (2) selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in the case of a public center, establishes general policies for the center.

The purpose of an FQHC is to provide community-based, family-oriented primary care. The statutory governance requirement ensures that the services that are provided are responsive to the health needs and concerns of the community. An academic health science center can qualify as an FQHC if its board meets the requirements of sections 329, 330 or 340 of the PHS Act and the provisions of this regulation.

Comment: One commenter noted that § 491.5 requires that a center be located in a rural or urban area that is designated as a shortage area. The commenter requested that shortage area be clearly defined in the regulations. Several commenters noted that the PHS law does not require the FQHC to be located in a medically underserved area, but merely to document that it serves a medically underserved population.

Response: Section 491.2 defines a shortage area as a geographic area designated by the Department as having either a shortage of personal health services (under section 1302 of the PHS Act) or a shortage of primary medical care manpower (under section 332 of that Act). The designation of shortage areas is quite complex and is handled by HRSA.

Section 491.5(d) specifies the criteria for designation of shortage areas. Factors considered include the ratio of primary care physicians practicing in the area to the resident population and the infant mortality rate.

The commenter is correct in that HRSA does not require that the FQHC be located in a shortage area. Rather HRSA requires that the FQHC either be located in a medically underserved area (MUA) or serve a medically underserved population (MUP).

According to 42 CFR 51c.102(e), an MUP is defined as the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. This designation was developed because there were populations that required medical care but were located in areas that did not receive MUA designation. The Secretary analyzes the demographics and medical manpower of the population to determine whether or not the population should receive designation. Therefore, an MUP can be located in an area that is not an MUA.

In response to the concern expressed by this commenter, we are revising § 491.5(a) to specify that an FQHC may be located in a shortage area or may serve a medically underserved population. We are also adding a new paragraph (e) that defines medically underserved population in the same way as HRSA does, as indicated above.

Comment: Two commenters objected to application of the ''four walls test'' in § 491.5 to an FQHC. They believed that this provision limits cost-based payment to only those services provided at the clinic or center site. The commenters noted that it may be difficult to have some specialists come to the center site to provide care and recommended that all services furnished under arrangements with the FQHC be payable on a cost basis.

Response: The ''four walls test'' requires that the objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic or center be housed in a permanent structure or mobile unit that has fixed, scheduled locations. The requirement that the clinic or center be housed in a permanent structure ensures that the equipment, records, supplies and whatever else is necessary to provide the defined services are in one permanent place.

The ''four walls test'' is not a requirement that limits cost-based payment to only those services provided at the clinic or center, and it does not restrict a physician from providing services off-site. A physician, including any specialist under contract to the FQHC, can have an agreement with the FQHC to provide FQHC services off-site.

For reasons discussed later in this preamble, we have reconsidered our policy on contracting for professional staff members other than physicians. FQHCs may provide services of physician assistants, nurse practitioners and other professionals under contract. These professionals may provide services in skilled nursing facilities or in the homes of beneficiaries. However, an FQHC may not bill services provided to hospital patients as FQHC services.

Comment: Several commenters noted that § 491.8 requires that nurse practitioners or physician assistants be

available to furnish patient care services at least 60 percent of the time. However, the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) changed the requirement to 50 percent. They recommended that we revise the regulation to state that such coverage is required 50 percent of the time.

Response: We note that the referenced RHC requirements pertaining to staffing mix percentages in § 491.8 do not apply to FQHCs. When the FQHC regulations were published on June 12, 1992, the existing RHC regulations had not been updated to include changes from the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), OBRA '89 and OBRA '90. As a result, the FQHC regulations were incorporated into the existing RHC regulations, which still reflected earlier statutory thresholds for such coverage. We are preparing to issue a proposed rule that incorporates these changes and will update the RHC provisions in § 491.8 and solicit public comment. We are, however, authorized by OBRA '90 to issue a final rule for FQHCs that includes only the OBRA '90 amendments.

Comment: One commenter objected to the exclusion of psychologists from the list of practitioners in § 491.8(a)(6), which specifies staff that must be available in order for the center to be open. The commenter recommended that we revise the regulation to include specialty providers in all areas of operation of the centers. Further, the commenter was concerned that the language with regard to medical direction in § 491.8(b)(1)(i) could be interpreted to require that a physician may supervise psychological services that are within the scope of the psychologist to furnish without medical direction.

Response: As noted above, OBRA '90 authorizes us to implement the FQHC regulations as a final rule. We do not have authority under that law to modify the RHC provisions without publishing a notice and soliciting public comment. When the FQHC regulations were published June 12, 1992, the existing RHC regulations had not been updated to include any changes in the law. As a result, the regulations concerning the policy board and medical supervision did not contemplate involvement of psychologists, as psychologists' services were not RHC covered services at the time the regulations were promulgated.

Section 1861(ii) of the Act provides coverage for clinical psychologist services that would otherwise be covered if furnished by a physician or as incident to a physician's service. In addition, under this statutory provision clinical psychologists can provide services as authorized under State law without the supervision of a physician. We are revising § 491.8(b)(1) to clarify that clinical psychologists can provide services, as permitted under State law, without the supervision of a physician in FQHCs.

Comment: Two commenters objected to the requirement in § 491.9(b)(2) regarding the development of patient care policies. This paragraph requires that the policy development committee of the center include at least one member who is not on the center's staff. They expressed concern that the use of non-staff personnel is an unnecessary expense and is burdensome. They also believed the requirement is unnecessary given the level of review already in place by HRSA for its grantees.

Response: We believe that the provisions of § 491.9(b)(2) are necessary to ensure the health and safety of beneficiaries. Patient care policies were developed to provide guidelines on how a facility will care for its patients. In addition, the policies ensure that the providers adhere to appropriate procedures and protocols. The requirement for a non-staff representative to assist in developing patient care policies is necessary to ensure that the services are responsive to the needs of the community. The non-staff representative does not have financial interests in the provider and, as such, will likely be more objective and unbiased in favor of the provider in the decision making process. This requirement is intended to ensure that the concerns of the population served will be paramount and that the provider will address the specific health needs of the community. Given the HRSA governance requirement for a constituent majority board, we believe this requirement will not be burdensome to most FQHCs.

Comment: One commenter objected to annual surveys of RHCs and FQHCs as wasteful.

Response: We are not planning to conduct routine surveys of FQHCs, and FQHCs will not be routinely required to submit documentation to HCFA demonstrating compliance with program requirements. However, we plan to survey an FQHC if we receive a complaint about a health and safety issue at the FQHC. During the survey, the FQHC must provide documentation of compliance with the requirements in part 491.

Comment: Two commenters noted that FQHC grantees are subject to extensive review by the HRSA on an annual basis. They believed this review is sufficient to meet any evaluation assurances that should be necessary. Therefore, the requirement in § 491.11 that a clinic or center carry out or arrange for an annual evaluation of its total program should not be applicable to FQHCs.

Response: An FQHC is expected to conduct annual evaluations in accordance with § 491.11, which specifies what the annual program evaluation must include and what the evaluation must determine, but it does not prescribe how the annual program evaluation must be conducted or the kind of evaluation that must be conducted. The purpose of the annual evaluation is to evaluate utilization of services, evaluate compliance with established policies, and determine if changes are needed. We would expect that every organization would conduct this self-assessment at least annually regardless of Medicare requirements.

With regard to the concern that HRSA reviews are adequate and, in support of elimination of this requirement for FQHCs, we note that not all FQHCs are grantees under the PHS Act; thus, all FQHCs would not be subject to the HRSA standards. In support of retaining the requirement, we note that the standard should not be burdensome to the centers because, to the extent that HRSA reviews cover the scope of the requirement, additional evaluation and documentation will not be necessary. Thus, should we survey an FQHC for compliance with part 491 conditions in response to a complaint, documentation submitted to HRSA for HRSA program purposes would be acceptable as evidence of compliance with 42 CFR 491.11 if the review included the items specified in the requirement.

Comment: Another commenter was in favor of annual compliance reporting and recommended that, to ease administrative burden, HCFA and HRSA use a single form, and HCFA provide additional details specifying when such reporting is to be completed and where it is to be forwarded.

Response: We are not requiring annual compliance reporting. FQHCs must review themselves, and they must maintain documentation of their review in the event that we choose to survey a center. We will evaluate an FQHC only if we discover a problem or receive a complaint. In such cases, the review would encompass only the matter addressed in the Medicare regulations, but we would coordinate the review with HRSA to avoid duplicative efforts. Section 491.11 requires that an FQHC perform an annual self-evaluation of its program. We believe this is a reasonable requirement so that an FQHC assesses utilization of services, compliance with

established policies, and determines if changes are needed.

Comment: One commenter wanted to know when a listing of FQHCs would be available.

Response: There is a list of FQHCs currently available from the Health Standards and Quality Bureau, System Management Branch, 6325 Security Blvd., Baltimore, Maryland, 21207. The charge for the list is $25.00. For more information, you may telephone Mike Moran at (410) 597–5851.

Content and Term of the Agreement

Comment: One commenter requested that we clarify the recertification process for FQHCs.

Response: For Medicare purposes, there will be no routine recertification of FQHCs. Once a facility is approved, it will remain a Medicare-participating FQHC until termination of the agreement, as provided in § 405.2436. We plan to survey an FQHC if we receive a complaint about a health and safety issue at an FQHC or if a health and safety problem is identified in another way.

HRSA has an annual process to determine eligibility for FQHC status. For grantees, this consists of an application process for funding, and for look-alikes, this consists of an annual application and review, either of which could result in HRSA recommending decertification of the FQHC to HCFA.

Comment: Two commenters noted that the RHC law and regulations provide that an RHC retains its status even if the area in which it is located loses its rural shortage area designation. They requested similar protection for FQHCs.

Response: Section 1861(aa)(2)(K) of the Act specifies that an RHC may maintain its approval even if the area in which it is located loses its rural shortage area designation. In accordance with the Act, § 491.5(b)(1) allows an RHC to retain its approval. The Act, however, does not include a similar provision for an FQHC.

We note that the current language in the regulation does not clearly state that the protection for area designation applies exclusively to RHCs. Therefore, we are revising § 491.5(b)(1) to clarify this.

