

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Parts 405, 491, and 493**

[CMS-1443-P]

RIN 0938-AR62

**Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish methodology and payment rates for a prospective payment system (PPS) for federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act. This proposed rule would also establish a policy which would allow rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and make other technical and conforming changes to the RHC and FQHC regulations. Finally, this proposed rule would make changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referral.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 18, 2013.

**ADDRESSES:** In commenting, please refer to file code CMS-1443-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1443-P, P.O. Box 8013, Baltimore, MD 21244-1850.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1443-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

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

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

**FOR FURTHER INFORMATION CONTACT:** Corinne Axelrod, (410) 786-5620 for FQHCs and RHCs.

Melissa Singer, (410) 786-0365 for CLIA Enforcement Actions for Proficiency Testing Referral.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have

been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

**Acronyms**

AIR All-Inclusive Rate  
 APM Alternative Payment Methodology  
 CCN CMS Certification Number  
 CCR Cost-To-Charge Ratio  
 CFR Code of Federal Regulations  
 CLIA Clinical Laboratory Improvement Amendments of 1988  
 CMP Civil Money Penalty  
 CMS Centers for Medicare & Medicaid Services  
 CNM Certified Nurse Midwife  
 CP Clinical Psychologist  
 CSW Clinical Social Worker  
 CY Calendar Year  
 DSMT Diabetes Self-Management Training  
 E/M Evaluation and Management  
 FQHC Federally Qualified Health Center  
 FSHCAA Federally Supported Health Centers Assistance Act  
 GAF Geographic Adjustment Factor  
 GAO Government Accountability Office  
 GPCI Geographic Practice Cost Index  
 HCPCS Healthcare Common Procedure Coding System  
 HCRIS Healthcare Cost Report Information System  
 HBV Hepatitis B Vaccines  
 HRSA Health Resources and Services Administration  
 IDR Integrated Data Repository  
 IPPE Initial Preventive Physical Exam  
 MA Medicare Advantage  
 MAC Medicare Administrative Contractor  
 MCO Managed Care Organization  
 MEI Medicare Economic Index  
 MIPPA Medicare Improvements for Patients and Providers Act  
 MNT Medical Nutrition Therapy  
 MUA Medically Underserved Area  
 MUP Medically Underserved Population  
 NP Nurse Practitioner  
 OBRA Omnibus Budget Reconciliation Act  
 PA Physician Assistant  
 PHS Public Health Service  
 PFS Physician Fee Schedule  
 PPS Prospective Payment System  
 PT Proficiency testing  
 ResDAC Research Data Assistance Center  
 RIA Regulatory Impact Analysis  
 RHC Rural Health Clinic  
 SNF Skilled Nursing Facility  
 UDS Uniform Data System  
 USPSTF U.S. Preventive Services Task Force  
 UPL Upper Payment Limit



indicates that less than 0.5 percent of all billed visits were for more than 1 visit per day for the same beneficiary.

We understand that there may be many possible reasons why the rate of billing for more than one visit per day has been low, and that there are many ways that FQHCs are providing integrated, patient-centered health care services. Since the option to bill for more than one visit per day is rarely utilized by FQHCs and continuation of the exception to the single, all-inclusive payment per day requires additional complexity to the PPS, we are proposing to eliminate these exceptions for payment for multiple visits on the same day and limit FQHCs to 1 encounter payment per day. We believe this approach is consistent with an all-inclusive methodology and reasonable cost principles, and would not significantly impact FQHC reimbursement. However, we are interested in comments that address whether there are factors that we have not considered, particularly in regards to mental health services, and we would reconsider this approach if information is presented that this may impact on beneficiaries' access to services or the integration of services in underserved communities. For additional information on billing for multiple visits on the same day, see section B of this proposed rule.

#### c. Beneficiary Coinsurance

Under the current reasonable cost system, beneficiary coinsurance for FQHC services is assessed based on the FQHC's charge, which can result in the coinsurance amount being higher than what it would be if it was based on the AIR, which is derived from costs. Section 1833(a)(1)(Z) of the Act requires that Medicare payment under the FQHC PPS shall be 80 percent of the lesser of the actual charge or the PPS rate, and we are proposing that coinsurance would be 20 percent of the lesser of the actual charge or the PPS rate. While the statute makes no specific provision to revise the methodology for determining coinsurance amounts under the new PPS, we believe that this is consistent with statutory language in sections 1866(a)(2)(A) and 1833(a)(3)(A) of the Act and elsewhere that addresses coinsurance amounts and Medicare cost principles.

#### d. Waiving Coinsurance for Preventive Services

Effective January 1, 2011, Medicare waives beneficiary coinsurance for eligible preventive services furnished by a FQHC. Medicare requires detailed Healthcare Common Procedure Coding

System (HCPCS) coding on FQHC claims to ensure that coinsurance is not applied to the line item charges for these preventive services.

For FQHC claims that include a mix of preventive and non-preventive services, we are proposing to use physician office payments under the Medicare PFS to determine the proportional amount of coinsurance that should be waived for payments based on the PPS encounter rate, and we would continue to use provider-reported charges to determine the amount of coinsurance that should be waived for payments based on the provider's charge. Total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the provider's charge or the PPS rate.

#### e. Transition Period and Annual Adjustment

The statute requires implementation of the FQHC PPS for FQHCs with cost reporting periods beginning on or after October 1, 2014. FQHCs would transition into the PPS based on their cost reporting periods. The claims processing system would maintain the current system and the PPS until all FQHCs have transitioned to the PPS. We are proposing to transition the PPS to a calendar year update for all FQHCs, beginning January 1, 2016, to be consistent with many of the PFS files that are updated on a calendar year basis. The statute also requires us to adjust the FQHC PPS by the MEI in the first year after implementation, and either the MEI or a FQHC market basket in subsequent years.

#### f. Other FQHC/RHC Provisions

In addition to proposing to codify the statutory requirements for the FQHC PPS in this proposed rule, we are proposing to allow RHCs to contract with non-physician practitioners, consistent with statutory requirements that require at least one nurse practitioner (NP) or physician assistant (PA) be employed by the RHC. The ability to contract with NPs, PAs, certified nurse midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) would provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners.

We are also proposing edits to correct terminology, clarify policy, delete irrelevant code, and make other conforming changes for existing mandates and the new PPS.

#### g. CLIA Enforcement Actions for Proficiency Testing Referral

The "Taking Essential Steps for Testing Act of 2012" (Pub. L. 112-202) amended section 353 of the Public Health Service Act to provide the Secretary with discretion as to which sanctions may be applied to cases of intentional PT referral in lieu of the automatic revocation of the CLIA certificate and the subsequent ban preventing the owner and operator from owning or operating a CLIA certified laboratory for 2 years. Based on this discretion, we would amend the CLIA regulations by adding three categories of sanctions for PT referral based on the severity and extent of the violation.

#### 3. Summary of Cost and Benefits

##### a. For the FQHC PPS

As required by section 1834(o)(2)(B)(i) of the Act, initial payments (Medicare and coinsurance) under the FQHC PPS must equal 100 percent of the estimated amount of reasonable costs, as determined without the application of the current system's UPL or productivity standards that can reduce a FQHC's per visit rate. The proposed FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 30 percent. The annualized cost to the federal government associated with the proposed FQHC PPS is estimated to be between \$183 million and \$186 million, based on 5 year discounted flows using 3 percent and 7 percent factors.

##### b. For Other FQHC and RHC Changes

The ability to contract with NPs, PAs, CNMs, CP, and CSWs would provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners, which may result in increasing access to care in rural areas. There is no cost to the Federal government and we are unable to estimate a cost savings for RHCs. In addition, we believe that there are no costs associated with the technical and conforming regulatory changes that would be made in conjunction with the establishment of the FQHC PPS.

##### c. CLIA Enforcement Actions for Proficiency Testing Referral Changes

Over a 4-year span, we estimate that an average of 6 cases per year may have fit the terms of described in this proposed rule to have alternative sanctions applied. We believe that the largest single type of cost is the expense to the laboratory or hospital to contract out for management of the laboratory, and to pay laboratory director fees, due

to the 2-year ban that prohibits the owner and operator from owning or operating a CLIA-certified laboratory in accordance with revocation of the CLIA certificate. Estimating the expense of alternative sanctions at \$150,000 per laboratory, the annual fiscal savings of the proposed changes for affected laboratories would be approximately \$2.6 million (\$578,400—\$150,000 for 6 laboratories). We note that there are a number of factors (known and unknown) that could impact this estimate. We also note that the total savings may not be large, but the savings to the individual laboratory or hospital that would be affected may be significant. However, we note that the \$2.6 million estimated savings to laboratories may overstate or understate the provision's net benefits. While we recognize that there are several potential inaccuracies in our estimates, we lack data to account for these considerations.

### B. Overview and Background

#### 1. FQHC Description and General Information

FQHCs are facilities that provide services that are typically furnished in an outpatient clinic setting. They are currently paid an AIR per visit for qualified primary and preventive health services furnished to Medicare beneficiaries.

The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in section 1861(aa)(4) of the Act. Based on these provisions, the following three types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program grantees: Organizations receiving grants under section 330 of the PHS Act (42 U.S.C. 254b).
- Health Center Program "look-alikes": Organizations that have been identified by the Health Resources and Services Administration (HRSA) as meeting the requirements to receive a grant under section 330 of the PHS Act, but which do not receive section 330 grant funding.
- Outpatient health programs/facilities operated by a tribe or tribal organization (under the Indian Self-Determination Act) or by an urban Indian organization (under Title V of the Indian Health Care Improvement Act).

Section 330 Health Centers are the predominant type of FQHC. Originally known as Neighborhood Health Centers, they have evolved over the last 45 years to become an integral component of the Nation's health care safety net system, with more than 1,100 centers operating approximately 8,900 delivery sites that

serve more than 21 million people each year from medically underserved communities. They include community health centers (section 330(e) of the PHS Act), migrant health centers (section 330(g) of the PHS Act), health care for the homeless (section 330(h) of the PHS Act), and public housing primary care (section 330(i) of the PHS Act).

FQHCs may be either not-for-profit or public organizations. The main purpose of the FQHC program is to enhance the provision of primary care services in underserved urban, rural and tribal communities. FQHCs that are not operated by a tribe or tribal organization are required to be located in or treat people from a Federally-designated medically underserved area (MUA) or medically underserved population (MUP) and to comply with all the requirements of section 330 of the PHS Act. Some of these section 330 requirements include offering a sliding fee scale to persons with incomes below 200 percent of the federal poverty level, and being governed by a board of directors of whom a majority of the members receive their care at the FQHC. According to HRSA's Uniform Data System (UDS),<sup>1</sup> approximately 8 percent of FQHC patients were Medicare beneficiaries, 41 percent were Medicaid recipients, and 36 percent were uninsured in 2012. The remainder was privately insured or had other public insurance. Medicare and Medicaid accounted for approximately 9 percent and 47 percent of their total billing, respectively.

Congress has authorized several programs to assist FQHCs in increasing access to care for underserved and special populations. Many FQHCs receive section 330 grant funds to offset the costs of uncompensated care and provide other services. All FQHCs are eligible to participate in the 340B Drug Pricing Program for pharmaceutical products. FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102-501) and FSHCAA of 1995 (Pub. L. 104-73 amending section 224 of the PHS Act) and may be eligible for Federal loan guarantees for capital improvements when funds for this purpose are appropriated. Title VIII of the American Recovery and Reinvestment Act (Pub. L. 111-5) appropriated \$2 billion for construction, equipment, health information

<sup>1</sup> The UDS collects and tracks data such as patient demographics, services provided, staffing, clinical indicators, utilization rates, costs, and revenues from section 330 health centers and health center look-alikes.

technology, and related improvements to existing section 330 grantees and for the establishment of new grantees sites. The Affordable Care Act appropriated an additional \$11 billion over a 5-year period (\$1.5 billion for capital improvements and \$9.5 billion for support and expansion of the 330 health centers). HRSA administers the 330 grant program and other programs that assist FQHCs in increasing access to primary and preventive health care in underserved communities.

#### 2. Medicare's FQHC Coverage and Payment Benefit

The FQHC coverage and payment benefit under Medicare was added effective October 1, 1991, when section 1861(aa) of the Act was amended by section 4161 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 (Pub. L. 101-508, enacted on November 5, 1990) and implemented in regulations via the June 12, 1992 final rule with comment period (57 FR 24961) and the April 3, 1996 final rule (61 FR 14640). Regulations pertaining to FQHCs are found primarily in 42 CFR Part 405, and 42 CFR Part 491.

FQHC covered services and supplies include the following:

- Physician, NP, PA, CNM, CP, and CSW services.
- Services and supplies furnished incident to a physician, NP, PA, CNM, CP, or CSW services.
- FQHC covered drugs that are furnished by, a FQHC practitioner.
- Outpatient diabetes self-management training (DSMT) and medical nutrition therapy (MNT) for beneficiaries with diabetes or renal disease.
- Statutorily-authorized preventive services.
- Visiting nurse services to the homebound in an area where CMS has determined that there is a shortage of home health agencies.

#### 3. Legislation Pertaining to Medicare and Medicaid Payments for FQHC Services

FQHCs currently receive cost-based reimbursement, subject to an upper payment limit (UPL) and productivity standards, for services furnished to Medicare beneficiaries, and PPS payment, based on their historical cost data, for services furnished to Medicaid recipients (section 1902(bb) of the Act). The UPL for Medicare FQHC services is adjusted annually based on the Medicare Economic Index (MEI), as described in 1842(i)(3) of the Act. Authority to apply productivity standards is found in 1833(a) and 1861(v)(1)(A) of the Act. Section 151(a)

of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275, enacted on July 15, 2008) increased the UPL for FQHC by \$5, effective January 1, 2010. Section 151(b) of the MIPPA required the Government Accountability Office (GAO) to study and report on the effects and adequacy of the Medicare FQHC payment structure.

Based on a GAO analysis of 2007 Medicare cost report data, about 72 percent of FQHCs had average costs per visit that exceeded the UPL, and the application of productivity standards reduced Medicare payment for approximately 7 percent of FQHCs. In 2007, application of the limits and adjustments currently in place reduced FQHCs' submitted costs of services by approximately \$73 million, about 14 percent (Medicare Payments to Federal Qualified Health Centers, GAO–10–576R, July 30, 2010).

The Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554, enacted December 21, 2000) created section 1902(bb) of the Act which established a PPS for Medicaid reimbursement. The law allowed state Medicaid agencies to establish their own reimbursement methodology for FQHCs provided that total reimbursement would not be less than the payment under the Medicaid PPS, and that the FQHC agreed to the alternative payment methodology (APM). For beneficiaries enrolled in a managed care organization (MCO), the MCO pays the FQHC an agreed upon amount, and the state Medicaid program pays the FQHC a wraparound payment equal to the difference, if any, between the PPS rate and the payment from the managed care organization.

The Affordable Care Act established a Medicare PPS for FQHCs. Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act, requiring the Medicare FQHC PPS to be implemented starting October 1, 2014. The new PPS for FQHCs is required to take into account the type, intensity, and duration of services furnished by FQHCs and may include adjustments, including geographic adjustments, determined appropriate by the Secretary. A detailed discussion of the statutory requirements for the Medicare FQHC PPS is discussed in section I.B. of this proposed rule.