Comment: One commenter objected to the requirement that centers must terminate other provider agreements prior to, or simultaneous with, signing an FQHC participation agreement. The commenter believed that there is no statutory support for this requirement, and this requirement may adversely affect some centers. One example cited by the commenter is that an RHC could be adversely affected if it gave up its RHC status to become an FQHC and the area is redesignated from medically underserved because the protection afforded an RHC is not offered to an FQHC.

Response: We are revising § 405.2430(a)(1)(iii) to clarify that a freestanding FQHC must terminate other provider agreements for entities that operate at the same time as the FQHC. The intent of this provision is to prohibit an entity from using the same space, staff, and resources simultaneously as two distinct provider types. We believe this provision is necessary to ensure the health and safety of our beneficiaries and to avoid program abuse.

We do not intend by this provision that an FQHC and another provider/supplier type may not be commonly owned or housed in the same building. Rather, the intent of the provision limiting freestanding FQHCs to a single provider agreement is to prevent the entity from using the same staff, space, and resources for two or more different provider types at the same time.

We believe that this provision is necessary to ensure the health and safety of our beneficiaries. That is, if an FQHC is using the same space, staff and resources as two different providers at the same time, there is no assurance that the staff will be devoting its efforts to the FQHC operation and not the other provider type. Without these assurances, it is possible that beneficiaries could come to the FQHC expecting to receive adequate health care, only to learn that the other provider type is using the FQHC's resources at that time.

In addition, we established a very simplified cost report mechanism for FQHCs. This cost report does not permit the allocation of costs among multiple provider types. If we were to allow the simultaneous use of the same space, staff and resources as multiple providers, we would need to develop a more sophisticated cost report. A more complicated report could place an administrative burden on the centers, the vast majority of which do not wish to engage in multiple provider activities.

We note that the Medicare program does not generally allow the concurrent use of a facility as multiple health care providers. For example, the regulations require that ambulatory surgical centers be used exclusively for providing surgery to patients who do not require hospitalization. Furthermore, the skilled nursing facility regulations require separate space, staff and resources (or distinct part) for its non-certified portion. Thus, we believe there is ample precedent for the requirement we are establishing.

Coinsurance

Comment: One commenter noted the distinction between the basis of coinsurance (charges) and the basis of payment (all inclusive rate) and asked for clarification.

Response: The commenter is correct. There is a difference between the basis of coinsurance and the basis of payment. In accordance with section 1833(a)(3) of the Act, payment for FQHC services may not exceed 80 percent of its cost. Section 1866(a)(2)(A) of the Act, referred to in section 1830(a)(3), addresses coinsurance liability of beneficiaries, providing that coinsurance be based on charges. Consequently, our regulations provide that an FQHC may not charge beneficiaries more than 20 percent of the charge for the service furnished regardless of the payment the FQHC receives from Medicare.

We believe that, on average, many FQHCs will recover their costs under this provision. While it is possible that, in situations involving minimal services, the FQHC will recover less than its cost, it will recover more than its costs in certain other visits involving high charge services.

We acknowledge that FQHCs must use a sliding fee schedule for beneficiaries within 200 percent of poverty levels. Thus, FQHCs with a high proportion of Medicare beneficiaries subject to the sliding fee could receive less than cost from their Medicare population. However, we believe that the law is clear regarding Medicare payment and beneficiary coinsurance liability.

Effective Date

Comment: One commenter requested clarification of the effective date for those centers that had previously obtained ''look-alike'' status under the Medicaid program.

Response: In accordance with § 405.2434(b)(2), an FQHC's effective date may be October 1, 1991, if it met all Federal requirements on that date and if it applied to be a Medicare FQHC by August 11, 1992. An entity that requested to become an FQHC by filing a signed agreement within 60 days of publication of the regulation could elect to choose an effective date from October 1, 1991 (the effective date of the law) up to and including August 11, 1992. An entity does not qualify as an FQHC on October 1, 1991 unless it met all Federal requirements on that date. The preamble to the June 12, 1992 regulation states that Medicare will pay for FQHC

services furnished on or after October 1, 1991 by entities that met the criteria in the regulation on that date and file a signed statement within 60 days of the date of publication.

More specifically, an entity that is not receiving a grant under the PHS Act but meets grant requirements, and applied for and obtained FQHC status under the Medicaid program, and was approved without a waiver could be paid for services from October 1991 if the entity met the requirements in part 491 and applied to Medicare timely. The earliest date for which an entity can qualify is October 1, 1991. HRSA makes a recommendation about an entity's status after the entity has applied and met all HRSA requirements, and we make the decision to approve the entity as an FQHC. If an entity was approved as a Medicaid FQHC ''look-alike'' without waiver after October 1, 1991, the earliest date of FQHC approval for such a center is the date we approve the entity as an FQHC.

Comment: One commenter objected to the August 11, 1992 date for filing for approval as an FQHC from October 1991. The commenter believed that we should permit exceptions to the August 11, 1992, date for centers that provide a ''good cause'' explanation for their delay.

Response: We and the National Association of Community Health Centers (NACHC) have made extensive efforts to assist centers in applying to become FQHCs. Letters were sent to each grantee, ''look-alike,'' and FFHC to make them aware of the process for FQHCs to receive payment as an FQHC from October 1, 1991.

We have already processed payment adjustments to take into account entities that acted timely to apply for FQHC status effective October 1, 1991. Making payment to 1991 for FQHCs that did not file in time would be administratively burdensome because it involves the entity refunding previously collected deductibles to beneficiaries and billing for past preventive services. We believe the ''window'' we permitted for FQHCs to qualify to October 1991 was generous, and we believe that our letters and the letters from NACHC gave facilities adequate time and information to apply and qualify. Therefore, we are maintaining the policy in our 1992 rule.

Scope of Services

Comment: One commenter believed the law defines FQHC services as those generally furnished by community health centers (CHCs). He noted that this is considerably different from RHC services and recommended revision of the scope of services to reflect this.

Response: The Act does not define FQHC services as the services provided by CHCs. Section 1861(aa)(3)(A) and (B) of the Act defines the scope of FQHC benefits in terms of those benefits enumerated in the RHC law (section 1861(aa)(1)(A)–(C) of the Act) and preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. The law does not require that a center be a CHC to qualify as an FQHC; it does provide that a facility may qualify as an FQHC if it meets the requirements to become a CHC under section 330 of the PHS law. We do not have the authority to expand the FQHC scope of benefits beyond those specified in the law.

Comment: Several commenters objected to the regulation's definition of preventive primary health services. Some commenters believed that all services required under section 330 of the PHS Act, such as transportation services, should be covered as preventive services.

Response: Section 1861(aa)(3) of the Act specifies that FQHC services include those benefits defined as RHC services in section 1861(aa)(1)(A)–(C) of the Act and preventive primary health services that are required under sections 329, 330 and 340 of the PHS Act. A service must first be recognized as a preventive primary health service under PHS law and HRSA guidelines to be included as a preventive primary health service for Medicare FQHC purposes. If a service is not included as a primary preventive service under the PHS Act and the HRSA guidelines, there is no authority for Medicare to cover the service.

42 CFR parts 51c and 56 define preventive services as medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations and voluntary family planning. Based on the U.S. Preventive Services Task Force Report for persons age 65 or older, HRSA further requires its grantees to provide additional preventive services that are specified in § 405.2448.

Transportation services are helpful in promoting access to preventive health care, especially for individuals living in underserved areas. Such services, however, are not defined as preventive services by HRSA, thus we do not have the authority to include such services as FQHC preventive services.

Comment: One commenter recommended that the rule be clarified to allow for the inclusion of advanced practice mental health nurses under the FQHC benefit. The commenter believed it was the intent of the law to include these practitioners under ''specialized nurse practitioners;'' however, they are not all technically classified as nurse practitioners.

Response: The Act does not recognize or specifically refer to the services of advanced practice mental health nurses. We do not have the authority to expand the FQHC scope of benefits beyond those the services of practitioners described in the Act. The FQHC scope of benefits includes some, but not all, categories of advanced practice nursing. For example, it does not include clinical nurse specialists. Other categories of advanced practice nursing such as physician assistants and nurse practitioners may provide mental health services covered under the FQHC benefit. Services provided by clinical nurse specialists, for example, could be covered only if they were ''incident to'' services as provided in section 1861(aa)(1)(B) of the Act. This section provides for coverage of services furnished incident to the services of physicians, certain mid-level practitioners, clinical psychologists, or clinical social workers.

Comment: Numerous commenters objected to the provision that limits FQHC services to those furnished outside a hospital. FQHCs routinely follow their patients to the hospital setting and noted that it is burdensome to bill the carrier separately for these services as non-FQHC services. Further, this mechanism provides an opportunity for duplicate billing. Some commenters noted that RHCs may bill for hospital services and believe the same policy should be applicable to FQHCs.

Response: There are two reasons why FQHC services are limited to those furnished outside of the hospital: (1) Section 1861(aa)(3) of the Act requires that FQHC services be provided only to outpatients, and (2) section 1862(a)(14) of the Act prohibits payment for services furnished to hospital patients, except as specified in the law. Section 1862(a)(14) of the Act, in enumerating those who may receive payment for services furnished in a hospital, does not include either RHCs or FQHCs. Therefore, payment cannot be made for FQHC services to hospital patients.

The Social Security Amendments of 1983, Pub. L. 98–21, on April 7, 1983, added section 1862(a)(14) to the Act. This section prohibits payment under Medicare for any service provided to a hospital inpatient that is not furnished by the hospital itself or furnished under arrangements made by the hospital with

the entity furnishing the service. Section 1862(a)(14) of the Act also states that certain services are specifically excluded from this prohibition. The exclusion is limited to physicians' services, services described by section 1861(s)(2)(K)(i) of the Act (certain physician assistant services, nurse practitioner, clinical nurse specialist, and nurse-midwife services), qualified psychologist services, and services of a certified registered nurse anesthetist.

Section 1862(a)(14) of the Act was further revised by section 9343(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Pub. L. 99–509, to apply to hospital outpatients as well as hospital inpatients. As a result, the law now prohibits payment, except as specifically enumerated, for both hospital outpatients and inpatients. By its terms, then, section 1862(a)(14) of the Act prohibits Medicare payment for FQHC services provided to a hospital patient.