#### 4. Medicare's Current Reasonable Cost-Based Reimbursement Methodology

FQHCs are paid an AIR per visit for medically-necessary professional services that are furnished face-to-face (one practitioner and one patient) with a FQHC practitioner (42 CFR 405.2463).

Services and supplies furnished incident to a FQHC professional service are included in the AIR and are not billed as a separate visit. Technical components such as x-rays, laboratory tests, and durable medical equipment are not part of the AIR and are billed separately to Medicare Part B.

The AIR is calculated by dividing total allowable costs by the total number of visits. Allowable costs may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of FQHC services. Cost reports are filed in order to identify all incurred costs applicable to furnishing covered FQHC services. Freestanding FQHCs complete Form CMS–222–92, “Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report”. FQHCs based in a hospital complete the Worksheet M series of Form CMS–2552–10, “Hospital and Hospital Care Complex Cost Report”. FQHCs based in a skilled nursing facility (SNF) complete the Worksheet I series of Form CMS–2540–10, “Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report”. FQHCs based in a home health agency complete the Worksheet RF series of Form CMS–1728–94, “Home Health Agency Cost Report”. Information on these cost report forms is found in Chapters 29, 40, 41 and 32, respectively, of the “Provider Reimbursement Manual—Part 2” (Publication 15–2). Per 42 CFR 413.65(n), only FQHCs that were operating as provider-based clinics prior to 1995 and either received funds under section 330 of the PHS Act or were determined by CMS to meet the criteria to be a look-alike clinic are eligible to be certified as provider-based FQHCs. FQHCs that do not already have provider-based status are no longer permitted to receive the designation.

At the beginning of a FQHC's fiscal year, the Medicare Administrative Contractor (MAC) calculates an interim AIR based on actual costs and visits from the previous cost reporting period. For new FQHCs, the interim AIR is estimated based on a percentage of the per-visit limit. FQHCs receive payments throughout the year based on their interim rate. After the conclusion of the fiscal year, the cost report is reconciled and any necessary adjustments in payments are made.

Allowable costs are subject to tests of reasonableness, productivity standards, and an overall payment limit (42 CFR 405.2464, 405.2466, and 405.2468). The productivity standards require 4,200 visits per full-time equivalent physician and 2,100 visits per full-time equivalent

non-physician practitioner (NP, PA or CNM) on an annual basis. If the FQHC has furnished fewer visits than required by the productivity standards, the allowable costs would be divided by the productivity standards numbers instead of the actual number of visits.

The payment limit varies based on whether the FQHC is located in an urban or rural area (as defined in section 1886(d)(2)(D) of the Act). The 2013 payment limits per visit for urban and rural FQHCs are \$128.00 and \$110.78, respectively. FQHCs with multiple sites may elect to file a consolidated cost report (CMS Pub. 100–04, Medicare Claims Processing Manual, chapter 9, § 30.8), and if the FQHC has both urban and rural sites, the MAC applies a weighted UPL based on the percentage of urban and rural visits as the percentage of total site visits. The AIR is equal to the FQHC's cost per visit (adjusted by the productivity standard if appropriate) or the payment limit, whichever is less.

Medicare beneficiaries receiving services at a FQHC are not subject to the annual Medicare deductible for FQHC-covered services (section 1833(b) of the Act). Medicare beneficiaries pay a copayment based on 20 percent of the charges (section 1866(a)(2)(A)(ii) of the Act), except for: (1) Mental health treatment services, which are subject to the outpatient mental health treatment limitation until January 1, 2014, when beneficiary coinsurance is reduced to the same level as most other Part B services; (2) FQHC-supplied influenza and pneumococcal and Hepatitis B vaccines (HBV); and (3) effective January 1, 2011, personalized prevention plan services and any Medicare covered preventive service that is recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

The administration and payment of influenza and pneumococcal vaccines is not included in the AIR. They are paid at 100 percent of reasonable costs through the cost report. The cost and administration of Hepatitis B vaccine (HBV) is covered under the FQHC's AIR.

#### 5. Summary of Requirements Under the Affordable Care Act for the FQHC PPS and Other Provisions Pertaining to FQHCs

Section 10501(i)(3)(A) of the Affordable Care Act amended section 1834 of the Act by adding a new subsection (o), “Development and Implementation of Prospective Payment System”. Section 1834(o)(1)(A) of the Act requires that the system include a process for appropriately describing the services furnished by FQHCs. Also, the

system must establish payment rates based on such descriptions of services, taking into account the type, intensity, and duration of services furnished by FQHCs. The system may include adjustments (such as geographic adjustments) as determined appropriate by the Secretary of HHS.

Section 1834(o)(1)(B) of the Act specifies that, by no later than January 1, 2011, FQHCs must begin submitting information as required by the Secretary, including the reporting of services using HCPCS codes, in order to develop and implement the PPS.

Section 1834(o)(2)(A) of the Act requires that the FQHC PPS must be effective for cost reporting periods beginning on or after October 1, 2014. For such cost reporting periods, reasonable costs will no longer be the basis for Medicare payment for services furnished to beneficiaries at FQHCs.

Section 1834(o)(2)(B)(i) of the Act requires that the initial PPS rates must be set so as to equal in the aggregate 100 percent of the estimated amount of reasonable costs that would have occurred for the year if the PPS had not been implemented. This 100 percent must be calculated prior to application of copayments, per visit limits, or productivity adjustments.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining payments in subsequent years. After the first year of implementation, the PPS payment rates must be increased by the percentage increase in the MEI. After the second year of implementation, PPS rates shall be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations, or, if not available, the MEI that is published in the Physician Fee Schedule (PFS) final rule.

Section 10501(i)(3)(B) of the Affordable Care Act added section 1833(a)(1)(Z) to the Act to specify that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the PPS amount determined under section 1834(o).

Section 10501(i)(3)(C) of the Affordable Care Act added section 1833(a)(3)(B)(i)(II) of the Act to require that FQHCs that contract with Medicare Advantage (MA) organizations be paid at least the same amount they would have received for the same service under the FQHC PPS.

Section 10501(i)(2) of the Affordable Care Act amended the definition of FQHC services as defined in section 1861(aa)(3)(A) of the Act by replacing the specific references to services provided under section 1861(qq) and

(vv) of the Act (DSMT and MNT services, respectively) with preventive services as defined in section 1861(ddd)(3) of the Act, as established by section 4014(a)(3) of the Affordable Care Act. These changes were effective for services provided on or after January 1, 2011. Accordingly, in the CY 2011 Medicare PFS final rule (75 FR 73417 through 73419, November 29, 2010) we adopted conforming regulations by adding a new § 405.2449, which added the new preventive services definition to the definition of FQHC services effective for services provided on or after January 1, 2011 (see that rule for a detailed discussion regarding preventive services covered under the FQHC benefit and the requirements for waiving coinsurance for such services).

Section 1833(b)(4) of the Act stipulates that the Medicare Part B deductible shall not apply to FQHC services. The Affordable Care Act made no change to this provision; therefore Medicare will continue to waive the Part B deductible for all FQHC services in the FQHC PPS, including preventive services added by the Affordable Care Act.

## 6. Approach to the FQHC PPS

To enhance our understanding of the services furnished by FQHCs and the unique role of FQHCs in providing services to people from medically underserved areas and populations, we worked closely with HRSA in the development of this proposed rule. They provided valuable expertise on the challenges facing FQHCs in increasing access to health care for underserved populations and the importance of Medicare reimbursement to the overall financial viability of the health centers. In addition to providing patient population and services data from their UDS, HRSA also enabled us to gain additional data on insurance coverage among a subset of FQHC patients from the Community Health Applied Research Network. We believe that the proposals in this proposed rule benefited greatly from their assistance.

Our goal for the FQHC PPS is to create a system in accordance with the statute whereby FQHCs are fairly reimbursed for the services they provide to Medicare patients in the least burdensome manner possible, so that they may continue to provide primary and preventive health services to the communities they serve. We will continue to evaluate our approach based on the comments we receive to this proposed rule in the context of balancing payment requirements, regulatory burden, and the need for

appropriate accountability and oversight.

## II. Establishment of the Federally Qualified Health Center Prospective Payment System (FQHC PPS)

### A. Design and Data Sources for the FQHC PPS

#### 1. Overview of the PPS Design

In developing the new PPS for FQHCs, we considered the statutory requirements at 1834(o)(1)(A) of the Act requiring that the new PPS take into account the type, intensity, and duration of services furnished by FQHCs, and allows for adjustments, including geographic adjustments, as determined appropriate by the Secretary. We explored several approaches to the methodology and modeled options for calculating payment rates and adjustments under a PPS based on data from Medicare FQHC cost reports and Medicare FQHC claims. Each option was evaluated to determine which approach would result in the most appropriate payment structure with the least amount of reporting requirements and administrative burden for the FQHCs.

One approach we considered would align payment for FQHCs with payment for services typically furnished in physician offices, making separate payment for each coded service and adopting the relative values from the PFS. While this approach follows established payment policy for services furnished in an outpatient clinic setting, it unbundles a FQHC encounter-based payment into a fee schedule structure, which could encourage excess utilization in the long-term, and would increase coding and billing requirements for FQHCs.

Another approach for the PPS would be to pay a single encounter-based rate per beneficiary per day. The encounter-based rate would be based on an average cost per visit, which would be calculated by aggregating the data for all FQHCs and dividing their total costs by their total visits incurred during a specified time period. An encounter-based payment rate is consistent with the agency's commitment to greater bundling of services, which gives FQHCs the flexibility to implement efficiencies to reduce over-utilization of services. FQHCs are accustomed to billing for a single visit, as they are currently paid through an AIR that is based on a FQHC's own average cost per visit. An encounter-based payment is also similar to Medicaid payment systems, and Medicaid constitutes a large portion of FQHC billing (approximately 47 percent, compared to

approximately 9 percent for Medicare). We believe an encounter-based payment rate for the FQHC PPS would provide appropriate payment while remaining administratively simple. Therefore, we propose an encounter-based rate per beneficiary per day as the basis for payment under the proposed FQHC PPS. Additional details regarding the encounter-based rate setting methodology, including adjustments to the encounter-based rate, are discussed in section II. C. of this proposed rule.

## 2. Medicare FQHC Cost Reports

As required by section 1834(o)(2)(B)(i) of the Act, initial payments (Medicare and coinsurance) under the FQHC PPS must equal 100 percent of the estimated amount of reasonable costs, as determined without the application of the current system's UPLs or productivity standards that can reduce a FQHC's per visit rate. In order to estimate 100 percent of reasonable costs, we obtained Medicare cost report data for free-standing FQHCs (Form CMS 222-92) from the March 31, 2013, Healthcare Cost Report Information System (HCRIS) quarterly update. We included in our analysis FQHC costs reports that had allowable costs (excluding pneumococcal and influenza vaccines) and Medicare visits, and we used one cost report for each FQHC cost reporting entity. For 69 percent of cost reporting entities, the only available cost report covered 1 full year (with cost reporting periods ending between June 30, 2011 and June 30, 2012). For the remaining 31 percent of cost reporting entities, there were multiple cost reports available or the cost reporting period was not exactly 1 year. For cost reporting entities with multiple cost reports available, we selected the most recent cost report, unless an earlier cost report provided us with a better match to the FQHC claims data that was used to model potential adjustments. Because FQHCs with multiple sites can file consolidated cost reports, we also ensured that we selected only one cost report for each delivery site.

As required by statute, we estimated 100 percent of reasonable costs that would have occurred for this period prior to the application of copayments, per visit limits, or productivity adjustments (see discussion of the baseline for the PPS in section II. D. of this proposed rule). We also note that, under section 1833(c) of the Act, outpatient mental health services will be paid on the same basis as other Part B services as of January 1, 2014. As the FQHC PPS is to be implemented for cost reporting periods beginning on or after October 1, 2014, we adjusted the cost

report data to remove the application of the outpatient mental health limitations that were in effect when these reported services were incurred.

After eliminating the current payment limits and adjustments, we calculated the average cost per visit for each cost reporting entity by dividing the total estimated Medicare costs (excluding vaccines) reported by the total number of Medicare visits reported. We found that the mean cost per visit for all cost reporting entities was about 11 percent higher than the median cost per visit.

In developing the FQHC PPS, section 1834(o)(1)(A) of the Act allows for adjustments determined appropriate by the Secretary. Consistent with this authority, we excluded statistical outliers from the sample. We identified all cost reporting entities with an average cost per visit that was greater than three standard deviations above or below the geometric mean of the overall average cost per visit among cost reporting entities, and we excluded their data from our sample. In the aggregate, after trimming the data for outliers and before adjustments for price inflation, we estimate that eliminating current payment limits and adjustments would increase payments to FQHCs by about 28 percent. For additional information on the impact of the FQHC PPS, see section VII. of this proposed rule.

## 3. Medicare FQHC Claims

In developing the Medicare FQHC PPS, section 1834(o)(1)(A) of the Act requires us to take into account the type, intensity, and duration of FQHC services, and allows other adjustments, such as geographic adjustments. Section 1834(o)(1)(B) of the Act also granted the Secretary of HHS (the Secretary) the authority to require FQHCs to submit such information as may be required in order to develop and implement the Medicare FQHC PPS, including the reporting of services using HCPCS codes. The provision requires that the Secretary impose this data collection submission requirement no later than January 1, 2011.

Beginning with dates of service on or after January 1, 2011, when billing Medicare, FQHCs are required to report all pertinent services provided and list the appropriate HCPCS code for each line item along with revenue code(s) for each FQHC visit. The additional line item(s) and HCPCS code reporting were for informational and data gathering purposes to inform development of the PPS rates and potential adjustments. Other than for calculating the amount of coinsurance to waive for preventive services for which the coinsurance is

waived, these HCPCS codes are not utilized to determine current Medicare payment to FQHCs. We propose to use the HCPCS codes in the FQHC claims data to support the development of the FQHC PPS rate and adjustments and for making payment under the PPS.

In order to model potential adjustments, we obtained final action Medicare FQHC claims (type of bill 73X and 77X) from the CMS Integrated Data Repository (IDR) with dates of service between January 2010 and December 2012. We excluded claims that did not list a revenue code or HCPCS code that represented a face-to-face encounter, as these services would not qualify for an AIR payment. We also excluded claim lines with revenue codes that did not correspond to FQHC services or that lacked valid HCPCS codes.

In 2011, approximately 90 percent of FQHC claims listed a single HCPCS code that defined the overall type of encounter (for example, a mid-level office visit (HCPCS code 99213)). We found similar reporting trends in 2012 FQHC claims. We sought to validate the completeness of HCPCS reporting by analyzing coding on primary care physician claims for PFS data. When compared, the findings from the simulated PFS data and actual FQHC data were similar in the type and distribution of the reported encounter code (that is, the HCPCS code that represents the visit that qualifies the FQHC encounter for an AIR payment). When ancillary services (services that are not separately billable in a FQHC) were billed with an office visit code, both FQHC and analogous primary care physician office claims demonstrated a tendency to include only one to two ancillary services in addition to the encounter code about 35 percent of the time, and FQHCs billed only a single ancillary service about 10 percent of the time.

We believe that the reporting trends in the FQHC claims are consistent with the coding of analogous primary care physician office claims, thereby suggesting that the limited number of ancillary services listed on FQHC claims appropriately describe the services furnished during an encounter.

## 4. Linking Cost Reports and Claims To Compute the Average Cost per Visit

In order to compute the adjusted charges or "estimated cost" for determining the average cost per visit, we linked claims to cost reports by delivery site, as determined by the CMS Certification Number (CCN) reported on the claim. Since the HCPCS code reporting requirement on claims did not go into effect until January 1, 2011,

claims for earlier dates of service did not include the detail required to model adjustments based on type, intensity, or duration of services. Cost reports with reporting periods that began on or after January 1, 2011, accounted for 81 percent of the sample, and we linked these cost reports to Medicare FQHC claims with service dates that matched their respective cost reporting periods. For cost reports that were at least 1 full year in length and with a cost reporting period that began in 2010, we linked these cost reports to 2011 Medicare FQHC claims.

The linked cost report and claims data were then used to calculate a cost-to-charge ratio (CCR) for each cost-reporting entity. To approximate data not available on the cost report, we developed these CCRs to convert each FQHC's charge data, as found on its claims, to costs. We calculated an average cost per visit by dividing the total allowable costs (excluding pneumococcal and influenza vaccinations) by the total number of visits reported on the cost report. We calculated an average charge per visit by dividing the total charges of all visits for all sites under a cost-reporting entity and dividing that sum by the total number of visits for that cost-reporting entity. We calculated a cost-reporting entity-specific CCR by dividing the average cost per visit (based on cost report data) by the average charge per visit (based on claims data). We multiplied the submitted charges for each claim by these cost-reporting entity-specific CCRs to estimate FQHC costs per visit. We note that other Medicare payment systems calculate CCRs based on total costs and total charges reported on Medicare cost reports. However, this information is not currently available on the free-standing FQHC cost report, Form CMS-222-92.

We found that the mean estimated cost per visit in the linked claims data was about 9 percent higher than the median estimated cost per visit. In developing the FQHC PPS, section 1834(o)(1)(A) of the Act allows for adjustments determined appropriate by the Secretary. Consistent with this authority, we excluded statistical outliers from the linked claims sample. We identified visits with estimated costs that were greater than three standard deviations above or below the geometric mean of the overall average estimated cost per visit, and we excluded those visits from our sample.

After trimming the linked claims data for outliers, the final data set included 5,245,961 visits from 5,236,607 distinct claims encompassing 6,135,830 claim

lines. This included 5,223,512 daily visits furnished to 1,244,873 beneficiaries that visited 3,509 delivery sites under 1,141 cost-reporting entities.

#### *B. Policy Considerations for Developing the FQHC PPS Rates and Adjustments*

In developing the FQHC PPS rates and adjustments, we considered existing payment policies to determine potential interactions with the implementation of the FQHC PPS. We discuss these policies and our proposed changes below.

##### 1. Multiple Visits on the Same Day

The current all-inclusive payment system was designed to reimburse FQHCs for services furnished to Medicare beneficiaries at a rate that would take into account all costs associated with the provision of services (for example, space, supplies, practitioners, etc.) and reflect the aggregate costs of providing services over a period of time. In some cases, the per visit rate for a specific service is higher than what would be paid based on the PFS, and in some cases it is lower than what would be paid based on the PFS, but at the end of the reporting year when the cost report is settled, the Medicare payment is typically higher for FQHCs than if the services were billed separately on the PFS.

The current payment system was also designed to minimize reporting requirements, and as such, the all-inclusive payment reflects all the services that a FQHC provides in a single day to an individual beneficiary, regardless of the length or complexity of the visit or the number or type of practitioners seen. This would include situations where a FQHC patient has a medically-necessary face-to-face visit with a FQHC practitioner, and is then seen by another FQHC practitioner, including a specialist, for further evaluation of the same condition on the same day, or is then seen by another FQHC practitioner (including a specialist) for evaluation of a different condition on the same day. Except for certain preventive services that have coinsurance requirements waived, FQHCs have not been required to submit coding of each service in order to determine Medicare payment.

Although the all-inclusive payment system was designed to provide enhanced reimbursement that reflects the costs associated with a visit in a single day by a Medicare beneficiary, an exception to the one encounter payment per day policy was made for situations when a patient comes into the FQHC for a medically-necessary visit, and after leaving the FQHC, has a medical issue

that was not present at the visit earlier that day, such as an injury or unexpected onset of illness. In these situations, the FQHC has been permitted to be paid separately for two visits on the same day for the same beneficiary.

In response to a comment to the June 12, 1992 final rule with comment period (57 FR 24961), in the April 3, 1996 final rule (61 FR 14640), we revised the regulations to allow separate payment for mental health services furnished on the same day as a medical visit. The CY 2007 PFS final rule (71 FR 69665) subsequently revised the regulations to allow FQHCs to receive separate payment for DSMT and MNT. The ability to bill separately for Medicare's IPPE is in manuals only and not in regulation, with the manual language noting this is a once in a lifetime benefit. There are no statutory requirements to pay FQHCs separately for these services when they occur on the same day as another billable visit.

In developing the new PPS for FQHCs, we reviewed all existing policies for FQHC payments to determine if the policies should remain the same as under the current system, or if the policies should be updated or in some cases revised. As part of this process, we reviewed the existing regulations and policies that allow separate payment for subsequent illness or injury, mental health services, DSMT/MNT, or IPPE when they occur on the same day as an otherwise billable visit. To do this, we examined 2011 Medicare FQHC claims data in order to determine the frequency of FQHCs billing for more than one visit per day for a beneficiary. We then analyzed the potential financial impact on FQHCs and the potential impact on access to care if billing for more than 1 visit per day for these specific situations was no longer permitted. We also considered several alternative options, such as an adjustment of the per visit rate when multiple visits occur in the same day, or the establishment of a separate per visit rate for subsequent visit due to illness or injury, mental health services, DSMT/MNT, or IPPE.

An analysis of data from Medicare FQHC claims with dates of service between January 1, 2011 and June 30, 2012, indicate that it is uncommon for FQHCs to bill more than one visit per day for the same beneficiary (less than 0.5 percent of all visits), even though the ability to do so has been in place since 1992 for subsequent illness/injury, since 1996 for mental health services, and since 2007 for DSMT/MNT. Even allowing for any underreporting in the data, it is clear that billing multiple visits on the same day for an individual

is a rare event, and eliminating the ability to do so would not significantly impact either the FQHC payment or a beneficiary's access to care. Eliminating this ability to bill for multiple visits on the same day would also simplify billing by removing the need for modifier 59, which signifies that the conditions being treated are totally unrelated and services are provided at separate times of the day, and the subsequent claims review that occurs when modifier 59 appears on a claim.

Because the data show that multiple visits are infrequently occurring on the same day, we determined that the level of effort required to develop an adjustment or a separate rate for each of these services when furnished on the same day as a medical visit would not be justified. Therefore, we are proposing to revise § 405.2463(b) to remove the exception to the single encounter payment per day for FQHCs paid under the proposed PPS. This policy is consistent with an all-inclusive methodology and reasonable cost principles and would simplify billing and payment procedures. Thus, the proposed PPS encounter rate will also reflect a daily (per diem) rate and result in a slightly higher payment than one calculated based on multiple encounters on the same day.

Based on the Medicare claims data provided by FQHCs that indicates a very low occurrence of multiple visits billed on the same day, we believe this proposal would not significantly impact total payment or access to care. However, we understand that there may be many possible reasons why the rate of billing for more than one visit per day has been low (for example, difficulty in scheduling more than one type of visit on the same day) and that FQHCs can provide integrated, patient-centered health care services in a variety of ways. Therefore, we are interested in comments that address whether there are factors that we have not considered, particularly in regards to the provision of mental health services. We invite public comment on whether this change would impact access to these services or the integration of services in underserved communities. The benefits of retaining the ability to bill for more than one visit on the same day should be considered along with the proposed increased per diem payment rate under the PPS and the complexity of developing a claims processing system to allow for this exception in the new PPS.

## 2. Preventive Laboratory Services and Technical Components of Other Preventive Services

The core services of the FQHC benefit are generally billed under the professional component. The benefit categories for laboratory services and diagnostic tests generally are not within the scope of the FQHC benefit, as defined under section 1861(aa) of the Act. For services that can be split into professional and technical components, we have instructed FQHCs to bill the professional component as part of the AIR, and separately bill the Part B MAC under different identification for the technical portion of the service on a Part B practitioner claim (for example, Form CMS-1500). If the FQHC operates a laboratory, is enrolled under Medicare Part B as a supplier, and meets all applicable Medicare requirements related to billing for laboratory services, it may be able to bill as a supplier furnishing laboratory services under Medicare Part B. When FQHCs separately bill these services, they are instructed to adjust their cost reports and carve out the cost of associated space, equipment, supplies, facility overhead, and personnel for these services.

As part of the implementation of the FQHC benefit, we used our regulatory authority to enumerate preventive primary services, as defined in 42 CFR 405.2448, which may be paid for when provided by FQHCs (57 FR 24980, June 12, 1992, as amended by 61 FR 14657, April 3, 1996). These preventive primary services include a number of laboratory tests, such as cholesterol screening, stool testing for occult blood, dipstick urinalysis, tuberculosis testing for high risk patients, and thyroid function tests. The preventive services added to the FQHC benefit pursuant to the Affordable Care Act, as defined by section 1861(ddd)(3) of the Act and codified in 42 CFR 405.2449, include laboratory test and diagnostic services, such as screening mammography, diabetes screening tests, and cardiovascular screening blood tests.

Professional services or professional components of primary preventive services (as defined in § 405.2448) and preventive services (as defined in § 405.2449) are billed as part of the AIR. The preventive laboratory tests and technical components of other preventive tests are not paid under the AIR and FQHCs are instructed to bill separately for these services. We are not proposing a change in billing procedures, and we do not intend to include payment for these services under the FQHC PPS. We note this

payment structure simplifies billing procedures as laboratory tests and technical components of diagnostic services are always billed separately to Part B and are never included as part of the FQHC's encounter rate. (Note that both the professional and technical components of FQHC primary preventive services and preventive services remain covered under Part B).

An analysis of FQHC claims indicates that FQHCs are listing some preventive laboratory tests and diagnostic services on their claims. In 2011 through 2012, less than 5 percent of Medicare FQHC claims listed HCPCS codes related to laboratory tests or diagnostic services. For purposes of modeling adjustments to the FQHC PPS rate, we considered excluding these line items from the encounter charge and proportionately reducing the cost-reporting entity's related cost report data. However, it was not always clear whether the line item charges for these laboratory tests or diagnostic services were included in the total charge for the claim or were listed for informational purposes only. As such, we chose not to adjust the claims or cost report data based on the presence of the related HCPCS codes on the claims. As part of the implementation of the FQHC PPS, we plan to clarify the appropriate billing procedures through program instruction.

## 3. Vaccine Costs

Section 1834(o)(2)(B)(i) of the Act requires that the initial PPS rates must be set so as to equal in the aggregate 100 percent of the estimated amount of reasonable costs that would have occurred for the year if the PPS had not been implemented. This 100 percent must be calculated prior to application of copayments, per visit limits, or productivity adjustments. We believe that this language directed us to develop a PPS to pay for items currently affected by the UPL and the productivity screen, which would pay for items currently included in the calculation of reasonable costs and paid under the AIR.

The administration and payment of influenza and pneumococcal vaccines is not included in the AIR. They are paid at 100 percent of reasonable costs through the cost report. The cost and administration of HBV is covered under the FQHC's AIR when furnished as part of an otherwise qualifying encounter. We are not proposing any changes to this payment structure. We would continue to pay for the costs of the influenza and pneumococcal vaccines and their administration through the cost report, and other Medicare-covered

vaccines as part of the encounter rate. The costs of hepatitis B vaccine and its administration were included in the calculation of reasonable costs used to develop the FQHC PPS rates, and we would pay for these services under the FQHC PPS when furnished as part of an otherwise qualifying encounter.

### C. Risk Adjustments

Section 1834(o)(1)(A) of the Act provides that the FQHC PPS may include adjustments, including geographic adjustments, that are determined appropriate by the Secretary. We discuss our proposed adjustments below.

#### 1. Alternative Calculations for Average Cost per Visit

As discussed in section II. of this proposed rule, we used the claims data to calculate an average cost per visit by dividing the total estimated costs (\$788,547,531) by the total number of daily visits (5,223,512).

$$\text{Average cost per daily visit} = \frac{\$788,547,531}{5,223,512} = \$150.96$$

We also examined how the average cost per visit would differ under current policy, which allows separate payment for subsequent illness or injury, mental health services, DSMT/MNT or IPPE when they occur on the same day as an otherwise billable visit. While the total estimated cost was the same (\$788,547,531), the total number of visits in the denominator (5,245,961) did not combine multiple visits on the same day of service into 1 daily visit.

$$\text{Average cost per visit} = \frac{\$788,547,531}{5,245,961} = \$150.32$$

We also derived an average cost per visit from the cost reports by dividing the total estimated Medicare costs (excluding vaccines) reported (\$832,387,663) by the total number of Medicare visits reported (5,374,217). Unlike the previous calculations based on claims data, the variables derived from the cost reports summarize total costs and visits by cost reporting entity and could not be trimmed of individual visits with outlier values. Also, we note that the total number of Medicare visits reported on the cost reports reflects current policy which allows for multiple visits on the same day of service, and we could not calculate an average cost per daily visit using only cost report data.

$$\text{Average cost per visit from cost report data} = \frac{\$832,387,663}{5,374,217} = \$154.89$$

Consistent with our proposal to remove the exception to the single encounter payment per day, we propose

to use the average cost per daily visit of \$150.96, as calculated based on adjusted claims data as the PPS rate prior to any risk adjustment. We note that the alternative calculations yield an average cost per visit that differs from \$150.96 by less than 3 percent. We also note that these calculations were derived based on the cost report and claims data available during our development of this proposed rule and are subject to change in the final rule based on more current data.

#### 2. Geographic Adjustment Factor

We propose to adjust the FQHC PPS rate for geographic differences. This adjustment will be made to the cost of inputs by applying an adaptation of the GPCIs used to adjust payment under the PFS. Established in 1848(e) of the Act, GPCIs adjust payments for geographic variation in the costs of providing services and consist of three component GPCIs: the physician work GPCI, the practice expense GPCI, and the malpractice insurance GPCI.

Because FQHCs furnish services that are analogous to those furnished by physicians in outpatient clinic settings, we believe it would be consistent to apply geographic adjustments similar to those applied to services furnished under the PFS. We calculated a geographic adjustment factor (GAF) for each encounter based on the delivery site's locality using the proposed CY 2014 work and practice expense GPCIs and the proposed cost share weights for the CY 2014 GPCI update, as published in the CY 2014 PFS proposed rule (July 19, 2013 (78 FR 43282)).

For modeling geographic adjustments for this FQHC PPS proposed rule, we did not use the proposed CY 2015 work and practice expense GPCIs that also were published in the CY 2014 PFS proposed rule. We note that the FQHC PPS GAFs are subject to change in the final FQHC PPS rule based on more current data, including the finalized PFS GPCI and cost share weight values.

We excluded the PFS malpractice GPCI from the calculation of the GAF as FQHCs that receive section 330 grant funds are eligible to apply for medical malpractice coverage under FSHCAA of 1992 and FSHCAA of 1995. Without the cost share weight for the malpractice GPCI, the sum of the proposed PFS work and PE cost share weights (0.50866 and 0.44839, respectively) is less than one. In calculating the FQHC GAFs, prior to applying the proposed work and PE cost share weights to the GPCIs, we scaled these proposed cost share weights so they would total 100 percent while still retaining weights

relative to each other (0.53149 and 0.46851, respectively).