However, we do not believe it is the intent of the law to prohibit FQHC practitioners from following their patients to a hospital setting. The law provides two alternative payment mechanisms for such services. First, the FQHC may look to the hospital for payment for the services. Second, FQHC practitioners can follow patients to a hospital and provide services, but the practitioner may not bill those services as FQHC services. Instead, FQHC physician visits are covered under other Part B provisions of Medicare as physician services, and the FQHC practitioner must bill the Medicare carrier to receive payment.

Section 1842(b)(6) of the Act provides that a facility, under certain conditions, may bill the program for the services of its employees. In such a case, it is not necessary that a FQHC practitioner employed by an FQHC bill for the services provided in hospitals; rather, the FQHC may bill the program on behalf of its employees using the form HCFA–1500. These bills must be sent to the local carrier instead of the intermediary processing cost-based claims are paid using the routine part B payment methodology (in most cases resource-based relative value system fee schedules).

Despite the commenters' allegations to the contrary, an RHC cannot bill for hospital services. The same statutory requirements that extend to an FQHC apply to an RHC as well.

Comment: Several commenters objected to the exclusion of diagnostic x-rays from the definition of FQHC services. They supported inclusion of such services under the FQHC benefit as incident to a physician's service. They argued that this would promote administrative ease in bill submission.

Response: Section 1861(aa)(1)(A) of the Act defines RHC (and, thus FQHC) services to include physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) of the Act if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10) of the Act (pneumococcal and influenza vaccine).

The technical component of x-ray services, as distinct from physician services, is covered under section 1861(s)(3) of the Act. Therefore, it is not included in the definition of FQHC services. We have no authority to change this requirement under current law. However, we are interpreting the law as permitting the professional component of the x-ray to be included as an FQHC-covered service as a physician service. Moreover, though the technical component of x-ray services is not covered under the FQHC benefit, it may be claimed under Part B of Medicare by billing the carrier.

Comment: One commenter noted that the exclusion of radiology and hospital services from the scope of FQHC services presents a problem in waiver of the deductible. By virtue of its mission, an FQHC is treating a population that generally has insufficient funds to meet necessary medical expenses. The exclusion of some services from the scope of FQHC services will result in a deductible liability for those excluded services and present a financial hardship for low income beneficiaries. The commenter recommended that we waive the deductible for all services provided in an FQHC, regardless of whether they are FQHC services or not.

Response: Section 1833(b)(5) of the Act provides that the Medicare deductible does not apply to FQHC services. Section 1861(aa)(3) (A) and (B) of the Act defines the scope of FQHC services in terms of those services furnished by an RHC and preventive primary health services that a center is required to provide under the PHS law and HRSA guidelines.

The rationale for excluding the technical component of radiology services to hospital inpatients from the definition of FQHC services has been discussed in the prior two responses. Section 1861(s)(3), and not 1861(s)(2)(A), of the Act is the basis for the diagnostic x-ray benefit; thus, the technical component of x-ray services is not included within the FQHC benefit. In accordance with sections 1861(aa)(3) and 1862(a)(14) of the Act, FQHC services cannot be provided to hospital patients. We have no authority to waive the deductible for these services, which are not FQHC services.

We acknowledge that paying the deductible for these services may be difficult for some beneficiaries. Beneficiaries suffering financial hardship may be eligible for assistance under the Qualified Medicare Beneficiaries (QMB) Program. A qualified Medicare beneficiary is an individual who is entitled to Medicare hospital insurance benefits under Part A, with or without payment of premiums, who also has an income that does not exceed 100 percent of the Federal poverty level and has resources that do not exceed twice the maximum amount established for Supplemental Security Income eligibility.

Under the QMB program, Federal financial participation is available to State Medicaid agencies for medical assistance for the beneficiary's Medicare cost sharing expenses. The expenses include Medicare Part A and Part B deductibles and coinsurance. Medicaid pays the coinsurance and the deductible. This will help beneficiaries to avoid the out-of-pocket costs. The QMB program provides a mechanism to assist those beneficiaries with limited means to pay the deductible.

Comment: One commenter noted that although nurse-midwives are mentioned in several places throughout the FQHC regulation, § 405.2446, which defines the FQHC covered scope of services, does not include nurse-midwives.

Response: We agree with the commenter and are revising § 405.2446 to include the services of nurse-midwives as covered FQHC services. We intend to propose a change to the definition of nurse-midwife in a proposed rule on RHCs currently in process, which will also affect FQHCs. In the meantime, State law governs which nurse-midwives qualify to provide services in FQHCs.

Comment: One commenter recommended coverage of clinical nurse specialists as FQHC practitioners. These health care practitioners are registered nurses with master's degrees in a defined clinical area of nursing. They are similar to nurse practitioners and are educated and trained to provide preventive services and primary care. OBRA '90 recognizes these health care practitioners as independent providers in rural areas. Therefore, the commenter believed that we should cover the individual services of these practitioners within the scope of FQHC services. In addition, the commenter wanted the phrase ''clinical nurse specialist'' added to the definition of an FQHC visit.

Response: The Act does not clearly provide coverage for clinical nurse specialists services in an RHC or FQHC. Although the definition of a clinical nurse specialist is included in section 1861(aa)(5) of the Act, the Act does not explicitly include these practitioners in the scope of the benefit.

Comment: One commenter recommended that the adjective ''specialized'' be removed as a modifier to nurse practitioner as most States do not use this term in licensing nurse practitioners.

Response: We have been advised by nursing associations that the term ''nurse practitioner,'' which is defined in § 405.2401(c)(17), encompasses all specialties among nurse practitioners. Consequently, it is not necessary to use the term ''specialized'' and we are removing the definition of ''specialized nurse practitioner'' from § 405.2401.

Primary Preventive Services

Comment: Several commenters objected that we did not include dental services as preventive care covered under the FQHC benefit. They noted that the U.S. Preventive Services Task Force Report includes an oral health component and argued that such services are essential for elderly patients. Further, preventive primary dental services are separately mandated in section 329 and 330 of the PHS Act. Therefore, the commenters believed that the Congress did not intend to exclude dental services from the FQHC benefit and that its failure to amend section 1862(a)(12) of the Act was a technical oversight.

Response: Dental services are not included in the HRSA definition of preventive primary health services; they are considered a separate benefit under HRSA services. The PHS Act provides for preventive dental services as a primary health care benefit separate from preventive primary health services. That is, section 329(a)(6)(C) of the PHS Act defines preventive primary health services, while a different section of the law, section 329(a)(6)(F), defines preventive dental services. In defining the scope of FQHC preventive services, the Act specifically refers only to preventive primary health care services in sections 329, 330 and 340 of the PHS Act.

Further, section 1862 of the Act contains an exclusion for dental services, prohibiting payment for services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting the teeth. OBRA '90 did not amend section 1862(a)(12) of the Act to remove the exclusion of dental services for FQHCs. However, it did amend other provisions of section 1862(a). As a result, the regulations exclude dental services from the definition of FQHC preventive primary health services and will continue to do so.

Although the U.S. Preventive Services Task Force Report includes an oral health component for the elderly, that oral component is categorized as a counseling service by the Task Force. The report intended that a primary care practitioner would briefly examine a patient's mouth for visible signs of disease and counsel the patient to see a dentist if there is a need for routine prophylactic services. If the beneficiary had need of prophylactic or other dental services, he or she would be referred to a dentist. The oral health component is not the same as dental services.

Comment: Several commenters objected to the exclusion of screening mammography services as an FQHC preventive service. Although this service is payable under Part B, they note that application of the deductible and having to make an appointment to have the mammogram performed at another facility would deter some of the most needy population from getting this valuable service.

Response: Sections 1834(c) and 1861(s)(13) of the Act provide for coverage of screening mammography for certain women entitled to Medicare, subject to frequency limitations, quality standards and special payment rules. The Act provides coverage of screening mammography services only in a facility that meets the Medicare requirements for certification. An FQHC may provide and bill for screening mammography services under the mammography benefit as long as it meets the applicable quality standards and coverage requirements. The quality standards are designed to protect the health and safety of Medicare beneficiaries.

As explained above, the scope of benefits under FQHCs does not include radiological services. In addition, the Act contains special provisions for the coverage of screening mammography as a Medicare benefit, and those provisions apply to FQHCs in the same manner as they apply to other entities.

Comment: One commenter believed that we should recognize services listed in the U.S. Preventive Services Task Force Report for people under age 65 as preventive services for purposes of the FQHC benefit.

Response: By definition, the Medicare program is a Federal health insurance program for people age 65 or older and certain disabled individuals. Section 1861(aa)(3)(B) of the Act specifies that FQHC services include preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. A service must first be recognized as a preventive primary health service under HRSA guidelines in order to be included as an FQHC preventive primary health service.

HRSA defines preventive primary health services in 42 CFR parts 51c and 55 as medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations, and voluntary family planning services. These are the required preventive primary health services as defined by HRSA. Thus, these are the preventive primary health services that we require in an FQHC.

In preparing the final rule with comment period for FQHC preventive services, we noted that this list of services was not likely to significantly benefit the majority of Medicare beneficiaries. We worked with HRSA to expand the HRSA-required preventive primary health services. The ''Guide to Clinical Preventive Services,'' prepared under the supervision of the U.S. Preventive Services Task Force, provides further recommendations for clinical practice on additional preventive interventions. HRSA adopted the policy that the list of preventive primary health services recommended by the task force in the ''Guide to Clinical Preventive Services'' for people aged 65 or older is consistent with the preventive primary health services that its grantees are already required to provide.

The commenter believed that we should recognize services recommended for people under age 65 as preventive services for purposes of the FQHC benefit. The ''Guide to Clinical Preventive Services'' lists the same preventive services for both the under age 65 and the over age 65 populations, with the exception of counseling regarding sexual practices. The sexual practices category includes sexually transmitted diseases, partner selection, contraceptive devices, and unintended pregnancy. Since, the HRSA regulations at 42 CFR part 55 already include the majority of these services under preventive health education and family planning, we do not believe it is appropriate to explicitly include these in the list of preventive primary care services under Medicare.

Comment: One commenter noted the value of proper nutrition in health outcomes, particularly with diseases of

hypertension, obesity and diabetes. The commenter requested clarification regarding the provision of dietician services under the ''incident to'' provision if they are provided by a consultant.

Response: The FQHC benefit includes services furnished by certain professionals. Section 1861(aa)(1) of the Act defines these professionals as a physician, nurse practitioner, physician assistant, clinical psychologist or clinical social worker. The benefit also includes services furnished ''incident to'' the services of these professionals as long as the individual furnishing the service is an employee of the FQHC.

Dietician services could be covered FQHC services if provided to the beneficiary as ''incident to'' services. Dietician services must meet the criteria for ''incident to'' services established in sections 406 and 410 of the Medicare RHC and FQHC Manual. These sections state that services and supplies incident to a physician's or mid-level practitioner's professional services are covered as FQHC services as long as they are: furnished as an incidental, although integral, part of a professional's services; of a type commonly furnished either without charge or included in the FQHC's bill; of a type commonly furnished in a physician's office; services provided by clinic employees other than those services listed in section 400A of the Medicare RHC and FQHC Manual furnished under the direct, personal supervision of a physician or mid-level practitioner; and furnished by a member of the clinic or center's staff who is an employee of the clinic or center. These criteria follow the longstanding criteria for services ''incident to'' physician services.

The Medicare RHC and FQHC Manual provides that there must be a physician's or mid-level practitioner's personal service furnished to which the non-physician's services is an incidental, although integral, part. This does not mean, however, that each occasion of service by a nonphysician need also always be the occasion of the actual rendition of personal professional services by the physician or mid-level practitioner. This requirement is also met for nonphysician services furnished during a course of treatment in which the physician or mid-level practitioner performs an initial and subsequent service with a frequency that reflects his or her active participation in, and management of, the course of treatment. This means that there must have first been a direct, personal, professional service furnished by a physician or mid-level practitioner to initiate the course of treatment of which the nonphysician service is an incidental part. In addition, there must be subsequent services performed by the physician or mid-level practitioner of a frequency that indicates his or her continuing active participation in and arranging the patient's course of treatment.

Dietician services that are provided in an FQHC may be covered if they are provided directly by a physician or appropriate mid-level practitioner or are incident to his or her services. This does not include services that are provided independently by a dietician without the active involvement of the FQHC physician or mid-level practitioners.

Consistent with our longstanding policy, as reflected in section 406 of the Medicare RHC and FQHC Manual, ''incident to'' services must be furnished by a member of the clinic staff who is an employee of the clinic. Thus, in order for dietician services to be covered FQHC services, the dietician must be an employee of the FQHC. To determine the employer/employee relationship, the ''usual common law rules,'' that are referred to in section 210(j)(2) of the Act, are applied. In applying these rules, we consider not only who pays a person's salary and fringe benefits but also other factors including who has hiring and firing authority and who pays Federal Income Contributions Act (FICA) taxes and withholds income tax.

The requirement that personnel who perform ''incident to'' services must be employees of the clinic or center for purposes of coverage is a longstanding Medicare policy. The basis for this requirement is in section 1861(s)(2)(A) of the Act. This section limits coverage of ''incident to'' services to those services that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills. We have consistently interpreted this provision to exclude coverage of ''incident to'' services provided by non-employees of physicians, and in this case, of clinics. In addition, the employer/employee relationship requirement ensures that physicians will have the authority to exercise appropriate medical supervision and management control over the qualifications and performance of non-physicians for whose services he or she will be billing Medicare. Since the PHS Act encourages FQHCs to contract to provide services, we do not wish to create barriers to, and burdens on, FQHCs that wish to contract for non-physician professional services. Therefore, payment may be made for services provided by FQHC contracted professionals. However, this FQHC provision does not apply to RHC services. We plan to address this issue in a future proposed rule.

Comment: One commenter recommended that nutritional education and counseling be listed as a separate preventive primary health service.

Response: As noted above, the Act links preventive primary health services to the PHS requirements. Although HRSA guidelines include nutritional assessment, they do not include nutritional counseling and education. Because the HRSA guidelines do not specifically include nutritional education and counseling as a preventive primary health service, we do not have the authority to include these as preventive services in the FQHC regulations.

Nutritional education and counseling are tools to maintain or improve an individual's nutritional status. Generally, nutritional education and counseling can be defined as a means of educating the patient. Nutritional education and counseling for a Medicare beneficiary could be covered if it is provided to the beneficiary as a service that is ''incident to'' the service of a particular practitioner. The beneficiary must see an attending FQHC professional for a medical reason to which the nutritional education and counseling is incident. For example, nutritional education for a diabetic patient being actively monitored by an FQHC practitioner could be covered as an ''incident to'' service.

We note that encounters with a nurse or dietitian that are not associated with a visit by an FQHC practitioner are not billable as visits. The costs of the personnel providing the educational services, however, may be included in the center's allowable costs.

Comment: One commenter requested clarification of what is meant by nutrition assessment and who could perform the assessment. The commenter recommended that a registered dietitian is the best qualified professional to provide the service.

Response: HRSA guidelines include nutritional assessments and referrals as preventive primary health services; therefore they are covered as FQHC preventive primary health services. Because nutritional assessments are FQHC covered preventive services, any professional in an FQHC can provide these services. We believe that most physicians, nurse practitioners, and physician assistants, have the skills necessary to conduct a nutritional assessment as a preventive primary health service for Medicare beneficiaries.

However, the physician may use the services of a dietician employed by the FQHC for those beneficiaries who require extensive assistance in making dietary changes. As noted above, the services of a dietician may be covered under the FQHC benefit when the service is provided to the beneficiary as ''incident to'' the services of a physician, nurse practitioner, or a physician's assistant service. An FQHC professional must see the beneficiary for a medical reason to which the services of a dietician are incident. The initial face-to-face encounter with the attending professional is necessary for the service to be billed as an FQHC visit. The definition of a visit is discussed at § 405.2463.

Comment: Several commenters voiced strong objections to the exclusion of group counseling as a preventive service. They believed it is more efficient for the center to furnish needed counseling services, such as diabetic education, in a group setting rather than to use valuable physician time.

Response: As noted above, the Act links the definition of preventive primary health services under the FQHC benefit to the PHS law. Group counseling is not included as a preventive primary health service in the PHS law. As a result, we do not have the authority to include such services as FQHC preventive services.

In addition, group counseling is seldom a medical service, and generally, no active medical treatment is provided during a classroom situation. Moreover, there is an absence of scientific evidence that group counseling, such as smoking cessation classes, alters behavior or health status of individuals. Although group counseling services, such as diabetic education, are not covered preventive services, individual counseling services could be considered covered FQHC services if they are provided to the beneficiary as an ''incident to'' service.

Comment: One commenter noted that items five and six in the preventive services list both say prenatal. The commenter believed that one of the preventive services should be perinatal care.

Response: Section 1861(aa)(3)(B) of the Act specifies that FQHC services include preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act. In developing the FQHC regulations, we looked to 42 CFR parts 51c and 56 of the HRSA regulations. These regulations are repeated in § 405.2448 exactly as they are in the HRSA regulations; the HRSA regulations do not include perinatal services. However, the PHS law (see 45 U.S.C 329(a)(6)(C)) does provide for perinatal services. Therefore, we are revising § 405.2448 to include perinatal care as a covered preventive service.

Comment: Several commenters objected to the requirement in the preventive services definition that services be furnished by a physician or an employee of the center. The commenters noted that many centers make extensive use of contract services in the provision of preventive care services that may not be needed on a daily basis.

Response: The FQHC benefit includes a provision for services furnished ''incident to'' the services of FQHC professionals as long as the individuals furnishing the services are employees of the FQHC. As we noted above, it is a longstanding Medicare policy, based on our interpretation of section 1861(s)(2)(A) of the Act, that an individual who performs ''incident to'' services must be an employee of the clinic or center for purposes of coverage.

The list of FQHC preventive primary health services includes the type of services that does not generally require the skill level of a specialist. It is our intent that preventive primary health services, for the most part, involve a screening process to detect health conditions that could indicate adverse health outcomes. Patients should be referred for diagnostic services if the initial screening indicates a potential problem. Thus, we believe that the preventive primary health services specified in the regulations can be provided by the staff of the FQHC. As a result, we are retaining the requirement that FQHC preventive services be provided by either a physician or an employee of the center.

Comment: One commenter questioned how his facility, which provides noninvasive diagnostic services can be reimbursed through FQHCs.

Response: It is not clear what the commenter meant by ''noninvasive diagnostic services.'' Diagnostic laboratory services must be billed by the entity providing the services. Consequently, if the commenter intended to refer to laboratory services, the entity must bill for such services itself. As noted previously, diagnostic radiological services are not covered FQHC services. Thus, an entity could not be paid under the FQHC benefit for the technical component of radiological services. Although diagnostic radiological services are not covered FQHC services, a supplier can be paid for these services furnished to FQHC patients under normal Medicare Part B payment rules.

Comment: One commenter expressed concern that physicians and nurse practitioners are untrained in hearing testing and the fitting of hearing aids. The commenter recommended that Medicare ensure that beneficiaries have access to hearing aid distributors either for the initial FQHC covered hearing screening service or for follow-up services. The commenter suggested that we require that any patient whose screening shows that follow-up care is necessary be referred to a State licensed or National Board for Certification-Hearing Instrument Sciences (NBC-HIS) certified hearing aid distributor.

Response: According to section 1862(a)(7) of the Act, diagnostic audiological services for the purpose of fitting a hearing aid are not Medicare covered services. It would be inappropriate for the Medicare program to regulate referrals for such noncovered services.

The HRSA guidelines provide that hearing screening is a preventive primary health service. The skills that are needed to provide diagnostic services for hearing screening are minimal, and they can be acquired by staff with minimal training. Therefore, we believe that FQHC staff generally are qualified to perform hearing screening services for Medicare beneficiaries.

According to the Medicare Carrier's Manual, section 2070.3, additional diagnostic services beyond hearing screening are covered by Medicare when a physician orders such testing for the purpose of obtaining additional information necessary for his or her evaluation of the need for or appropriate type of medical or surgical treatment for a hearing deficit or related medical problem. However, additional service is not covered when the medical or surgical treatment is already known by the physician or is not under consideration and the diagnostic services are performed only to determine the need for or the appropriate type of hearing aid.