We calculated each locality's GAF as follows:

$$\text{Geographic adjustment factor} = (0.53149 \times \text{Work GPCI}) + (0.46851 \times \text{PE GPCI})$$

We included the GAF adjustment when modeling all other potential adjustments. The GAF will be applied based on where the services are furnished and may vary among FQHCs that are part of the same organization. The list of proposed GAFs by locality is in Addendum A of this proposed rule and is also available as a downloadable file at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

#### 3. New Patient or Initial Medicare Visit

Based on an analysis of claims data, we found that the estimated cost per encounter was approximately 33 percent higher when a FQHC furnished care to a patient that was new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit (that is, an IPPE or an initial AWW). We propose to adjust the encounter rate to reflect the 33 percent increase in costs when FQHCs furnish care to new patients or when they furnish a comprehensive initial Medicare visit, which could account for the greater intensity and resource use associated with these types of services. Our proposed risk adjustment factor is 1.3333 (as discussed further in section V. of this proposed rule).

#### 4. Other Adjustment Factors Considered

We considered multiple other adjustments such as demographics (age and sex), clinical conditions, duration of the encounter, etc. However, we found many of these other adjustments to have limited impact on costs or to be too complex and largely unnecessary for the FQHC PPS.

We modeled whether there were differences in resource use for mental health visits and preventive care visits when compared to medical care visits. We found that mental health encounters had approximately 1 percent lower estimated costs per visit relative to medical care visits, and we did not consider this a sufficient basis for proposing a payment adjustment. We found that preventive care encounters had approximately 18 percent higher estimated costs per visit. This difference in resource use declines to an 8 percent higher estimated cost per visit after adjusting for the GAF and the proposed 1.3333 risk adjustment factor for a patient that is new to the FQHC or for

a beneficiary receiving a comprehensive initial Medicare visit (that is, an IPPE or an initial AWW), indicating that a significant amount of preventive care visits were IPPEs or initial AWWs. We are not proposing a payment reduction for preventive care encounters and we note that a significant amount of the more costly preventive care encounters would otherwise be recognized and paid for with the proposed 1.3333 risk adjustment factor for a beneficiary receiving a comprehensive initial Medicare visit. We note that an 8 percent adjustment would increase payment for preventive visits, and we welcome comments on whether an adjustment for preventive care encounters would be appropriate, noting that there would be redistributive effect which would result in a decrease in the payment rate for other visits.

We considered patient age and sex as potential adjustment factors as these demographic characteristics have the advantage of being objectively defined. However, both of these characteristics had a limited association with estimated costs, which did not support the use of these demographic characteristics as potential adjustment factors.

We tested for an association between commonly reported clinical conditions and the estimated cost per visit. A number of clinical conditions were found to be associated with approximately 5 to 10 percent higher costs per visit, but we are concerned that claims might not include all potentially relevant secondary diagnoses. In addition, we would need to consider how to minimize the complexity of such an adjustment with a limited number of clinically meaningful groupings.

We considered the duration of encounters (in minutes) as a potential adjustment factor. Many of the evaluation and management (E/M) codes commonly seen on FQHC claims are associated with average or typical times, and there was a strong association between these associated times and the estimated cost per encounter. However, these minutes are guidelines that reflect the face-to-face

time between the FQHC practitioner and the beneficiary for that E/M service, and they would not indicate the total duration of the FQHC encounter. Moreover, many of the codes used to describe the face-to-face visit that qualifies an encounter, such as a subsequent annual wellness visit, are not associated with average or typical times.

We considered adjusting payment based on the types of services furnished during a FQHC encounter. Our analysis of FQHC claims data indicates that information regarding ancillary services provided by FQHCs appears to be limited. As a result, there is a risk that adjustments for the types of services being provided would be based on incomplete information and result in payments under the PPS that do not accurately reflect the cost of providing those services.

#### 5. Report on PPS Design and Models

We contracted with Arbor Research for Collaborative Health to assist us in designing a PPS for FQHCs. Arbor Research modeled options for calculating payment rates and adjustments under a PPS based on data from Medicare FQHC cost reports and Medicare FQHC claims. A report detailing the options modeled in the development of the PPS will be available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

#### D. Base Rate Calculation

We calculated a base rate for the FQHC PPS by adjusting the average cost per visit to account for the proposed adjustment factors. We calculated an average payment multiplier using the average GAF (0.9944) multiplied by the average risk adjustment for non-new patient/initial visits (1.0), as weighted by the percent of encounters that represented non new patient/initial visits (0.9722), and we added this to the average GAF (0.9944) multiplied by the average risk adjustment for new patient/initial visits (1.3333), as weighted by the percent of encounters that represented new patient/initial visits (0.0278):

$$\begin{aligned} \text{Average payment multiplier} &= \\ &0.9721(1.00)(0.9944) + \\ &0.0279(1.3333)(0.9944) = 1.0036 \end{aligned}$$

We calculated a base rate amount by multiplying the reciprocal of the average payment multiplier by the average cost per visit. Using the average cost per daily visit:

$$\begin{aligned} \text{Base rate per daily visit} &= \$150.96 \times \\ &(1/1.0036) = \$150.42 \end{aligned}$$

The base rate per daily visit of \$150.42 reflects costs through June 30, 2012, and does not include an adjustment for price inflation. As the FQHC PPS is to be implemented beginning October 1, 2014, we propose to update the base rate to account for the price inflation through September 30, 2014. We propose to use the MEI as finalized in the CY 2011 PFS final rule (75 FR 73262 through 73270). The MEI is an index reflecting the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity.

We propose to inflate the base rate by approximately 1.8 percent, reflecting the growth in the MEI from July 1, 2012 through September 30, 2014. We also propose to use a forecasted MEI update of 1.7 percent for the 15-month period of October 1, 2014, through December 31, 2015, to calculate the first year's base payment amount under the PPS. The 15-month update factor is based on the 2013Q2 forecast of the 2006-based MEI, the most recent forecast available at the time of this proposed rule. The adjusted base payment that reflects the MEI historical updates and forecasted updates to the MEI is \$155.90. This payment rate incorporates a combined MEI update factor of 1.0364 that trends dollars forward from July 1, 2012 through December 31, 2015. We also propose if more recent data became available (for example, a more recent estimate of the FY 2006-based MEI), we would use such data, if appropriate, to determine the 15-month FQHC PPS update factor for the final rule.

TABLE 1—BASE RATE PER DAILY VISIT

Total estimated costs	Daily encounters	Average payment multiplier	Average cost per daily visit	Estimated base rate without adjustment for price inflation	MEI update factor	MEI-adjusted base payment rate
\$788,547,531	5,223,512	1.0036	\$150.96	\$150.42	1.0364	\$155.90

*MEI-adjusted base payment rate* =  
 $\$150.96 \times (1/1.0036) \times 1.0364 =$   
 $\$155.90$

Thus, we propose a base payment rate of \$155.90 per beneficiary per day for the proposed FQHC PPS. We note that this base rate is subject to change in the final rule based on more current data. (See the Impact Analysis in section VII of this proposed rule for comparisons of the PPS rates to payments under the AIR.)

Payments to FQHCs would be calculated as follows:

Base payment rate  $\times$  GAF = PPS  
 payment

In calculating the payment, the proposed base payment rate is \$155.90, and the GAF would be based on the locality of the delivery site. (See section II.C. of this proposed rule for a discussion of the GAF and the Addendum to this proposed rule for the list of proposed GAFs.)

If the patient is new to the FQHC, or the FQHC is furnishing an initial comprehensive Medicare visit, the payment would be calculated as follows:

Base payment rate  $\times$  GAF  $\times$  1.3333 =  
 PPS payment

In calculating the payment, 1.3333 represents the risk adjustment factor applied to the PPS payment when FQHCs furnish care to new patients or when they furnish a comprehensive initial Medicare visit. (See section II.C. of this proposed rule for a discussion of the risk adjustment for new patients or initial comprehensive Medicare visits.)

### E. Implementation

#### 1. Transition Period and Annual Adjustment

Section 1834(o)(2) of the Act requires implementation of the FQHC PPS for FQHCs with cost reporting periods beginning on or after October 1, 2014. Cost reporting periods are typically 12 months, and do not usually exceed 13 months. Therefore, we expect that all FQHCs would be transitioned to the PPS by the end of 2015, or 15 months after the October 1, 2014 implementation date.

FQHCs would transition into the PPS based on their cost reporting periods. We note that a change in cost reporting periods that is made primarily to maximize reimbursement would not be acceptable under established cost reporting policy (see 42 CFR 413.24(f)(3) and the Provider Reimbursement Manual Part I, section 2414, and Part II, section 102.3). The claims processing system will maintain the current system

and the PPS until all FQHCs have transitioned to the PPS.

We propose to transition the PPS to a calendar year update for all FQHCs, beginning January 1, 2016, because many of the PFS files we are proposing to use are updated on a calendar year basis. Section 1834(o)(2)(B)(ii)(I) of the Act requires us to adjust the FQHC PPS rate by the percentage increase in the MEI for the first year after implementation. However, while transitioning the PPS to a calendar year, we propose to defer the first MEI statutory adjustment to the PPS rate from October 1, 2015, to December 31, 2015 (we note that our proposed base payment rate incorporates a forecasted percentage increase in the MEI through December 31, 2015).

#### 2. Medicare Claims Payment

Claims processing systems would need to be revised through program instruction to accommodate the new rate and associated adjustments. Medicare currently pays 80 percent of the AIR for all FQHC claims, except for mental health services that are subject to the mental health payment limit. Section 1833(a)(1)(z) of the Act requires that Medicare payment under the FQHC PPS should be 80 percent of the lesser of the provider's charge or the PPS rate. We are considering revisions to the claims processing system that would reject claims in which the qualifying visit describes a service that is outside of the FQHC benefit, such as inpatient hospital E/M services or group sessions of DSMT and MNT. We are considering revisions that would reject line items for technical components such as x-rays, laboratory tests, and durable medical equipment which will not be paid as part of the FQHC PPS and would be billed separately to Medicare Part B. We also are considering revisions that would allow for the informational reporting of influenza and pneumococcal vaccines and their administration, while excluding the line item charges, as these items would continue to be paid through the cost report.

#### 3. Beneficiary Coinsurance

Section 1833(a)(1)(Z) of the Act requires that FQHCs be paid up to 80 percent of their reasonable costs by Medicare after subtracting beneficiary coinsurance. Under the current reasonable cost payment system, beneficiary coinsurance for FQHC services is assessed based on the FQHC's charge, which can be more than coinsurance based on the AIR, which is based on costs. An analysis of a sample of FQHC claims data for dates of service

between January 1, 2011 through June 30, 2012 indicated that beneficiary coinsurance based on 20 percent of the FQHCs' charges was approximately \$23 million higher, or 18 percent more, than if coinsurance had been assessed based on 20 percent of the lesser of the FQHC's charge or the applicable all-inclusive rate.

Section 1833(a)(1)(Z) of the Act requires that Medicare payment under the FQHC PPS should be 80 percent of the lesser of the actual charge or the PPS rate. The statute makes no specific provision to revise the coinsurance. We propose that coinsurance would be 20 percent of the lesser of the FQHC's charge or the PPS rate. We believe that the proposal to change the method to determine coinsurance is consistent with the statutory change to the FQHC Medicare payment and is consistent with statutory language in section 1866(a)(2)(A) and 1833(a)(3)(A) of the Act and elsewhere that addresses coinsurance amounts and Medicare cost principles. If finalized, total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the FQHC's charge or the PPS rate.

#### 4. Waiving Coinsurance for Preventive Services

Effective January 1, 2011, Medicare waives beneficiary coinsurance for eligible preventive services furnished by a FQHC. Medicare requires detailed HCPCS coding on FQHC claims to ensure that coinsurance is not applied to the line item charges for these preventive services.

For FQHC claims that include a mix of preventive and non-preventive services, we propose that Medicare contractors compare payment based on the FQHC's charge to payments based on the PPS encounter rate and pay the lesser amount. However, the current approach to waiving coinsurance for preventive services, which relies solely on FQHC reported charges, would be insufficient under the FQHC PPS. As Medicare payment under the FQHC PPS is required to be 80 percent of the lesser of the FQHCs charge or the PPS rate, we also need to determine the coinsurance waiver for payments based on the PPS rate.

We considered using the proportion of the FQHC's line item charges for preventive services to total claim charges to determine the proportion of the FQHC PPS rate that would not be subject to coinsurance. This approach would preserve the encounter-based rate while basing the coinsurance reduction on each FQHC's relative assessment of resources for preventive services. However, the charge structure among

FQHCs varies, and beneficiary liability for the same mix of FQHC services could differ significantly based on the differences in charge structures.

Where preventive services are coded on a claim, we propose to use payments under the PFS to determine the proportional amount of coinsurance that should be waived for payments based on the PPS encounter rate. While physician-administered Part B drugs and routine venipuncture will be paid under the FQHC PPS rate, we note that the Medicare Part B rates for these items are not included in the PFS payment files. Therefore, when determining this proportionality of payments, we would also consider PFS payment limits for Part B drugs, as listed in the Medicare Part B Drug Pricing File, and the national payment amount for routine venipuncture (HCPCS 36415). Although FQHCs might list HCPCS for which we do not publish a payment rate in these files, a review of 2011 claims data indicated that the vast majority of line items with HCPCS representing services that will be paid under the FQHC PPS were priced in these sources. As such, we believe that referencing only the payment rates listed in these sources would be both sufficient and appropriate for determining the amount of coinsurance to waive for preventive services provided in FQHCs, without changing the total payment (Medicare and coinsurance). Since Medicare payment under the FQHC PPS is required to be 80 percent of the lesser of the FQHC's charges or the PPS rate, we would continue to use FQHC-reported charges to determine the amount of coinsurance that should be waived for payments based on the FQHC's charge. Total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the FQHC's charge or the PPS rate.

Our proposed approach for waiving coinsurance for preventive services preserves an encounter-based rate, and the calculation is similar to the current coinsurance calculation based on charges. However, this calculation is fairly complex for the claims processing systems. It may also be difficult for providers to replicate, and FQHCs might not know how much coinsurance would be assessed before the MAC issues the remittance advice.

As an alternative approach, we considered unbundling all services when a FQHC claim includes a mix of preventive and non-preventive services, and we would exclude these types of claims from calculation of the FQHC base encounter rate. We would use payments under the Medicare PFS to pay separately for every service listed

on the claim. While this approach is inconsistent with an all-inclusive payment, it would simplify waiving coinsurance for preventive services and pay preventive services comparably to PFS settings. However, the vast majority of FQHC claims list only one HCPCS, and unbundling all services introduces coding complexity that might underpay FQHCs for an encounter if they do not code all furnished ancillary services. In addition, payment for preventive services under the PFS will be less, in many cases, than the PPS encounter rate.

Instead of unbundling all services when a FQHC claim includes a mix of preventive and nonpreventive services, we considered the use of PFS payment rates to pay separately for preventive services billed on the FQHC claim, while paying for the non-preventive services under the FQHC PPS rate. However, this would be problematic when the preventive services represent the service that would qualify the claim as a FQHC encounter (for example, IPPE, AWV, MNT). Under current payment policy, the remaining ancillary services would not be eligible for an encounter payment without an additional, qualifying visit on the same claim.