Comment: One commenter advised us of an upcoming HRSA directive requiring testing for tuberculosis of certain high risk patients. Since this will be a required preventive primary health service for all grantees, the commenter recommended that the Medicare list of preventive services be similarly amended.

Response: Since the Act links the definition of primary preventive services in an FQHC to the services required by HRSA of its grantees under sections 329, 330 and 340 of the PHS Act, we believe that the regulations should reflect HRSA guidelines. HRSA has sent a memorandum to grantees to

notify them that tuberculosis testing will be included as a preventive primary health service. Therefore, we are revising § 405.2448 to specify that FQHC covered preventive primary health services include testing of certain high risk patients for tuberculosis.

Clinical Psychologist and Clinical Social Workers

Comment: One commenter requested clarification as to why the RHC regulations were not similarly amended to include clinical psychologists and clinical social workers in accordance with changes made in the law years earlier.

Response: OBRA '87 added coverage of clinical psychologists in RHCs and OBRA '89 added coverage of clinical social workers in RHCs. We are in the process of developing a proposed rule to make those changes to the RHC regulations. Unlike the OBRA '89 provisions affecting RHCs, OBRA '90 authorized us to issue final regulations and add coverage of FQHCs without first issuing a proposed rule and soliciting public comment.

Comment: One commenter noted that the regulations state that clinical psychologist and clinical social worker services are covered if provided by a center employee. The commenter believed that it is often more efficient to contract for such service in the FQHC setting and recommends modification of the regulations to cover such purchased services.

Response: Previously, we permitted facilities to contract only for physician services. After considering the comment, we came to the conclusion that it would be inconsistent with the provisions of the PHS Act (as explained elsewhere in this preamble) to prohibit an FQHC from contracting for the services of clinical psychologists and clinical social workers. Therefore, we are revising § 405.2450 to provide that the services of clinical psychologists and clinical social workers may be covered if they are furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC. We are also revising §§ 405.2468 and 491.9(a)(3) to clarify that a clinical social worker or clinical psychologist may furnish services under contract to the FQHC.

Comment: One commenter objected to the limitation on clinical social worker service to those necessary to the diagnosis or treatment of mental illnesses. They noted that, given the special needs of the patient population served by FQHCs, social workers may perform other health related services for patients.

Response: Section 1861(hh)(2) of the Act provides that clinical social worker services include services performed by a clinical social worker for the diagnosis and treatment of mental illnesses. The Act does not indicate that any different definition of services provided by a clinical social worker should apply for purposes of the FQHC benefit.

The comment implies that the services of clinical social workers are needed to provide non-medical services to the FQHC population. Even if such services might be helpful to the FQHC population, non-medical services are not covered by Medicare under any circumstances.

Comment: Several commenters objected to the application of the 62½ percent mental health limitation to the FQHC clinical psychologist and clinical social worker. They argued that if the Congress had intended this limitation to apply, it would have explicitly stated so in the Act.

Response: Section 1833(c) of the Act states:

> Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psychoneurotic and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) only 62½ percent of such expenses.

This section of the Act clearly indicates that there is a mental health treatment limitation of 62½ percent for clinical psychologist and clinical social worker and other practitioner treatment services consistent with State law and makes clear that the limitation applies unless it is explicitly waived elsewhere in the law. This result is consistent with section 1861(hh)(2) of the Act, which defines clinical social worker services as services performed by a clinical social worker for the diagnosis and treatment of mental illnesses.

Since there is no statutory exception for FQHCs, the limitation on payment for mental health treatment applies to all FQHCs, free-standing and provider-based.

Payment Issues

Productivity Screening Guidelines

Comment: A commenter stated that the productivity standard of 4200 visits for a full time equivalent physician is not a reasonable standard and acknowledged that HRSA uses this standard but stated that HRSA applies the standard differently in regard to HRSA's encounters as opposed to HCFA's visits.

Response: Our use of the term ''visit'' is meant to be synonymous with the term ''encounter'' used by HRSA. The same concern about conflicting use of terms by us and HRSA was raised when we implemented productivity screens for the RHC program. At that time, we and HRSA agreed on the meaning of the terms ''encounter,'' as used by HRSA, and ''visit,'' as used by us; they were to be used interchangeably. (This issue was addressed in a final notice, Rural Health Clinic Payment Limits and Productivity Screening Guidelines, published in the Federal Register on December 1, 1982 at 47 FR 54165). We and HRSA agreed to a common definition of these two terms to eliminate any difficulties caused by the use of different terms. Clinics also found it difficult to comply with the separate productivity guidelines and reporting requirements used by us and HRSA. As a result we adopted the productivity screening guidelines used by HRSA. We continue to use the HRSA guidelines.

Since the time that we and HRSA originally reached agreement on the common meaning of ''encounter'' and ''visit,'' the RHC program has expanded and the FQHC program has been implemented. We have reexamined our definition. We are modifying the definition of a ''visit'' to accommodate the addition of clinical psychologists and clinical social workers (§ 405.2463). This change is discussed in more detail in answer to other comments. We will continue to use the HRSA productivity guideline of 4200 visits for full time equivalent.

Comment: A number of commenters stated that the screening guidelines are not appropriate for all FQHCs. For instance, a commenter stated that, without special attention, small rural health centers and those in frontier areas would be penalized by the productivity and overhead screens. Two other commenters stated that the standard should be lowered and that separate and lower standards should be developed to apply to FQHCs with home visiting and teaching programs. The commenter stated that Federal policy is clearly moving in the direction of providing incentives to increase the number of primary care physicians and that health centers will be increasingly asked to take on the role of residency training and argued that a productivity standard should not impede this policy direction. Additionally, two other commenters stated that the hourly standard, used in the past by the FFHCs, of 2.4 visits per hour is a more realistic standard than the one we had published.

Response: We use the same guidelines applied by HRSA in the grant review process and the ongoing monitoring of its programs. We believe it is appropriate to use uniform productivity guidelines rather than developing separate guidelines. If, however, an FQHC cannot meet these guidelines, the FQHC's intermediary has the authority to modify the productivity guidelines. An FQHC that has atypical circumstances may request exceptions to the guidelines from its intermediary.

Provider-Based/Freestanding FQHCs

Comment: Commenters questioned the need for different payment methodologies for freestanding and provider-based FQHCs and why provider-based FQHCs use an intermediary other than the intermediary used by the freestanding FQHCs and stated that the Act does not provide for a distinction between provider-based and freestanding FQHCs.

Response: As we stated in the June 12, 1992 final rule, the same qualification and coverage rules apply to both provider-based FQHCs and independent FQHCs. Section 1833(a)(3) of the Act allows the Secretary latitude in defining the payment methodology for FQHCs. Consistent with the RHC payment methodology, we believe, at this time, that two different methodologies should apply to provider-based and freestanding FQHCs, as well. Like an RHC, an FQHC that is an integral part of a provider should follow the rules applicable to the provider, since it is a provider component. Having the provider's intermediary pay the FQHC under the same cost reporting and payment procedures used by other components of the provider is more efficient, both from the standpoint of the intermediary and the provider. This promotes consistency and rationality in the payment system, eliminates duplicate audits and minimizes the possibility of program abuse.

Comment: A commenter pointed out that there is a cap for payment to freestanding FQHCs but not provider-based FQHCs.

Response: While there is no payment limit (cap) for provider-based FQHCs as there is for freestanding FQHCs, the allowable costs of provider-based FQHCs' are controlled by the Medicare principles of reimbursement. These principles permit us to determine if costs are reasonable and limit reimbursable costs to those that are allowable and necessary for the efficient delivery of services.

Comment: One commenter stated that freestanding FQHCs electing payment on a reasonable charge basis will not be reimbursed for preventive services and requested that the regulation clarify that provider-based FQHCs will be paid for preventive services. Another commenter suggested that the payment for these additional preventive services be specifically addressed and recommended that payment for these services be on an actual cost basis.

Response: All freestanding FQHCs are paid on an all-inclusive rate basis subject to tests of reasonableness. Freestanding FQHCs do not have the option to elect payment on a reasonable charge basis. Further, § 405.2446(b) specifies that FQHC services that are paid for under the Medicare program include preventive services specified in § 405.2448. This coverage applies to all FQHCs, freestanding as well as provider based. In addition, we do not believe that it is necessary to address specifically the payment method for these preventive services. Except for their purpose, these preventive services do not differ from the other services provided in a provider-based FQHC and therefore, are paid under the same reasonable cost principles as all other services.

Comment: One commenter questioned whether the lesser of costs or charges limitation, which currently is applied to provider-based FQHCs, should be applicable to any type of FQHC, as section 1833(a)(2) of the Act specifically provides that this limitation does not apply to FQHCs.

Response: Section 1833(a)(2) of the Act requires that the lesser of costs or charges limitation apply with respect to the facilities not excepted under that subparagraph; the requirement simply does not apply to FQHCs. Authority for payment for FQHCs is contained in section 1833(a)(3) of the Act, which provides that payment for FQHCs is based on reasonable costs that are ''related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations * * *''.

Given this broad grant of authority to use ''other tests of reasonableness,'' we are authorized to apply tests of reasonableness that are required to be applied to other Medicare facilities, such as the lesser of costs or charges provision.

Visits

Comment: Several commenters expressed concern with the number of visits per day we allow for payment purposes. They suggested that if a patient sees more than one physician or practitioner or has a medical and mental health service on the same day more than one visit should be allowed.

Response: We have considered the comments, and we are amending the regulations to permit payment for more than one visit per day under certain circumstances. We are revising the definition of visit in § 405.2401 and moving it to § 405.2463, ''What constitutes a visit.'' We now provide that Medicare pays for an additional visit per day if a patient has a ''medical visit'' and an ''other health visit'' on the same day. A ''medical visit'' is defined as a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse. An ''other health visit'' is defined as a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for therapeutic mental health services. This change permits payment for more than one visit, but it does not change any other part of the method for determining allowable visits. We still would allow only one medical visit per day. Readers should note that an increase in visits will affect the FQHC all-inclusive rate calculation, as provided in § 405.2464.

Pneumococcal Vaccine

Comment: A commenter noted that the preamble stated that pneumococcal vaccine would be paid at 100 percent of the Medicare reasonable cost of the vaccine and its administration. However, the Annual Reconciliation section of the regulation did not address how we would pay for pneumococcal vaccine.