We also considered using the dollar value of the coinsurance that would be waived under the PFS to reduce the FQHC encounter-based coinsurance amount when preventive services appear on the claim. However, this could lead to anomalous results, such as negative coinsurance if the preventive service(s) would have been paid more under the PFS than the FQHC PPS rate, and the amount of coinsurance waived under the PFS would exceed 20 percent of the FQHC PPS rate. We also were concerned that the reduction in coinsurance would seem insufficient if the payment rate for the preventive service(s) was very low under the PFS.

We believe that using the proportionality of PFS payments to determine the coinsurance waiver would facilitate the waiving of coinsurance while preserving the all-inclusive nature of the encounter-based rate with the least billing complexity. Therefore, we propose that where preventive services are coded on a claim, we would use payments under the PFS to determine the proportional amount of coinsurance that should be waived for payments based on the PPS encounter rate. We invite public comment on how this proposal would impact FQHCs' administrative procedures and billing practices.

## 5. Cost Reporting

Under section 1815(a) of the Act, providers participating in the Medicare program are required to submit financial and statistical information to achieve settlement of costs relating to health care services rendered to Medicare beneficiaries. This information is required for determining Medicare payment for FQHC services under 42 CFR 405, Subpart X.

The Medicare cost reporting forms show the costs incurred and the total number of visits for FQHC services during the cost reporting period. Using this information, the MAC determines the total payment amount due for covered services furnished to Medicare beneficiaries. The MAC compares the total payment due with the total payments made for services furnished during the reporting period. If the total payment due exceeds the total payments made, the difference is made up by a lump sum payment. If the total payment due is less than the total payments made, the overpayment is collected.

Under the FQHC PPS, Medicare payment for FQHC services will be made based on a predetermined national rate. For services included in the FQHC PPS rate, Medicare cost reports would not be used to reconcile Medicare payments with FQHC costs. However, the statute does not exempt FQHCs from submitting cost reports. In addition, Medicare payments for the reasonable costs of the influenza and pneumococcal vaccines and their administration, allowable graduate medical education costs, and bad debts would continue to be determined and paid through the cost report. We are also considering revisions to the cost reporting forms and instructions that would provide us with information that would improve the quality of our cost estimates, such as the reporting of a FQHC's overall and Medicare specific CCR. We are also considering the types of cost data that would facilitate the potential development of a FQHC market basket that could be used in base payment updates after the second year of the PPS. We also are exploring whether we have audit resources to include FQHCs in the pool of institutional providers that are subject to periodic cost report audits.

## 6. Medicare Advantage Organizations

Section 10501(i)(3)(C) of the Affordable Care Act added section 1833(a)(3)(B)(i)(II) to the Act to require that FQHCs that contract with MA organizations be paid at least the same amount they would have received for the same service under the FQHC PPS.

This provision ensures FQHCs are paid at least the Medicare amount for FQHC services, whether such amount is set by section 1833(a)(3) of the Act or section 1834(o) of the Act. Consistent with current policy, if the MA organization contract rate is lower than the amount Medicare would otherwise pay for FQHC services, FQHCs that contract with MA organizations would receive a wrap-around payment from Medicare to cover the difference. If the MA organization contract rate is higher than the amount Medicare would otherwise pay for FQHC services, there is no additional payment from Medicare. We propose to revise § 405.2469 to reflect this provision.

### III. Additional Proposed Changes Regarding FQHCs and RHCs

#### A. Rural Health Clinic Contracting

Due to the difficulty in recruiting and retaining physicians in rural areas, RHCs have had the option of hiring physicians either as RHC employees or as contractors. However, in order to promote stability and continuity of care, the Rural Health Clinic Services Act of 1977 required RHCs to employ a physician assistant or nurse practitioner (section 1861(aa)(2)(iii) of the Act). We have interpreted the term “employ” to mean that the employer issues a W-2 form to the employee. Section 405.2468(b)(1) currently states that RHCs are not paid for services furnished by contracted individuals other than physicians, and § 491.8(a)(3) does not authorize RHCs to contract with RHC practitioners other than physicians.

In the more than 30 years since this legislation was enacted, the health care environment has changed dramatically, and RHCs have requested that they be allowed to enter into contractual agreements with non-physician RHC practitioners as well as physicians. To provide RHCs with greater flexibility in meeting their staffing requirements, we propose to revise § 405.2468(b)(1) by removing the parenthetical “RHCs are not paid for services furnished by contracted individuals other than physicians,” and revising § 491.8(a)(3) to allow non-physicians to furnish services under contract in RHCs, when at least one NP or PA is employed.

The ability to contract with NPs, PAs, CNMs, CP, and CSWs would provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners. Practitioners should be employed or contracted to the RHC in a manner that enhances continuity and quality of care.

RHCs would still be required, under section 1861(aa)(2)(iii) of the Act, to

employ a PA or NP. However, as long as there is at least one PA or NP employed at all times (subject to the waiver provision for existing RHCs set forth at section 1861(aa)(7) of the Act), an RHC would be free to enter into contracts with other PAs, NPs, CNM, CPs or CSWs.

#### B. Technical and Conforming Changes

In addition to proposing to codify the statutory requirements for the FQHC PPS in this proposed rule and proposing to allow RHCs to contract with non-physician practitioners, we are proposing edits to correct terminology, clarify policy, delete irrelevant code, and make conforming changes for existing mandates and the new PPS. Some of these changes include the following:

- Removing the terms “fiscal intermediary and carriers” and replacing them with “Medicare Administrative Contractor” or “MAC”. Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the MACs to administer the work that was done by fiscal intermediaries and carriers in administering Medicare programs.
- Removing the payment limitations for treatment of mental psychoneurotic or personality disorders. This payment limitation is being phased out and will no longer be in effect beginning January 1, 2014.
- Updating the regulations to reflect section 410 of the Medicare Modernization Act of 2003 to exclude RHC and FQHC services furnished by physicians and certain other specified types of nonphysician practitioners from consolidated billing under section 1888(e)(2)(A)(ii) of the Act and allows such services to be separately billable under Part B when furnished to a SNF resident of a skilled nursing facility (SNF) during a covered Part A stay (see the July 30, 2004 final rule (69 FR 45818 through 45819). This statutory provision was effective with services furnished on or after January 1, 2005 and was previously implemented through program instruction (CMS Pub. 100-04, Medicare Claims Processing Manual, chapter 6, § 20.1.1).

### IV. Clinical Laboratory Improvement Amendments of 1988 (CLIA)—Enforcement Actions for Proficiency Testing Referral

#### A. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100-578. The purpose of

CLIA is to ensure the accuracy and reliability of laboratory testing for all Americans. Under this authority, which was codified at 42 U.S.C. 263a, the Secretary issued regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). The regulations specify the standards and specific conditions that must be met to achieve and maintain CLIA certification. CLIA certification is required for all laboratories, including but not limited to those that participate in Medicare and Medicaid, which test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings.

The regulations require laboratories conducting moderate or high-complexity testing to enroll in an HHS-approved proficiency testing (PT) program that covers all of the specialties and subspecialties for which the laboratory is certified and all analyses listed in Subpart I of the CLIA regulations. As of June 2013, there were 239,922 CLIA certified laboratories. Of these laboratories, 35,035 are required to enroll in an HHS-approved PT program and are subject to all PT regulations.

Congress emphasized the importance of PT when it drafted the CLIA legislation. For example, in discussing their motivation in enacting CLIA, the Committee on Energy and Commerce noted that it “focused particularly on proficiency testing because it is considered one of the best measures of laboratory performance” and that proficiency testing “is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results.” (See H.R. Rep. No. 100-899, at 15 (1988).) The Committee surmised that, left to their own devices, some laboratories would be inclined to treat PT samples differently than their patient specimens, as they would know that the laboratory would be judged based on its performance in analyzing those samples. For example, such laboratories might be expected to perform repeated tests on the PT sample, use more highly qualified personnel than are routinely used for such testing, or send the samples out to another laboratory for analysis. As such practices would undermine the purpose of PT, the Committee noted that the CLIA statute was drafted to bar laboratories from such practices, and to impose significant penalties on those who elect to violate those bars (H.R. Rep. No. 100-899, at 16 and 24 (1988)).

PT is a valuable tool the laboratory can use to verify the accuracy and

reliability of its testing. During PT, an HHS-approved PT program sends samples to be tested by a laboratory on a scheduled basis. After testing the PT samples, the laboratory reports its results back to the PT program for scoring. Review and analysis of PT reports by the laboratory director will alert the director to areas of testing that are not performing as expected and may also indicate subtle shifts or trends that, over time, could affect patient results. As there is no on-site, external proctor for PT testing in a laboratory, the testing relies in large part on an honor system. The PT program places heavy reliance on each laboratory and laboratory director to self-police their analysis of PT samples to ensure that the testing is performed in accordance with the CLIA requirements. For each PT event, laboratories are required to attest that PT samples are tested in the same manner as patient specimens are tested. PT samples are to be assessed by integrating them into the laboratory's routine patient workload, and the testing itself is to be conducted by the personnel who routinely perform such testing, using the laboratory's routine methods. The laboratory is barred from engaging in interlaboratory communication pertaining to results prior to the PT program's event cut-off date and must not send the PT samples or any portion of the PT samples to another laboratory for testing, even if it would normally send a patient specimen to another laboratory for testing.

Any laboratory that intentionally refers its PT samples to another laboratory for analysis risks having its certification revoked for at least 1 year, in which case, any owner or operator of the laboratory risks being prohibited from owning or operating another laboratory for 2 years (42 CFR 493.1840(a)(8), (b)). The phrase "intentionally referred" has not been defined by the statute or regulations, but we have consistently interpreted this phrase from the onset of the program to mean general intent, as in intention to act. Whether or not acts are authorized or even known by the laboratory's management, a laboratory is responsible for the acts of its employees. Among other things, laboratories need to have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to other laboratories even in instances in which they would normally forward a patient specimen for testing.

In the February 7, 2013 **Federal Register** (78 FR 9216), we published a proposed rule titled Part II—Regulatory Provisions to Promote Program

Efficiency, Transparency and Burden Reduction (hereafter referred to as the Burden Reduction proposed rule) to propose reforms to the Medicare and CLIA regulations that we had identified as unnecessary, obsolete, or excessively burdensome. In that rule, we proposed changes to the CLIA PT regulations to establish policies under which certain PT referrals by laboratories would generally not be subject to revocation of their CLIA certificate or a 2 year prohibition on laboratory ownership or operation. To do this, we proposed a narrow exception in our longstanding interpretation of what constitutes an "intentional" PT referral.

While that proposed rule was under development but before its publication, Congress enacted the "Taking Essential Steps for Testing Act of 2012" (Pub. L. 112–202, the "TEST Act") on December 4, 2012. The TEST Act amended section 353 of the PHS Act to provide the Secretary with discretion as to which sanctions she would apply to cases of intentional PT referral.

In the Burden Reduction proposed rule (78 FR 9216), we stated that we would address the TEST Act in future rulemaking, except that to comply with the TEST Act and begin to align the CLIA regulations with the amended CLIA statute, we proposed to revise the second sentence of § 493.801(b)(4) to state that a laboratory may (as opposed to "must") have its CLIA certification revoked when CMS determines PT samples were intentionally referred to another laboratory.

The regulatory changes that we are now proposing would add the remaining policies and regulatory changes needed to fully implement the TEST Act.

#### *B. Proposed Changes*

As noted earlier, the TEST Act provided the Secretary with the discretion to substitute intermediate sanctions in lieu of the 2 year prohibition on the owner and operator when a CLIA certificate is revoked due to intentional PT referral, and to consider imposing alternative sanctions in lieu of revocation in such cases as well. The TEST Act provides the Secretary with the opportunity to frame policies that will achieve a better correlation between the nature and extent of intentional PT referrals at a given laboratory, and the scope and type of sanctions or corrective actions that are imposed on that laboratory and its owners and operators, as well as any consequences to other laboratories owned or operated by those owners and operators.

We are proposing to divide the sanctions for PT referral into three categories based on severity and extent of the referrals. The first category is for the most serious, egregious violations, encompassing cases of repeat PT referral or cases where a laboratory reports another laboratory's test results as its own. In such cases, we do not believe that alternative sanctions would be appropriate. Therefore, we are proposing to revoke the CLIA certificate for at least 1 year in instances in which a laboratory has a repeat proficiency testing referral, ban the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and may also impose a civil monetary penalty (CMP). In keeping with the February 7, 2013 proposed rule (78 FR 9216), we propose to define, at § 493.2, "a repeat proficiency testing referral" as "a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization)." We believe that a repeat PT referral warrants revocation of a laboratory's CLIA certificate for at least 1 year because such laboratories have already been given opportunity to review their policies, correct their deficiencies and adhere to regulations, and adherence to the laboratory's established policy, and ensure effective training of their personnel. As there is no on-site, external proctor for PT testing in a laboratory, the testing relies in large part on an honor system. Therefore, when a PT referral has previously occurred prior to the event cut-off date within the two prior survey cycles, we do not believe that laboratories should be given additional opportunities to ensure that they are meeting the CLIA PT requirements and believe that revocation of the CLIA certificate should consequently occur. We also propose, in the first category, that the CLIA certificate be revoked, and the owner and operator banned from owning or operating a CLIA-certified laboratory for at least 1 year, in cases where the PT sample was referred to another laboratory, the referring laboratory received the results from the other laboratory, and the referring laboratory reported to the PT program the other laboratory's results on or before the event cut-off date. We note that PT

programs place heavy reliance on each laboratory and laboratory director to self-police their analysis of PT samples to ensure that the testing is performed in accordance with the CLIA requirements. PT performance and scores must reflect an individual laboratory's performance, and as such, reporting results from another laboratory is deceptive to the public. We believe these two scenarios are the most egregious forms of PT referral and merit the most severe sanctions.

For example, a laboratory may have two distinct sites, Laboratory A and Laboratory B, that operate under different CLIA numbers, where Laboratory A has received PT samples to be tested as part of their enrollment in PT as required by the CLIA regulations. If Laboratory A were to refer PT samples to Laboratory B, receive test results back at Laboratory A from Laboratory B prior to the event cutoff date, and report to the PT program those results obtained from Laboratory B, the scores for the PT event would not reflect the performance of Laboratory A, but rather the performance of Laboratory B. Since the PT scores would actually be reflective of the accuracy and reliability at Laboratory B rather than A, the purpose of the proficiency testing would be undermined. Further, as stated in the CLIA regulations at § 493.801(4)(ii), the laboratory must make PT results available to the public. In this scenario, any member of the public who sought to use the reported PT scores to select a high-quality laboratory would be deceived by the scores for the results submitted to the PT program, as they would expect that they were provided information about the performance of Laboratory B when that would not be the case.

In cases of PT referral where the CLIA certificate is revoked, the TEST Act provides the Secretary with discretion to ban the owner and operator from owning or operating a CLIA-certified laboratory for less than 2 years. Prior to the TEST Act, revocation of a CLIA certificate for PT violation always triggered a 2-year ban on the owner and operator. We are also proposing that the laboratory owner and operator would be banned from owning or operating a CLIA-certified laboratory for at least 1 year for any violation within the first category involving the revocation of a CLIA certificate.