Response: We are revising § 405.2466(b), Annual Reconciliation, to provide that, for RHCs and FQHCs, payment for pneumococcal vaccine and its administration is made at 100 percent of Medicare reasonable cost.

Additionally, we are making a corresponding revision to the Annual Reconciliation section of the regulation for influenza vaccine. In accordance with sections 4071 and 4072 of OBRA '87, influenza vaccine and its administration became a covered Medicare service under section 1861(s)(10)(A) of the Act effective May 1, 1993.

Section 1833(a)(3) of the Act specifies that services described in section 1861(s)(10)(A) are exempt from payment at 80 percent of reasonable costs. For RHCs and FQHCs, payment for influenza vaccine and its administration is at 100 percent of reasonable cost. Like pneumococcal vaccine, influenza vaccine will be treated as a pass through

and not included in the all-inclusive rate or subject to the payment limit.

Prior to this change, costs of influenza vaccine were included in the calculation of the all-inclusive rate and subject to the FQHC payment limit. Therefore, the FQHC payment limit(s) has been adjusted to reflect the removal of influenza vaccine from the calculation of the all-inclusive rate. Removal of the influenza vaccine and its administration results in a reduction of approximately 1 percent to the FQHC payment limits.

Note: Influenza vaccine costs were included in the original calculation of the preventive service adjustment as discussed in the June 12, 1992 final rule, at 57 FR 24972.

Contracted Services

Comment: A commenter stated that if a physician is an independent contractor on the staff of the facility and not a physician whose services are purchased on a limited basis the physician should not be characterized as a contracted physician that is subject to the fee schedule.

Response: To determine whether a physician is considered an employee, the ''usual common law rules,'' referred to in section 210(j)(2) of the Act, are applied. These rules not only consider who pays the practitioner's salary but other factors such as who has hiring and firing authority, and who pays FICA taxes and withholds income tax. When a physician is considered staff of the FQHC, the physician's salary is included on the cost report and is used in determining the facility's all-inclusive payment rate.

Comment: A commenter stated that the allowable cost of contracted physician services is limited to the resource based relative value scale (RBRVS) fee schedule for the Medicare program, which is significantly below market. The commenter further stated that this limit would restrict the FQHCs' ability to attract needed physicians and specialists to their communities. The commenter stated that we should establish another test of reasonableness.

Additionally, another commenter stated that a more appropriate test of reasonableness for contracted services would be the amount that non-participating physicians may receive for services they provide to Medicare beneficiaries.

Response: We believe that payment for contracted physician services should be limited to amounts accepted by the large majority of physicians. According to the Report to Congress on Physician Participation, Assignment, and Extra Billing in the Medicare Program, dated October 2, 1992, there has been a continuing increase in the number of physicians accepting assignment on claims. When a physician accepts assignment on a claim, he or she agrees to accept the Medicare allowed amount as payment in full for the services provided to the beneficiary. The Report to Congress stated that allowed charges for Medicare assigned claims represented 83.6 percent of the total allowed charges in 1991. This is consistent with trends indicating that physician assignment rates have increased and have maintained a high level. Moreover, readers should note that the limit on contracted physician services is a screening guideline and not an absolute payment limit. The guideline is applied to assess the reasonableness of payments for physician services purchased by the center. The fiscal intermediary may modify application of this screen for atypical circumstances. For example, the screen may be modified if the intermediary determines that access to care is significantly affected. We believe that the amounts paid under the physician fee schedule are appropriate limits for contracted physician services.

Payment Limit

In response to the FQHC payment methodology published on June 12, 1992, we received comments from 18 commenters regarding the application of a payment limit. Six of these were from health centers and eight were from organizations and persons representing the health centers' interests. The remaining four commenters were organizations representing hospitals, physicians, and nurses. Discussion of comments regarding the FQHC payment limit have been organized into the following categories: General Payment Limit; Adjustment For Projected FQHC Visit Mix; Primary Care Family Practice Adjustment; Urban and Rural Determination; Urban and Rural Payment Difference; and Exceptions Option.

General Payment Limit

Comment: Many of the commenters questioned the method used to calculate the payment limits. Commenters stated that a payment limit of this nature is not required by the Congress, is not consistent with Congressional intent and exceeds statutory authority. Commenters were concerned that we used the RHC payment limit as a base for determining the reasonable costs for FQHC services. In addition, commenters stated that the payment limit methodology is not based on empirical data, not based on cost and is not equitable.

Response: The same statutory payment authority applies to RHCs and FQHCs. This authority provides the Secretary latitude in determining a payment methodology and in determining costs based on tests of reasonableness defined in regulations. In order to implement this new benefit in a manner consistent with the language of the law, we adopted the RHC methodology for use in the FQHC program. We believe that the Congress designed the FQHC program as a parallel program to the RHC program. Not only is the payment authority identical but the core services are also the same. The Congress added preventive services to this core set of services for FQHCs, and these services are unique to the FQHC program.

Inherent in the adoption of the RHC methodology is the use of the productivity screens and an overall limit on payment. The RHC payment limit established for independent facilities in 1978 and updated in 1982 was not only accepted by the Congress, it was written into law in OBRA '87 as a test of reasonableness for costs of RHC services, including clinical psychologist services, which were added to the benefit in the same legislation. The law provided for an update to the limit for 1988 and an annual update each year thereafter. We agree that an annual update is important for the viability of both the RHC and FQHC benefits. We also believe that, while it is critical to apply an overall limit to ensure efficiency and economy, we must establish a limit that takes into account the differences in the two benefits.

The FQHC methodology we created adjusts for differences between the RHC and FQHC benefits using available cost data. We have made adjustments to the RHC limit accounting for the general increase in physician payments resulting from the physician fee schedule amounts, a projected higher ratio in FQHCs than in RHCs of physician visits compared to mid-level practitioner visits, the addition of primary preventive services, and the fact that some FQHCs are located in urban areas.

In constructing our preventive service adjustment, we used allowable charge data. We believe that the calculation of this adjustment is consistent with the methodology used to compute the RHC limit, which used allowable charge data and is now statutorily set. We do not see any conflict between our methods and the intent of the Congress.

Comment: One commenter stated that the payment limits are unreasonable with respect to actual reasonable costs. The commenter stated that FFHCs in

Massachusetts received rates in the $78 to $88 range with a limit of approximately $96. The commenter contended that the FQHC payment limits understate the actual cost per visit for these section 329 and 330 grantees that were previously paid as FFHCs. Another commenter recommended that we adopt the FFHC State-wide payment limits for the next 3 years while the reasonable costs of FQHCs are studied. The commenter stated that a limit should be developed based on future data.

Response: We do not believe it is appropriate to compare FFHC and FQHC limits. The FQHC payment methodology and scope of services is different from those in the former FFHC program. The comments indicate confusion regarding the differences between the two benefits. Even with these basic differences, we are concerned that we do not disadvantage centers that were paid as FFHCs and that is why we are allowing an exception for these entities for a 3-year period.

FFHCs were formerly paid on a ''cost related to reasonable charge basis,'' which also resulted in an all-inclusive rate per visit based on facility-specific costs. Application and computation of the FFHC all-inclusive rate is significantly different from application and computation of the FQHC rate. The FQHC all-inclusive rate is paid when there is an encounter between a patient and a physician, physician assistant, nurse practitioner, clinical psychologist, or clinical social worker. The FFHC all-inclusive rate was paid only when there was an encounter between a patient and a physician. The FQHC all-inclusive rate per visit is calculated based on total allowable FQHC cost divided by physician, physician assistant, nurse practitioner, clinical psychologist, and clinical social worker visits. The FFHC rate per visit was calculated based on total allowable FFHC costs divided by physician visits. As a result, the FFHC all-inclusive rate formula had a divisor of only physician visits thus yielding a higher rate per visit.

Further, the scope of services for the FQHC and FFHC benefits is different. Section 1861(aa)(3) of the Act identifies FQHC services as physician, physician assistant, nurse practitioner, clinical psychologist and clinical social worker services, and services and supplies incident to the services of these practitioners. In addition, preventive primary health services that a center is required to provide under sections 329, 330 and 340 of the PHS Act are also included as FQHC services. Medicare freestanding FQHCs are paid an all-inclusive rate for these services for each encounter that meets the definition of a visit. FQHCs could receive additional payment for Medicare covered services that are outside of the FQHC scope of services.

The FFHC scope of services could potentially have included all Medicare Part B services. Therefore, total allowable FFHC services could have included a broader array of services. Medicare Part B services outside of the FQHC scope of services (such as other diagnostic and therapeutic services that a clinic obtains from an independent laboratory) were covered FFHC services, and included in the rate paid to FFHCs. All Medicare Part B services performed in an FFHC were included in determining the all-inclusive rate and paid for under the FFHC methodology for each FFHC visit. For these reasons, we do not believe the FFHC payment limits are appropriate for the FQHC benefit.

Comment: One commenter stated that the use of FFHC information in combination with RHC data to develop the FQHC payment limits does not assure adequate reasonable cost reimbursement for all FQHCs. The RHC and FFHC programs are optional programs in which organizations choose to participate. Entities granted FQHC status under OBRA '90 that did not participate in the FFHC program may be significantly different from FFHCs and RHCs in case load.

Response: As discussed in a prior response, we believe that the Congress designed the FQHC program as a parallel program to the RHC program, and we used the RHC payment limit as a basis for developing the FQHC payment limits. We adjusted the RHC payment limit based on FFHC data for a projected higher physician visit mix and for the urban differential. We understand the concern that the cost experience of FFHCs may not necessarily be representative of the costs of FQHCs as a whole. We analyzed 1990 data provided by the Public Health Service's Bureau of Primary Health Care Common Reporting Requirements (BCRR) Report to determine whether the cost per encounter would differ for FFHCs and other section 329 and 330 grantees. The data indicate that the median cost per visit for FFHCs was slightly higher than the median cost per visit for community and migrant health centers that were not paid as FFHCs. Since FFHC costs were actually higher than other section 329 and 330 grantees, we believe that using FFHC data would result in adequate reasonable cost payments.

We also considered the application of a case mix adjustment; however, we do not believe one is necessary given the FQHC scope of services. We believe that, since the primary mission of the FQHC program is to provide outpatient primary care services, the services should not vary substantially from one patient population to another.

As discussed in the preamble to the June 12, 1992 final rule with comment period, we will collect and analyze FQHC cost report data to determine if a payment limit adjustment is necessary. If after analysis, we find it necessary to adjust the methodology used to determine the FQHC limits currently in place, we will issue a proposed notice and the public will have an opportunity to comment.

Comment: One commenter stated that we should describe the specific tests of reasonableness in regulation text so that these methods may not be changed without public review and comment.

Response: We agree that a change in specific tests of reasonableness used to determine the all-inclusive rate should receive the benefit of public notice and comment. We will issue a proposed notice and the public will have the opportunity to comment if it is necessary for us to change the productivity or utilization screens used to determine the FQHC all-inclusive rate or to change the methodology used to calculate the FQHC payment limit.

Adjustment for Projected FQHC Visit Mix

Comment: One commenter stated that the Secretary did not use factual data to determine the difference in cost created by the projected difference in case mix. The commenter believed there is no evidence that the ratio of physician to mid-level payments made under Part B have any relation to cost.

Response: Since entities eligible for section 329, 330, and 340 grants will comprise the majority of entities qualifying for the FQHC program, we anticipate that the frequency of physician services in FQHCs will be comparable to the frequency of such services in the former FFHC program, which consisted of section 329 and 330 grantees paid an all-inclusive rate. As discussed in the preamble to the June 12, 1992 rule, we studied RHC and FFHC visit data to determine whether there is a difference in the number of physician visits as a percentage of total visits between the RHC benefit and FFHC program. Visit data from RHC cost reports indicated that physician visits were 59 percent of total visits while data from FFHC cost reports indicated that

physicians visits were 83 percent of total visits.

We recognize that no specific FQHC study has been conducted to determine the differences in costs between the services of a physician and those of a mid-level practitioner. We used the amount of payment for nurse practitioners and physician assistants under usual Part B rules as a measure of the cost differences between a physician and a mid-level practitioner. Under Medicare Part B, the amount of payments for nurse practitioners (section 1833(r)(2)(B) of the Act) and physician assistants (section 1842(b)(12)(B) of the Act) are generally 75 percent (in the case of services provided in a hospital) and 85 percent (in the case of other services) of what a physician would be paid for the same service. We used the midpoint of these two percentages to arrive at 80 percent as proxy for the cost differences between mid-level practitioners and physicians.

Lacking more specific FQHC cost data, we believe that the payment amount under Medicare Part B is a reasonable basis for determining average cost differences between visits of physicians and mid-level practitioners and for increasing the payment limit to account for the projected higher number of physician visits under the FQHC benefit as compared to the RHC benefit. As discussed earlier, we plan to evaluate actual FQHC cost data. After analysis, we will determine the appropriateness of the visit mix adjustment.

Primary Care Family Practice Adjustment (15 Percent)

Comment: Section 6102 of OBRA '89 added section 1848 of the Act, which is the authority for the physician fee schedule. During the first year of transition to the physician fee schedule there was a general increase in payment of 15 percent for services provided by primary care and family practice physicians. As discussed in the preamble to the interim final rule, we made an adjustment to the FQHC payment limits accounting for this increase.

One commenter stated that the 15 percent adjustment to the payment limit only covers the first year of the transition to the fee schedule. The remaining 4 years to fully implement the fee schedule will result in further increases. These increases should be recognized.

Response: We have given consideration to the commenter's position. By 1996, the average payment amount for services typically provided by family practice physicians will increase by an estimated 28 percent under the fee schedule, as compared to reasonable charge payments. Since our intent in creating and applying the family practice adjustment is to reflect the circumstances of physicians being paid under the fee schedule, we have decided to provide a comparable increase to the FQHC payment limits. We are increasing the practitioner component of the FQHC payment limits by 13 percent to bring the total increase amount to 28 percent to simulate the estimated increase in average payment amounts for primary care physicians. This adjustment will be phased in over 3 years. For calendar year 1994, we have increased the practitioner portion of the FQHC payment limits by 6.5 percent to correspond with the increase in payments for primary care services which has resulted from the continued transition to the full physician fee schedule. We previously announced this increase in the RHC/FQHC Manual. We will increase the payment limits by 3.25 percent in calendar year 1995 and calendar year 1996 to account for the full 28 percent increase.

The 28 percent increase is based on estimates published in the Federal Register (56 FR 59618) regarding the physician fee schedule regulation dated November 25, 1991; Table 1—Physician Fee Schedule Impact By Specialty. The 28 percent increase reflects the original estimation of the difference in payment amounts between what would have been paid under the reasonable charges payment methodology as compared to payments under the RBRVS fee schedule for services typically provided by family practice physicians. We believe it provides the most appropriate representation of the estimated differences in payment amounts. We have decided not to reflect the impact of the Medicare Volume Performance Standards since FQHC services are not subject to these targets. By adjusting the FQHC limits, we would avoid disadvantaging FQHC physicians and practitioners relative to physicians paid under the fee schedule.

Comment: One commenter stated that payments for other practitioners should also reflect the 15 percent increase.

Response: Implementation of the physician fee schedule resulted in a general estimated increase of 15 percent in 1992 for family practice physicians. We applied this increase to the practitioner component of the payment limit which resulted in a $6.99 increase for fiscal year 1991. This increase applies to the payment limit for each FQHC visit, mid-level practitioner covered visits, as well as physician visits.

Urban and Rural Determination

Comment: Two commenters indicated that the determination of urban and rural is unclear. Specific concerns focused on the need for clarification of specific population standards and whether adjustments to the classification (as provided for hospitals in § 412.230) are applicable to FQHCs.

Response: The definition of urban and rural is based entirely upon the most recent available data from the Bureau of Census and issued by the Office of Management and Budget. To be classified as an urban center, an FQHC must be located in a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Primary Metropolitan Statistical Areas (PMSAs) and Consolidated Metropolitan Statistical Areas (CMSAs) are considered as urban for FQHC classification purposes. FQHCs that are not in an MSA, PMSA, CMSA or NECMA cannot be reclassified as an urban FQHC.

Urban areas can either be ''large'' or ''other.'' A large urban area means an urban area with a population of over one million (or more than 970,000 in NECMAs). An ''other'' urban area is an urban area that is not a large urban area and at a minimum includes a city with a population of 50,000 or more provided that the component county/counties of the metropolitan statistical area have a total population of at least 100,000. The intermediary classifies FQHCs based on these criteria.

Urban and Rural Payment Difference

Comment: Many commenters expressed concerns regarding the urban payment differential. Specific concerns include:

- Historical differences in payment policy have affected the recruitment and retention of qualified health professionals and have caused a false perception that rural areas are less expensive.
- Labor, transportation and other costs can be higher in rural areas.
- Rural centers may expand services to compensate for the closing of small rural hospitals. Thus, they may be providing the only available radiology and laboratory services in the area.
- The FFHC study used to determine urban and rural cost differences was not appropriate. Urban and rural visit mix and services are not necessarily comparable and cost differences are not related to location; cost differences are more likely the result of rural facilities providing a more limited scope of

services. Therefore, we do not think this factor is relevant to payment limits.

Response: Our analysis of FFHC all-inclusive rates indicates a difference in urban and rural costs. FFHCs were authorized to provide the same scope of services regardless of urban or rural status. The analysis of FFHC all-inclusive rates included 128 urban and 85 rural FFHCs throughout the country. The analysis indicates that the median all-inclusive rate for FFHCs located in urban areas (as determined by using Bureau of Census data) is 16.3 percent higher than the median all-inclusive rate in rural areas. Since FFHCs were subject to the same State-wide payment limit without regard to urban/rural location, rural FFHCs did not have different incentives than urban FFHCs to hold down costs. Further, we obtained data from the Public Health Service based on the BCRR Report data and compared the cost per visit of 129 urban and 260 rural Community/Migrant Health Centers (section 329/330 grantees) that did not participate in the FFHC program. The BCRR Report cost data indicated that the cost per visit for services was significantly higher in urban centers as compared to rural centers. While different costs are reported on the BCRR Report as compared to the Medicare cost report, we believe these data support our use of FFHC cost data as proxy for urban and rural FQHC cost differences. We will closely study urban and rural cost differences in the FQHC cost data analysis.

We understand that rural centers might expand services to compensate for the closing of small rural hospitals and that many of these services may be outside of the FQHC benefit. While the expansion of services may extend beyond the FQHC scope of services, the Medicare per visit payment limits apply to covered FQHC services only. Medicare FQHCs can receive additional payments through the carrier for Medicare Part B services that are not included as FQHC covered services. Therefore, we do not think this factor is relevant to setting the payment limits.

Comment: Some commenters believed that the urban and rural payment limit difference is inconsistent with general Federal policy direction. They stated that the Congress recognized that urban and rural providers should be treated equally by terminating the urban and rural Prospective Payment System (PPS) payment differential in fiscal year 1995.

Response: We would like to clarify that the Congress has not eliminated geographic payment differences for payment of PPS hospitals. Effective in fiscal year 1995, there will be two PPS standardized amounts, large urban and other. The rural and other urban PPS standardized amounts will be combined into one amount and a separate large urban standardized amount will continue to distinguish large urban areas. The hospital wage index will be applied to these standardized amounts. As such, payment amounts will generally be higher in urban areas as compared to rural areas. Given the current data limitations, alternative geographic payment limit adjustments are not feasible at this time. As mentioned previously, we will closely study urban and rural cost differences in the FQHC cost data analysis.

MEI Index

Comment: One commenter expressed concern that separate application of the MEI to urban and rural payment limits will steadily exacerbate the urban-rural differential.

Response: Although we recognize that the dollar difference between urban and rural payment limits will increase, the percentage difference of 16.3 percent will remain constant.

Comment: One commenter requested clarification regarding publication of the MEI increase.

Response: The annual MEI updates applicable to the FQHC payment limits will be announced in the RHC and FQHC manual, HCFA Publication 27 of the HCFA Program Instructions Issuances System.

We note that the preamble of the June 12, 1992 rule stated that FQHC payment limits would be updated by the MEI applicable to primary care physicians. We would like to clarify that in the absence of a specific MEI applicable to primary care physicians, the FQHC payment limits will be updated by the general MEI.