We believe that a second category of sanctions should be applied to certain PT referral situations in which the CLIA certificate would be suspended or limited (rather than revoked), in combination with alternative sanctions. We propose to use this approach in

those instances in which a laboratory refers PT samples to a laboratory that operates under a different CLIA number before the PT event close date and, while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the event close date. Such a referral situation would allow the referring laboratory an opportunity to confirm, check, or change its results prior to reporting its results to the PT program. If, upon investigation, surveyors determine that the referral does not constitute a repeat PT referral, we propose to suspend or limit the CLIA certificate for less than 1 year rather than revoke the CLIA certificate, and propose that we also impose alternative sanctions (as an alternative to revocation of the CLIA certificate). Further, an alternative sanction would always include required training of staff.

A suspension of the CLIA certificate means that no testing of human specimens for health care purposes may be performed by that laboratory during the period of suspension. In such cases, the owner or operator typically contracts out for laboratory services, or contracts with another operator to operate the laboratory under the contracted laboratory's CLIA certificate. In contrast to revocation of the CLIA certificate and its accompanying ban on the owner and operator, suspension usually applies only to the individual laboratory in question rather than all laboratories that are under the control of the owner or operator.

A limitation of the CLIA certificate means that the laboratory is not permitted to perform testing or to bill Medicare or Medicaid for laboratory work in the specialty or subspecialty that has been limited, but may continue to conduct all other testing under its own CLIA certificate.

In determining whether to suspend or limit the CLIA certificate, we propose to apply the criteria of § 493.1804(d). For example, we would examine the extent of the PT referral practice as well as its duration. We propose that if surveyors determine that in the prior two survey cycles there were prior PT referrals that occurred but were not cited by CMS, then the CLIA certificate would always be suspended rather than just limited. The duration of the suspension would reflect the number of samples referred, the period of time the referrals had been occurring, the extent of the practice, and other criteria specified at § 493.1804(d).

Further, for cases in the second category we propose that when the certificate is suspended or limited, alternative sanctions would be applied in addition to the principal sanctions of

suspension or limitation. We propose that, at a minimum, the alternative sanctions would include a CMP to be determined using the criteria set forth in § 493.1834, as well as a directed plan of correction. Additionally, if the CLIA certificate is suspended, we propose to also impose state on-site monitoring of the laboratory.

We believe that a third category of sanctions should be applied to those PT referral scenarios in which the referring laboratory does not receive test results prior to the event cut-off date from another laboratory as a result of the PT referral. We propose that in such scenarios, at a minimum, the laboratory will always be required to pay a CMP as calculated according to § 493.1834, as well as comply with a directed plan of correction. A directed plan of correction would always include training of staff.

For example, a laboratory may place PT samples in an area where other patient specimens are picked up by courier to take to a reference laboratory. The reference laboratory courier may take the PT samples along with the patients' specimens. The laboratory personnel notice that the PT samples are missing and contact the reference laboratory to inquire if they have received the PT samples along with the patients' specimens. The reference laboratory is instructed to discard the PT samples and not test them since they were picked up in error. In this case, the "referring" laboratory realized the error, contacted the receiving laboratory, and did not receive results back for any of the PT samples. In this scenario, we propose to impose only alternative sanctions. We welcome comments about other scenarios in which you believe lesser sanctions may also be appropriate.

In determining whether to impose alternative sanctions, we propose to rely on the existing considerations at § 493.1804(c) and (d), § 493.1806(c), § 493.1807(b), § 493.1809 and, in the case of civil money penalties, § 493.1834(d). These current regulations have proven effective as enforcement measures over time for CLIA noncompliance for all circumstances other than PT referral. We therefore believe these same criteria will be effective in the imposition of alternative sanctions for PT referral cases.

In summary, we propose to amend § 493.1840 by revising paragraph (b) to specify three categories for the imposition of sanctions for PT referrals. We believe these provisions, as amended, would provide the necessary detail to fairly and uniformly apply the discretion granted to the Secretary under the TEST Act, without being so

specific as to defeat the intent to provide appropriate flexibility when taking punitive or remedial action in the context of a PT referral finding.

We also propose to make three conforming changes to the CLIA regulations at the authority citation for Part 493 and at § 493.1 and § 493.1800(a)(2) to include references to the Public Health Service Act as amended by the TEST Act.

We invite the public to comment on our proposed categorization of potential PT referral situations, the criteria we propose for assessing the scope and severity of any violation, and the types of sanctions that correspond to each category.

## V. Other Required Information

### A. Requests for Data From the Public

Commenters can gain access to summarized FQHC data on an expedited basis by downloading the files listed in this section, which are available on the Internet without charge. For detailed claims data, requestors would follow the current research request process which can be found on the Research Data Assistance Center (ResDAC) Web site at <http://www.resdac.org/>.

1. FQHC Summary Data. This file contains data summarized by CCN, which can be used to model the proposed methodology and calculate projected payments and impacts under the proposed PPS. The data file is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

2. FQHC Proposed GAFs. This file contains the listed of proposed GAFs by locality, as published in Addendum A of this proposed rule. The data file is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

3. HCRIS Cost Report Data. The data included in this file was reported on Form CMS-222-92. The dataset includes only the most current version of each cost report filed with CMS and includes cost reports with fiscal year ending dates on or after September 30, 2009. HCRIS updates this file on a quarterly basis. The data file is available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/CostReports/HealthClinic.html>.

### B. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management

and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting public comment on the information collection requirements (ICRs) regarding the proposed FQHC rates and adjustments in § 405.2470.

Section II. of this proposed rule discusses the data that are used in computing the FQHC PPS rates and adjustments. As discussed, the data are derived from the RHC/FQHC cost report form CMS-222-92, and claims form UB-04 CMS 1450 (per CMS Pub. 100-04, Medicare Claims Processing Manual, Chapter 1). The reporting requirements for FQHCs are in § 405.2470 of the Medicare regulations. We note that, while the preamble does not contain any new ICRs, there is currently an OMB approved information collection request associated with the RHC/FQHC cost report. The OMB control number is 0938-0107, with an expiration date of August 31, 2014.

If you comment on this information collection and recordkeeping requirement, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-1443-P] Fax: (202) 395-6974; or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

## VI. Response to Comments

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

## VII. Regulatory Impact Analysis

### A. Statement of Need

This proposed rule is necessary to establish a methodology and payment rates for a PPS for FQHC services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirements of section 10501(i)(3)(A) of the Affordable Care Act. This proposed rule also is necessary to make—(1) contracting changes for RHCs; (2) conforming changes to other policies related to FQHCs and RHCs; (3) changes to enforcement actions for improper proficiency testing referrals.

### B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (having an annual effect on the economy of \$100 million or more in any 1 year, 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 referred to as “economically significant”); (2) creating a 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 the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100

million or more in any 1 year). This proposed rule is an economically significant rule because we estimate that the FQHC PPS will increase payments to FQHCs by more than \$100 million in 1 year. We believe that this regulation would not have a significant financial impact on RHCs. We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government jurisdictions. All RHCs and FQHCs are considered to be small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$35.5 million in any 1 year). The provisions in this proposed rule have an average of 30 percent increase in Medicare PPS payment to FQHCs and no financial impact on RHCs. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We are not preparing an analysis for section 1102(b) of the Act, because we have determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that is approximately \$141 million. This proposed rule does not include any

mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, that would exceed the threshold of \$141 million.

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

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

### C. Limitations of Our Analysis

Our quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective on FQHCs for cost reporting periods beginning on or after October 1, 2014. We estimated the effects of individual proposed policy changes by estimating payments per visit while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as the number of visits or the prevalence of new patients or comprehensive initial Medicare visits furnished to Medicare beneficiaries. To the extent that there are changes in the volume and mix of services furnished by FQHCs, the actual impact on total Medicare revenues will be different from those shown in Table 2 (Impact of the PPS on Payments to FQHCs).

### D. Anticipated Effects of the FQHC PPS

#### 1. Effects on FQHCs

As required by section 1834(o)(2)(B)(i) of the Act, initial payments (Medicare and coinsurance) under the FQHC PPS must equal 100 percent of the estimated amount of reasonable costs, as determined without the application of the current system's UPLs or productivity standards that can reduce a FQHC's per visit rate. As discussed in sections I and II. of this proposed rule, we propose to pay FQHCs a single encounter-based rate per beneficiary per day, adjusting for geographic differences in the cost of inputs by applying an adaptation of the GPCI used to adjust payment under the PFS, and further adjusting the encounter-based rate when

a FQHC furnishes care to a patient that is new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit (that is, an IPPE an initial AWV).

Based on comparisons of the proposed PPS rate to the AIRs (as listed on the FQHC cost reports), the proposed FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 30 percent. The FQHC PPS is effective for cost reports beginning on or after October 1, 2014. This impact is fully implemented when all FQHCs are paid under the FQHC PPS and reflects the additional payment rate update based on the MEI for all of 2015 (fiscal year through the end of the calendar year). (See section II.E. of this proposed rule for a discussion of the use of the MEI update to calculate the first year's base payment amount under the FQHC PPS.)

Table 2 shows the impact on cost reporting entities and their associated delivery sites of the fully implemented proposed FQHC PPS payments compared to current payments to FQHCs. The analysis is based on cost reports from freestanding FQHCs with cost reporting periods ending between June 30, 2011, and June 30, 2012. A FQHC with multiple sites has the option of filing a consolidated cost report, and this sample reflects 1,141 cost reporting entities that represent 3,509 delivery sites. The following is an explanation of the information represented in Table 2:

- Column A (Number of cost-reporting entities): This column shows the number of cost-reporting entities for each impact category. Urban/rural status and census division were determined based on the geographic location of the cost reporting entity. Categories for Medicare volume were defined from cost report data, based on tertiles for the percent of total visits that were identified as Medicare visits. Categories for total volume were defined from cost report data, based on tertiles for the total number of visits for each cost reporting entity.

- Column B (Number of delivery sites): This column shows the number of delivery sites associated with the cost reporting entities in each impact category. (Note that delivery sites that are part of a consolidated cost reporting entity might not fall into the same impact category if considered individually. For example, a cost reporting entity could include delivery sites in multiple census division, and delivery sites were categorized based on the geographic location of the cost reporting entity).

- Column C (Number of Medicare visits): This column shows the number of Medicare visits in the final data set that were used to model payments under the FQHC PPS.

- Column D (Effect of statutorily required changes): This column shows the estimated fully implemented combined impact on payments to FQHCs of changes to the payment structure that are required by statute. Removing both the UPL and the productivity screen is estimated to increase total Medicare payments to FQHCs by about 28 percent. The combined impact in column D also reflects the FQHC PPS requirement to calculate payment based on the costs of all FQHCs, rather than on an individual FQHC's costs. We note that the impacts for column D through H reflect the growth in the MEI from July 1, 2012 through September 30, 2014, prior to the application of the forecasted MEI update for the 15-month period of October 1, 2014 through December 31, 2015.

- Columns E through H (Effects of the Proposed Adjustments to the Average Cost per Visit): These columns show the estimated fully implemented impacts on Medicare payments to FQHCs due to the proposed policy changes. In developing the Medicare FQHC PPS, section 10501(i)(3)(A) of the Affordable Care Act requires CMS to take into account the type, intensity, and duration of FQHC services, and allows other

adjustments, such as geographic adjustments. As discussed in section I.I.C of this proposed rule, the cost report data are insufficient for modeling these types of adjustments, and we propose to use the HCPCS codes in the FQHC claims data to support the development of the FQHC PPS rate and adjustments and for making payment under the PPS. As demonstrated in columns E–H, the overall effect of these various adjustments is budget neutral.

- Column E (Effect of daily visit (per diem) rate): This column shows the estimated fully implemented impact on payments to FQHCs of the proposal to pay a single encounter-based rate per beneficiary per day, which eliminates the current exceptions that pay for more than one visit per beneficiary per day. As it is uncommon for FQHCs to bill more than one visit per day for the same beneficiary (less than 0.5 percent of visits), this adjustment would have minimal effect on most FQHCs.

- Column F (Effect of new patient/initial visit adjustment): This column shows the estimated fully implemented impact on payments to FQHCs of the proposal to adjust the encounter-based rate by 1.3333 when a FQHC furnished care to a patient that was new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit. As new patients and initial Medicare visits accounted for approximately 3 percent of all FQHC visits, this adjustment

would have limited reduction on the base encounter rate, after application of budget neutrality, and a limited redistribution effect among FQHCs.

- Column G (Effect of the GAF): This column shows the estimated fully implemented impact on payments to FQHCs of the proposal to adjust payments for geographic differences in costs by applying an adaptation of the GPCIs used to adjust payment for physician work and practice expense under the PFS.

- Column H (Combined effect of all PPS adjustments): This column shows the estimated fully implemented impact on payments to FQHCs of the proposed adjustments in columns E through G. Both the individual and combined effects of these adjustments on overall Medicare payment to FQHCs would be zero percent as the effects of these adjustments would be redistributive and would not change Medicare payments in the aggregate.

- Column I (Combined effect of all policy changes and MEI adjustment): This column shows the estimated fully implemented impact on payments to FQHCs of removing the UPL and productivity screen in Column D, the adjustments to the PPS rates in the preceding columns, and the application of the forecasted MEI update for the 15-month period of October 1, 2014 through December 31, 2015.

TABLE 2—IMPACT OF THE PPS ON PAYMENTS TO FQHCs

	Number of cost-reporting entities	Number of delivery sites	Number of Medicare visits	Effect of statutorily required changes (percent)	Effect of daily visit (per diem) rate (percent)	Effect of new patient/initial visit adjustment (percent)	Effect of geographic adjustment factor (GAF) (percent)	Combined effect of all PPS adjustments (percent)	Combined effect of all policy changes and MEI adjustment (percent)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)
All FQHCs .....	1,141	3,509	5,245,961	28.0	0.0	0.0	0.0	0.0	30.2
Urban/rural Status:									
Urban .....	647	1,756	2,518,395	21.8	-0.2	0.0	3.1	3.0	27.6
Rural .....	348	820	1,385,116	39.3	0.2	-0.9	-3.1	-3.0	37.4
Mixed rural-urban .....	146	933	1,342,450	29.6	0.2	0.0	-2.7	-2.5	28.5
Medicare Volume:									
Low (<6.9% of total visits)	380	1,039	851,771	22.6	-0.1	0.2	3.3	3.4	28.9
Medium (6.9%–13.2% of total visits) .....	381	1,235	1,751,498	25.5	-0.1	0.1	0.0	0.5	28.2
High (>13.2% of total visits) .....	380	1,237	2,642,692	31.7	0.1	-0.2	-1.3	-1.4	32.0
Total Volume:									
Low (<17,340 total visits)	380	502	426,346	31.8	0.0	0.1	-0.1	0.0	34.1
Medium (17,340–42,711 total visits) .....	381	903	1,253,817	29.6	0.0	0.1	-1.6	-1.5	29.8
High (>42,711 total visits)	380	2,123	3,565,798	27.1	0.0	-0.1	0.6	0.5	29.9
Census Division:									
New England .....	92	236	657,794	25.7	-0.4	-0.2	1.8	1.2	29.3
Middle Atlantic .....	108	314	457,798	23.1	0.1	0.0	3.1	3.2	29.1
East North Central .....	143	460	603,034	29.2	-0.2	0.1	-2.7	-2.7	27.7
West North Central .....	78	201	248,891	29.2	0.0	0.1	-5.1	-5.1	24.6
South Atlantic .....	187	688	1,049,755	31.0	0.2	0.0	-3.0	-2.9	29.3
East South Central .....	83	317	374,386	36.1	0.1	0.0	-6.8	-6.7	29.2
West South Central .....	107	287	337,375	29.4	0.1	0.2	-5.3	-5.0	25.0
Mountain .....	87	311	368,666	29.2	-0.1	0.3	-2.1	-1.9	28.9
Pacific .....	252	690	1,145,897	24.8	0.1	-0.1	7.5	7.5	36.4
US Territories .....	4	5	2,365	36.7	0.4	1.1	-0.5	1.0	41.2

2. Effects on RHCs

While we expect that removing the restriction on contracting will result in cost savings for RHCs that employ an NP or PA and will no longer need to conduct employment searches to meet their additional staffing needs, the financial impact on RHCs is expected be small and cannot be quantified.