Exceptions Option

Comment: Two commenters expressed opposition to the exceptions option. They stated that the exceptions option is an unreasonable imposition creating unnecessary administrative costs. In addition, requiring FQHCs to wait an entire year to file an exception will create cash flow problems for those granted an exception. Regional payment limits were also suggested as an alternative to the exceptions process.

Response: The exceptions process allows former FFHCs the opportunity to retain the FFHC method of payment with minor adjustments for the FQHC scope of services for a 3-year period under certain conditions. No FQHC is required to seek an exception; rather a center may choose this option if the center can document a disadvantage due to a decrease in revenues as a result of the application of the FQHC payment limit. As discussed in the preamble of the interim final rule, this determination will be made based on a filing of the FFHC cost report.

Any additional administrative costs resulting from the exceptions option are allowable costs that can be included in the determination of the all-inclusive rate. However, we expect exceptions to be limited in number and do not expect former FFHCs to be adversely affected. We believe it is essential that all centers, including former FFHCs, file based on the FQHC methodology so that we can gather cost data for our analysis.

We considered developing regional limits; however, we decided not to do so. We believe that the Congress designed the FQHC benefit to parallel the RHC benefit. Therefore, we want the FQHC payment methods to be as consistent as possible with the RHC payment methods, which do not include regional cost limits. As discussed earlier, we will collect and analyze FQHC cost data to determine if any changes are necessary.

Billing Issues

Comment: Two commenters requested clarification of the billing mechanism for non-FQHC services. One commenter noted that provisions for assignment of physician claims directly to the center were necessary so that the employment relationship between the physician and center is not disrupted.

Response: In order to bill for non-FQHC services a clinic must have a separate Part B billing number. The FQHC must obtain the billing number from the Medicare Part B carrier. Entities that already have supplier numbers for use in billing Part B carriers need to contact the carriers' Provider Relations Staff to see if their FQHC status necessitates the issuance of new Part B billing numbers. FQHC provider numbers assigned for the purpose of billing the intermediary (Aetna) cannot be used to bill Part B carriers. HCFA regional offices and Medicare carriers have been requested to assist FQHCs that require new Part B billing numbers.

We agree with the commenter on the issue of provisions of assignment. Section 1842(b)(6) of the Act specifies that Medicare may pay the center in which the physician provides services if there is a contractual arrangement between the facility and the provider. Therefore, there are existing provisions for assignment of physician claims directly to the center.

Comment: One commenter noted the difference in billing practices between Medicaid and Medicare, and

recommended that all FQHC services for both programs be billed on the HCFA–1500 using Common Procedure Terminology (CPT) Codes.

Response: There is no requirement for Medicare and Medicaid billing to be the same. Since payment for services covered under the FQHC benefit is made on a cost-related basis, claims are processed by a fiscal intermediary. All freestanding FQHC claims are processed by Aetna. Provider-based FQHC claims are processed by the intermediary that handles the main provider's claims.

The Medicare Fiscal Intermediaries' systems are set up to process bills using the HCFA–1450 and the Carriers' systems are set up to process claims using the HCFA–1500. The HCFA–1450 has different data elements from the HCFA–1500. To use the HCFA–1500 for cost-related payment would require a complete revision of the billing systems maintained by our contractors.

To recap, freestanding FQHCs must use the HCFA–1500 to bill for non FQHC services since they are not paid on a cost basis. The local Part B carrier pays for such services subject to the routine Part B coverage and payment provisions. Provider-based FQHCs bill the intermediary for all services on the HCFA–1450.

IV. Provisions of the Final Regulations

For the most part, as stated elsewhere in this preamble, this final rule does not change the provisions of the prior final rule on which we solicited comments. Those provisions of this final rule that differ significantly from the earlier rule are:

- The definition of specialized nurse practitioner is removed (§ 405.2401 and § 405.2468);
- A freestanding FQHC must terminate other provider agreements at the same time it becomes an FQHC (§ 405.2430(a)(1)(iii));
- The services of FQHC staff may be furnished under contract (§§ 405.2450, 405.2468(b)(1), and 491.8(a)(3));
- In the definition of ''visit,'' (now in § 405.2463) an allowance is made for two visits per day if the patient has a ''medical'' and an ''other'' health visit on the same day (§ 405.2463);
- Nurse-midwife services are added to the list of covered FQHC services (§ 405.2446);
- Perinatal care and tuberculosis testing for certain high risk patients are added to the list of preventive services that are covered by an FQHC (§ 405.2448);
- Payment for pneumococcal and influenza vaccines and their administration at 100 percent of Medicare reasonable cost is added to § 405.2466 (Note that payment for pneumococcal vaccine is not a new provision, as it was included in the June 12, 1992 final rule);
- We clarify that FQHCs must be located in a medically undeserved area or serve a medically undeserved population (§ 491.5);
- RHCs, but not FQHCs, retain certification even if the area loses its rural shortage designation (§ 491.5);
- Clinical psychologists provide FQHC services without the supervision of a physician (§ 491.8);
- We clarify that we have adjusted the FQHC payment limits to correspond with the estimated increase in payments for primary care services resulting from the continued transition to the full fee schedule. The current calendar year payment limits reflect this policy and a further increase is forthcoming in 1995.

V. Collection of Information Requirements

This final rule does not contain any information collection or recordkeeping requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

A. Introduction

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all FFHCs, FQHCs, and 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 the Secretary 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 50 beds.

B. Provisions of the Final Regulations

This final rule incorporates, with only minor technical and clarifying changes, the provisions of the final rule with comment published June 12, 1992 (57 FR 24961) which provided for coverage and payment of services provided by FQHCs, a category of health facility established by section 4161 of OBRA '90 and modified by OBRA '93. FQHC services are defined as the same type of primary health care services provided by rural health clinics under the Medicare program, plus preventive primary health services (services not previously covered by Medicare). An FQHC is an entity that is receiving a grant under section 329, 330, or 340 of the PHS Act; a non-grant receiving entity that is determined by the Secretary to meet the PHS Act requirements for receiving such a grant; a facility that has been identified by the Secretary as a comprehensive federally funded health center as of January 1, 1990; or is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act as of October 1, 1991. As of March 1994, there were 1,260 participating FQHCs.

C. Positive Effect of Regulations

In the initial regulatory impact statement, we indicated that the provisions of the final rule with comment will expand Medicare payment to community and migrant health center grantees and similar entities that qualify as FQHCs and serve the working poor. We noted that reporting requirements are less burdensome than previous requirements under the FFHC payment methodology (FQHCs are required to submit 2 cost reports annually, FFHCs were required to submit 3). In addition, these provisions benefit both beneficiaries and FQHCs by expanding Medicare coverage and payment to include primary and preventive health care services furnished by physicians and other health practitioners.

D. Comments on Initial Regulatory Impact Statement

We received one comment on the initial regulatory impact statement published in the Federal Register June 12, 1992. The commenter stated that the final rule with comment failed to include a certification that the rule would not have an effect on small entities. We disagree with the commenter. The final paragraph of the regulatory impact statement stated that we determined, and the Secretary certified, that the final rule did not meet the requirements to be determined a major rule, nor did it meet criteria as having a significant economic impact on a substantial number of small entities.

E. Summary

Because this final regulation makes only minor technical and clarifying changes to the final rule with comment published June 12, 1992, we are not preparing analyses for either the RFA or section 1102(b) of the Act, since we have determined, and the Secretary certifies, that this final 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 not reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

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

42 CFR Part 491

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

42 CFR chapter IV is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

A. Part 405, subpart X, is amended as follows:

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

Authority: Secs. 1102, 1833, 1861(aa), 1871 of the Social Security Act; 42 U.S.C. 1302, 1395l, 1395x(aa), and 1395hh.

§ 405.2401 Scope and definitions. [Amended]

2. In § 405.2401, paragraph (b) is amended by removing the definitions of ''specialized nurse-practitioner'' and ''visit.''

3. Section 405.2430 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 405.2430 Basic requirements.

(a) Filing procedures. (1) * * *

(iii) The FQHC terminates other provider agreements, unless the FQHC assures HCFA that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

* * * * *

4. Section 405.2446 is amended by revising paragraph (b) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

* * * * *

5. In § 405.2448(b), the semicolon at the end of each paragraph is changed to a period, paragraph (b)(20) is redesignated as (b)(21), paragraphs (b)(6) and (b)(19) are revised, and a new paragraph (b)(20) is added to read as follows:

§ 405.2448 Preventive primary services.

* * * * *

(b) * * *

(6) Perinatal services.

* * * * *

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

* * * * *

6. Section 405.2450 is amended by revising paragraph (a)(1) to read as follows:

§ 405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

* * * * *

7. A new § 405.2463 is added to read as follows:

§ 405.2463 What constitutes a visit.

(a) *Visit.* (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or clinical social worker.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) *Payment.* (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) *Medical visit.* For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(c) *Other health visit.* For purposes of paragraph (a)(3) of this section, an other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

8. Section 405.2466 is amended by adding a new paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

9. Section 405.2468 is amended by revising paragraphs (b)(1) and (b)(3), and (d)(2) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(b) * * *

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

* * * * *

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

* * * * *

(d) * * *

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

* * * * *

B. Part 491 is amended as follows:

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 Services Act (42 U.S.C. 263a).

2. In part 491, the term, ''Federally qualified health center'' is changed to ''FQHC'' wherever the term appears.

3. Section 491.5 is amended by revising paragraphs (a) and (b)(1), and adding new paragraphs (e) and (f) to read as follows:

§ 491.5 Location of clinic or center.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

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

(3) Both the RHC and the FQHC may be permanent or mobile units.

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

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

(iii) *Permanent unit in more than one location.* If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions.* (1) HCFA does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

* * * * *

(e) *Medically underserved population.* A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs.* An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

4. Section 491.8 is amended by revising paragraphs (a)(3), (a)(6) and (b)(1)(i) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* * * *

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

* * * * *

(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 rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities.* (1) The physician—

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

* * * * *

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

Dated: October 6, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: March 18, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–7787 Filed 4–2–96; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–7176]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Acting Associate Director, Mitigation Directorate, reconsider the changes. The modified elevations may be changed during the 90-day period.