There is no Medicare impact on RHCs as a result of the implementation of the FQHC PPS.

3. Effects on Other Providers and Suppliers

There would be no financial impact on other providers or suppliers as a result of the implementation of the FQHC PPS.

4. Effects on the Medicare and Medicaid Programs

We estimate that annual Medicare spending for FQHCs during the first 5 years of implementation would increase as follows:

TABLE 3—ESTIMATED INCREASE IN ANNUAL MEDICARE PAYMENTS TO FQHCs

Calendar year	Estimated increase in payments (\$ in millions)
2014 .....	33
2015 .....	204
2016 .....	226
2017 .....	236
2018 .....	248

We intend for estimated aggregate payments under the proposed FQHC PPS to equal 100 percent of the estimated amount of reasonable costs, as determined without the application of the current system's UPLs or productivity standards. We note that the estimated increase in payments for CY 2014 is significantly smaller than for subsequent years, primarily due to the implementation date of October 1, 2014, which will affect payments for only 3 months of CY 2014. In addition, an analysis of 2010 cost reporting data indicates that approximately 6 percent of FQHC cost reporting entities had cost reporting periods that began between October 1 and December 31, which indicates that we would expect a small percentage of cost reporting entities to be paid under the FQHC PPS between October 1, 2014 and December 31, 2014.

After the first year of implementation, the PPS payment rates must be increased by the percentage increase in the MEI. After the second year of implementation, PPS rates shall be increased by the percentage increase in

a market basket of FQHC goods and services as established through regulations, or, if not available, the MEI. While we will consider the merits of estimating a FQHC market basket for use in base payment updates after the second year of the PPS, payment estimates were updated annually by the MEI for purposes of this analysis.

There is no financial impact on the Medicaid program as a result of the implementation of the Medicare FQHC PPS.

5. Effects on Medicare Beneficiaries

FQHC PPS: As discussed in section II.E. of this proposed rule, we propose that coinsurance under the FQHC PPS would be 20 percent of the lesser of the FQHC's charge or the PPS rate. Under the current reasonable cost payment system, beneficiary coinsurance for FQHC services is assessed based on the FQHC's charge, which can be more than coinsurance based on the AIR. An analysis of a sample of FQHC claims data for dates of service between January 1, 2011 through June 30, 2012 indicated that beneficiary coinsurance based on 20 percent of the FQHC's charges was approximately \$23 million higher, or 18 percent more, than if coinsurance had been assessed based on 20 percent of the lesser of the FQHC's charge or the applicable all-inclusive rate.

Based on comparisons of the proposed PPS rate to the AIRs, the proposed FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 30 percent. This overall 30 percent increase translates to a 30 percent increase to beneficiary coinsurance if it were currently assessed based on the FQHC's AIR and if, under the PPS, it would always be assessed based on the PPS rate. Because the charge structure among FQHCs varies, and beneficiary liability for the same mix of FQHC services could differ significantly based on the differences in charge structures, we have insufficient data to estimate the change to beneficiary coinsurance due to the FQHC PPS.

E. Effects of Other Policy Changes

1. Effects of Policy Changes for FQHC's and RHC's

a. Effects of RHC Contracting Changes

In section III.A. of this proposed rule we discuss our proposal to remove the restrictions on RHCs contracting with nonphysician practitioners when the statutory requirement to employ an NP or a PA is met would provide RHCs with greater flexibility in meeting their

staffing requirements. The ability to contract with NPs, PAs, CNMs, CP, and CSWs would provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners, which may result in increasing access to care in rural areas. There is no cost to the Federal government and we cannot estimate a cost savings for RHCs.

b. Effects of the FQHC and RHC Conforming Changes

In section III.B. of this proposed rule, we present our proposals regarding clarifying, technical, conforming changes to the FQHC and RHC regulations that are necessary for implementation of the FQHC PPS. We believe that are no costs associated with these changes.

2. Effects of CLIA Changes for Enforcement Actions for Proficiency Testing Referral

As discussed in section IV. of this proposed rule, we would make a number of clarifications and changes pertaining to the regulations governing adverse actions for PT referral under CLIA to ensure conformance between the TEST Act and our regulations. The TEST Act provides the Secretary with the discretion to apply alternative sanctions in lieu of potential principal sanctions in cases of intentional PT referral. Alternative sanctions may include any combination of civil money penalties, directed plan of correction (such as required remedial training of staff), temporary suspension of Medicare or Medicaid payments, or state onsite monitoring. From 2007 through 2011 there were 41 cases of cited, intentional PT referral. Of these 41 cases (averaging 8 per year), we estimate that 28 (or 6 per year on average) may have fit the terms of this rule to have alternative sanctions applied. Based on discussions with the most recently affected laboratories that were cited for PT violations, we estimate that the average cost of the sanctions applicable under current regulations is approximately \$578,400 per laboratory. The largest single type of cost is the expense to the laboratory or hospital to contract out for management of the laboratory, and to pay laboratory director fees, due to the 2-year ban that prohibits the owner and operator from owning or operating a CLIA-certified laboratory in accordance with revocation of the CLIA certificate. We have not included legal expenses in this cost estimate, as it is not possible to estimate the extent to which laboratories may still appeal the imposition of the alternative sanctions in this proposed

rule. If the expense of alternative sanctions averaged \$150,000 per laboratory, we estimate the annual fiscal savings of the changes to average \$2.6 million (\$578,400 minus \$150,000 for 6 laboratories). While the total savings may not be large, the savings to the individual laboratory or hospital that is affected can be significant. However, we note that the \$2.6 million estimate may overstate or understate the provision's savings to laboratories. For example, if under current regulations the prior management is fired instead of being reassigned to other duties for the 2-year period, some of the costs of paying for the new management's salaries, benefits and training may be able to be drawn from funding that had previously been earmarked to pay those expenses for their predecessors. That is, the costs associated with the new employee could be offset by the savings gained when the former employee is terminated. Any such offset will result in lower savings than is estimated earlier. However, there

are also unknowns that may result in larger savings than estimated earlier. For example, we have no data on whether terminated management historically received severance packages. If they did, those savings would have to be added to the savings we noted earlier. Such changes in severance payments would represent transfer effects of the proposed rule, rather than net social costs or benefits. In general, it is only to the extent that new laboratory directors put forth more effort than temporarily-banned laboratory directors (due, for example, to the need to familiarize themselves with laboratories they have not previously operated) or that support staff put forth more effort to make the new management arrangements than they would addressing alternative sanctions that society's resources would be freed for other uses by the proposed provision; thus, a comprehensive estimate of laboratory savings would represent some combination of transfers and net social benefits. While we

recognize these potential inaccuracies in our estimates, we lack data to account for these considerations.

*F. Alternatives Considered*

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding sections of this proposed rule provide descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

*G. Accounting Statement and Table*

As required by OMB Circular A-4 (available at [http://www.whitehouse.gov/omb/circulars\\_a004\\_a-4/](http://www.whitehouse.gov/omb/circulars_a004_a-4/)), we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this proposed rule.

TABLE 4—ACCOUNTING STATEMENT—CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES UNDER THE FQHC PPS

Category	Estimates	Units		
		Year dollar	Discount rate (percent)	Period covered
Transfers:				
Federal Annualized Monetized Transfers (in millions) .....	183	2014	7	2014–2018
	187	2014	3	2014–2018
From Whom to Whom .....	Federal Government to FQHCs that receive payments under Medicare.			

*H. Conclusion*

The previous analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The previous analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**

*42 CFR Part 405*

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

*42 CFR Part 491*

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

*42 CFR Part 493*

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR parts 405, 491, and 493 as set forth below:

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

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

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

■ 2. Section 405.2400 is revised to read as follows:

**§ 405.2400 Basis.**

Subpart X is based on the provisions of the following sections of the Act: Section 1833—Amounts of payment for

supplementary medical insurance services. Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

- 3. In § 405.2401, paragraph (b) is amended as follows:
  - A. Removing the definition of “Act”.
  - B. Revising the definition of “Allowable costs”.
  - C. Removing the definition of “Carrier”.
  - D. Adding the definitions of “Certified nurse midwife (CNM),” “Clinical psychologist (CP),” and “Clinical social worker (CSW)”.
  - E. Revising the definitions of “Coinsurance” and “Deductible”.
  - F. Adding the definition of “Employee” and “HRSA.”
  - G. Revising paragraphs (1) through (3) of the definition of “Federally qualified health center”.
  - H. Removing the definition of “Intermittent nursing care”.

- I. Adding the definition of “Medicare Administrative Contractor (MAC)”.
- J. Removing the definitions of “Nurse-midwife”, “Nurse practitioner and physician assistant”, and Part-time nursing care”.
- K. Adding the definitions of “Physician assistant (PA)” and “Prospective payment system (PPS)”.
- L. Revising the definitions of “Reporting period” and “Rural health clinic”.
- M. In the definition of “Visiting nurse services,” removing the phrase “registered nurse” and adding in its place the phrase “registered professional nurse”.

The revisions and additions read as follows:

**§ 405.2401 Scope and definitions.**

\* \* \* \* \*

(b) \* \* \*

*Allowable costs* means costs that are incurred by a RHC or FQHC that is authorized to bill based on reasonable costs and are reasonable in amount and proper and necessary for the efficient delivery of RHC and FQHC services.

\* \* \* \* \*

*Certified nurse midwife (CNM)* means an individual who meets the applicable education, training experience and other requirements of § 410.77(a) of this chapter.

*Clinical psychologist (CP)* means an individual who meet the applicable education, training experience and other requirements of § 410.71(d) of this chapter.

*Clinical social worker (CSW)* means an individual who meet the applicable education, training experience and other requirements of § 410.73(a) of this chapter.

\* \* \* \* \*

*Coinsurance* means that portion of the RHC’s charge for covered services or that portion of the FQHC’s charge or PPS rate for covered services for which the beneficiary is liable (in addition to the deductible, where applicable).

\* \* \* \* \*

*Deductible* means the amount incurred by the beneficiary during a calendar year as specified in § 410.160 and § 410.161 of this chapter.

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

*Federally qualified health center (FQHC)* \* \* \*

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

(2) Is determined by the HRSA to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center as of January 1, 1990; or

\* \* \* \* \*

*HRSA* means the Health Resources and Services Administration.

\* \* \* \* \*

*Medicare Administrative Contractor (MAC)* means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

*Nurse practitioner (NP)* means individuals who meet the applicable education, training experience and other requirements of § 410.75(b) of this chapter.

\* \* \* \* \*

*Physician assistant (PA)* means an individual who meet the applicable education, training experience and other requirements of § 410.74(c) of this chapter.

*Prospective payment system (PPS)* means a method of payment in which Medicare payment is made based on a predetermined, fixed amount.

*Reporting period* generally means a period of 12 consecutive months specified by the MAC as the period for which a RHC or FQHC must report required costs and utilization information. The first and last reporting periods may be less than 12 months.

*Rural health clinic* means a facility that has—

(1) Been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval; and

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

\* \* \* \* \*

■ 4. Section 405.2402 is amended as follows:

- A. Revising the section heading.
- B. Revising paragraphs (b) introductory text and (c) introductory text.
- C. Revising paragraph (d).
- D. Revising paragraph (e).
- E. Redesignating paragraph (f) as paragraph (e).
- F. Revising newly redesignated paragraph (e).

The revisions read as follows:

**§ 405.2402 Rural health clinic basic requirements.**

\* \* \* \* \*

(b) *Acceptance of the clinic as qualified to furnish RHC services.* If the Secretary, after reviewing the survey agency or accrediting organization recommendation, as applicable, and other evidence relating to the qualifications of the clinic, determines that the clinic meets the requirements of this subpart and of part 491 of this chapter, the clinic is provided with—

\* \* \* \* \*

(c) *Filing of agreement by the clinic.* If the clinic wishes to participate in the program, it must—

\* \* \* \* \*

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the clinic, the Secretary returns to the clinic one copy of the agreement with a notice of acceptance specifying the effective date.

(e) *Appeal rights.* If CMS declines to enter into an agreement or if CMS terminates an agreement, the clinic is entitled to a hearing in accordance with § 498.3(b)(5) and (6) of this chapter.

■ 5. Section 405.2403 is amended as follows:

- A. Revising the section heading.
- B. Amending paragraphs (a) introductory text and (a)(2) by removing the term “rural health clinic” and by adding in its place the term “RHC”.
- C. Amending paragraph (a)(3)(ii)(B) by removing the term “rural health clinic’s” and adding in its place the term “RHC’s”.
- D. Amending paragraphs (a)(1), (a)(2) introductory text, (a)(3)(i), and (a)(4)(i) and (ii) by removing the term “clinic” and adding in its place the term “RHC”.

The revision reads as follows:

**§ 405.2403 Rural health clinic content and terms of the agreement with the Secretary.**

\* \* \* \* \*

■ 6. Section 405.2404 is amended as follows:

- A. Revising the section heading.
- B. Amending paragraphs (a) introductory text, (b)(1) introductory text, (b)(2), (b)(3), (c), (e) introductory text, by removing the term “rural health clinic” each time it appears and by adding in its place the term “RHC”.
- C. Amending paragraph (a)(1), (a)(2)(i), (a)(2)(ii)(A), (a)(3), and (d)(1) by removing the term “clinic” each time it appears and adding in its place the term “RHC”.
- D. Amending paragraph (a)(2)(i) by removing the term “clinic’s” and adding in its place the term “RHC’s”.
- E. In paragraph (a)(2)(ii) introductory text, removing the phrase “if he

determines” and adding place “if the Secretary determines”.

■ F. In paragraph (a)(3), removing the phrase “that shall be deemed” and adding in its place the phrase “The Secretary deems it”.

■ G. In paragraph (b)(2), removing the phrase “The Secretary will give” and adding in its place the phrase “The Secretary gives”.

The revisions read as follows:

**§ 405.2404 Termination of rural health clinic agreements.**

\* \* \* \* \*

**§ 405.2410 [Amended]**

■ 7. Section 405.2410 is amended as follows:

■ A. In paragraph (a)(1), removing the term “rural health clinic” and adding in its place the term “RHC”.

■ B. In paragraph (a)(2), removing the term “Federally qualified health center” and adding in its place the term “FQHC”.

■ C. Revising paragraph (b).

The revision reads as follows:

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

\* \* \* \* \*

(b) *Application of coinsurance.* The beneficiary’s responsibility is based on either of the following:

(1) For RHCs and FQHCs that are not being paid in accordance with section 1834(o) of the Act —

(i) A coinsurance amount that does not exceed 20 percent of the RHC’s or FQHC’s reasonable customary charge for the covered service; and

(ii)(A) For any one item or service furnished by the RHC, a deductible and coinsurance liability that does not exceed twenty percent of a reasonable customary charge by the RHC for that particular item or service; or

(ii) For any one item or service furnished by a FQHC, a coinsurance liability that does not exceed 20 percent of a reasonable customary charge by the FQHC for that particular item or service.

(2) For FQHCs authorized to bill under the PPS, a coinsurance amount which is 20 percent of the lesser of—

(i) The FQHC’s charge; or

(ii) The PPS rate for the covered service.

■ 8. Section 405.2411 is amended as follows:

■ A. Revising paragraph (a) introductory text.

■ B. In paragraphs (a)(1) through (a)(3), removing “;” and adding in its place “.”.

■ C. Revising paragraphs (a)(4) and (5).

■ D. Adding a new paragraph (a)(6).

■ E. Revising paragraph (b).

The revisions and addition read as follows:

**§ 405.2411 Scope of benefits.**

(a) The following RHC services are reimbursable under this subpart:

\* \* \* \* \*

(4) Services and supplies furnished as incident to a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker service.

(5) Visiting nurse services when provided in accordance with 1861(aa)(1) of the Act and § 405.2416.

(6) Clinical psychologists and clinical social worker services as specified in § 405.2450.

(b) Rural health clinic services are—

(1) Covered when furnished in a RHC setting or other outpatient setting, including a patient’s place of residence;

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife or clinical psychologist employed or under contract with the RHC at the time the services are furnished; and

(3) Not covered in a hospital as defined in section 1861(e) of the Act; or critical access hospital as defined in 1861(mm)(1) of the Act.

■ 9. Section 405.2412 is revised to read as follows:

**§ 405.2412 Physicians’ services.**

Physicians’ services are professional services that are furnished by either of the following:

(a) By a physician at the RHC or FQHC.

(b) Away from the RHC or FQHC by a physician whose agreement with the RHC or FQHC provides that he or she will be paid by the RHC or FQHC for such services and certification and cost reporting requirements are met.

**§ 405.2413 [Amended]**

■ 10. Section 405.2413 is amended as follows:

■ A. Amending paragraphs (a)(2) and (a)(5) by removing the term “clinic’s” and by adding in its place the term “RHC’s”.

■ B. Amending paragraph (a)(5) by removing the term “clinic” and by adding in its place the term “RHC”.

■ 11. Section 405.2414 is amended as follows:

■ A. Revising paragraphs (a) introductory text and (a)(1).

■ B. In paragraphs (a)(2) and (3), removing “;” and adding in its place “.”.

■ C. Revising paragraph (a)(4).

■ D. In paragraph (a)(5), removing the phrase “They would” and adding in its place the phrase “The services would”.

■ E. In paragraph (c), removing the phrase “physician assistants, nurse midwives or specialized nurse practitioners” and adding in its place the phrase “physician assistants or certified nurse midwives”.

The revisions read as follows:

**§ 405.2414 Nurse practitioner, physician assistant, and certified nurse midwife services.**

(a) Professional services are payable under this subpart if the services meet all of the following:

(1) Furnished by a nurse practitioner, physician assistant, or certified nurse midwife who is employed by, or receives compensation from, the RHC or FQHC.

\* \* \* \* \*

(4) The services are of a type which the nurse practitioner, physician assistant, or certified nurse midwife who furnished the service is legally permitted to perform by the State in which the service is rendered.

■ 12. Section 405.2415 is revised to read as follows:

**§ 405.2415 Services and supplies incident to nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker services.**

(a) Services and supplies incident to a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker service are payable under this subpart if the service or supply is all of the following:

(1) Of a type commonly furnished in physicians’ offices.

(2) Of a type commonly rendered either without charge or included in the RHC’s bill.

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker.

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

(5) In the case of a service, furnished by a member of the RHC’s health care staff who is an employee of the RHC.

(b) The direct personal supervision requirement is met in the case of any of the following persons only if the person is permitted to supervise these services under the written policies governing the RHC:

- (1) Nurse practitioner.
- (2) Physician assistant.
- (3) Certified nurse midwife.
- (4) Clinical psychologist.
- (5) Clinical social worker.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

■ 13. Section 405.2416 is amended as follows:

- A. Revising paragraphs (a) introductory text and (a)(1).
- B. In paragraph (a)(2), removing the semicolon and adding a period in its place.
- C. Revising paragraphs (a)(3) and (4).
- D. Revising paragraphs (b) introductory text and (b)(1).

The revisions read as follows:

**§ 405.2416 Visiting nurse services.**

(a) Visiting nurse services are covered if the services meet all of the following:

(1) The RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of home health agencies.

\* \* \* \* \*

(3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC or FQHC.

(4) The services are furnished under a written plan of treatment that is both of the following:

(i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC or FQHC; or

(B) Established by a nurse practitioner, physician assistant, or certified nurse midwife and reviewed at least every 60 days by a supervising physician.

(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC or FQHC.

(b) The nursing care covered by this section includes the following:

(1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.

\* \* \* \* \*

**§ 405.2417 [Amended]**

■ 14. Section 405.2417 is amended as follows:

- A. In the introductory text, removing the phrase “rural health clinic” and adding in its place “RHC or FQHC”.
- B. In paragraph (a), removing the phrase “rural health clinic” and adding in its place “RHC or FQHC”.
- C. In paragraph (b), removing “; or” and adding in its place “.”.

■ 15. Section 405.2430 is amended as follows:

- A. Revising paragraphs (a)(1) introductory text and (a)(1)(i) and (ii).
- B. In paragraph (a)(4), removing the phrase “Federally qualified health center” and adding in its place the term “FQHC”.
- C. Revising paragraph (b).
- D. Removing paragraph (c).
- E. Redesignating paragraph (d) as paragraph (c).

The revisions read as follows:

**§ 405.2430 Basic requirements.**

(a) \* \* \*

(1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when all of the following occur:

(i) HRSA approves the entity as meeting the requirements of section 330 of the PHS Act.

(ii) The entity assures CMS that it meets the requirements specified in this subpart and part 491, as described in § 405.2434(a).

\* \* \* \* \*

(b) *Prior HRSA FQHC determination.* An entity applying to become a FQHC must do the following:

(1) Be determined by HRSA as meeting the applicable requirements of the PHS Act, as specified in § 405.2401(b).

(2) Receive approval by HRSA as a FQHC under section 330 of the PHS Act (42 U.S.C. 254b).

\* \* \* \* \*

■ 16. Section 405.2434 is amended as follows:

■ A. In the introductory text, removing the phrase “Federally qualified health center” and adding in its place the term “FQHC”.

■ B. In paragraph (a)(1), removing the phrase “Federally qualified health center” and adding in its place the term “FQHC” each time it appears.

■ C. In paragraph (a)(2), removing the term “Centers” and adding in its place the term “FQHCs”.

■ D. Revising paragraphs (b) and (c)(1).

■ E. In paragraph (c)(3), removing the phrase “Federally qualified health center” and adding in its place the term “FQHC” each time it appears.

■ F. Revising paragraph (c)(4).

■ G. In paragraphs (d)(1), (d)(3) introductory text, and (e)(1) through (3) by removing the phrase “Federally qualified health center” and adding in its place the term “FQHC”.

■ H. In paragraphs (d)(3)(ii) and (e)(2) by removing the phrase “Federally qualified health center’s” and adding in its place the term “FQHC’s”.

The revisions read as follows:

**§ 405.2434 Content and terms of the agreement.**

\* \* \* \* \*

(b) *Effective date of agreement.* The effective date of the agreement is determined in accordance with the provisions of § 489.13.

(c) \* \* \*

(1) For non-FQHC services that are billed to Part B, the beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the center for the covered services.

\* \* \* \* \*

(4) The FQHC may charge the beneficiary for items and services that are not FQHC services. If the item or service is covered under Medicare Part B, the FQHC may not charge the beneficiary more than 20 percent of the Part B payment amount.

\* \* \* \* \*

**§ 405.2436 [Amended]**

■ 17. Section 405.2436 is amended as follows:

■ A. In paragraphs (a) introductory text, (a)(2), (b)(1)(i), (b)(3), (c)(1) introductory text, (c)(2), (c)(3), and (d) by removing the phrase “Federally qualified health center” each time it appears and adding in its place the term “FQHC”.

■ B. In paragraphs (b)(1) introductory text, (b)(1)(ii), (b)(2) introductory text, and (d) by removing the phrase “Federally qualified health center’s” and adding in its place the term “FQHC’s”.

■ 18. Section 405.2440 is amended by revising the introductory text to read as follows.

**§ 405.2440 Conditions for reinstatement after termination by CMS.**

When CMS has terminated an agreement with a FQHC, CMS does not enter into another agreement with the FQHC to participate in the Medicare program unless CMS—

\* \* \* \* \*

**§ 405.2442 [Amended]**

■ 19. Section 405.2442 is amended as follows:

■ A. In paragraph (a) introductory text by removing the phrase “Federally qualified health center” and adding in its place the term “FQHC”.

■ B. In paragraph (b) by removing the phrase “Federally qualified health center’s” and adding in its place the term “FQHC’s”.

**§ 405.2444 [Amended]**

■ 20. Section 405.2444 is amended as follows:

■ A. In paragraph (c), removing the phrase “Federally qualified health center” and adding in its place the term “FQHC” each time it appears.

■ B. In paragraphs (a)(2) and (c) by removing the term “center” each time it appears, and by adding in its place the term “FQHC”.

■ 21. Section 405.2446 is amended as follows:

■ A. Revising paragraphs (a), (b)(2), (3), (4), and (6).

■ B. Removing paragraph (b)(8).

■ C. Redesignating paragraphs (b)(9) and (10) as (b)(8) and (9), respectively.

■ D. In paragraphs (c) and (d), removing the phrase “Federally quality health center” and adding in its place the term “FQHC”.

The revisions read as follows:

**§ 405.2446 Scope of services.**

(a) For purposes of this section, the terms rural health clinic and RHC when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers and FQHCs.

(b) \* \* \*

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

(3) Nurse practitioner, physician assistant or certified nurse midwife services as specified in § 405.2414.

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

\* \* \* \* \*

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

\* \* \* \* \*

■ 22. Section 405.2448 is amended as follows:

■ A. Revising paragraphs (a)

introductory text and (a)(1) through (3).

■ B. In paragraph (b) introductory text, removing the phrase “Federally quality health centers” and adding in its place the term “FQHCs”.

■ C. In paragraph (d), removing the phrase “a Federally qualified health center service, but may be provided at a Federally qualified health center if the center” and adding in its place the phrase “FQHC service, but may be provided at a FQHC if the FQHC”.

The revisions read as follows:

**§ 405.2448 Preventive primary services.**

(a) Preventive primary services are those health services:

(1) A FQHC is required to provide as preventive primary health services under section 330 of the PHS Act.

(2) Furnished by or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist or clinical social worker.

(3) In the case of a service, furnished by a member of the FQHC’s health care staff who is an employee of the FQHC or by a physician under arrangements with the FQHC.

\* \* \* \* \*

**§ 405.2449 [Amended]**

■ 23. Section 405.2449 is amended as follows:

■ A. In the introductory text, removing the phrase “Federally qualified health center” and adding in its place the term “FQHC”.

■ B. In paragraph (b), removing “; and” and adding in its place “.”.

**§ 405.2452 [Amended]**

■ 24. Section 405.2452 is amended as follows:

■ A. In paragraph (a)(2), by removing the phrase “Federally quality health center’s” and adding in its place the term “FQHC’s”.

■ B. In paragraph (b), by removing the phrase “Federally quality health center” and adding in its place the term “FQHC”.

■ C. In paragraph (a)(5), removing the term “center” and adding in its place the term “FQHC”.

■ 25. Section 405.2460 is revised to read as follows:

**§ 405.2460 Applicability of general payment exclusions.**

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by RHCs and FQHCs, except that preventive primary services, as defined in § 405.2448, are statutorily authorized in FQHCs and not excluded by the provisions of section 1862(a) of the Act.

■ 26. Section 405.2462 is revised to read as follows:

**§ 405.2462 Payment for RHC and FQHC services.**

(a) *Payment to provider-based RHCs and FQHCs that are authorized to bill under the reasonable cost system.* A RHC or FQHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC or FQHC is—

(1) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(2) Operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent RHCs and freestanding FQHCs that are authorized to bill under the reasonable cost system.*

(1) RHCs and FQHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (e)(1) and (2) of this section.

(c) *Payment to FQHCs that are authorized to bill under the prospective payment system.* A FQHC that is authorized to bill under the prospective payment system is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. This rate is adjusted for the following:

(1) Geographic differences in cost based on the Geographic Practice Cost Indices (GPCIs) in accordance with 1848(e) of the Act and 42 CFR 414.2 and 414.26 and used to adjust payment under the physician fee schedule, limited to only the work and practice expense GPCIs.

(2) Furnishing of care to a new patient with respect to the FQHC, including all sites that are part of the FQHC, or to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit). A new patient is one that has not been seen in the FQHC’s organization within the previous 3 years.

(d) For FQHC visits, Medicare pays 80 percent of the all-inclusive rate for FQHCs that are authorized to bill under the reasonable cost system, and 80 percent of the lesser of the FQHC’s charge or the PPS encounter rate for FQHCs authorized to bill under the PPS. No deductible is applicable to FQHC services.

(e) For RHCs visits, payment is made in accordance with one of the following:

(1) If the deductible has been fully met by the beneficiary prior to the RHC, Medicare pays 80 percent of the all-inclusive rate.

(2) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC’s reasonable customary charge for the services that is applied to the deductible is less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-

inclusive rate and 80 percent of the remainder, if any, is paid to the RHC.

(3) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(f) To receive payment, the FQHC or RHC must do all of the following:

(1) Furnish services in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter.

(2) File a request for payment on the form and manner prescribed by CMS.

27. Section 405.2463 is revised to read as follows:

**§ 405.2463 What constitutes a visit.**

(a) *Visit.* (1) *General.* (i) For RHCs, a visit is a face-to-face encounter between a RHC patient and one of the following:

- (A) Physician.
- (B) Physician assistant.
- (C) Nurse practitioner.
- (D) Certified nurse midwife.
- (E) Visiting registered professional or licensed practical nurse.
- (G) Clinical psychologist.
- (H) Clinical social worker.
- (I) Qualified transitional care management service.

(ii) For FQHCs, a visit is either of the following:

(A) A face-to-face encounter as described in paragraph (a)(1)(i) of this section.

(B) A face-to-face encounter between a patient and one of the following:

(1) A qualified provider of medical nutrition therapy services as defined in part 410 subpart G of this chapter.

(2) A qualified provider of outpatient diabetes self-management training services as defined in part 410 subpart H of this chapter.

(2) *Medical visit.* (i) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

- (A) Physician.
- (B) Physician assistant.
- (C) Nurse practitioner.
- (D) Certified nurse midwife.
- (E) Visiting registered professional or licensed practical nurse.

(i) A medical visit for FQHCs may also include a—

- (A) Medical nutrition therapy visit; or
- (B) Diabetes outpatient self-management training visit.

(3) *Mental health visit.* A mental health visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

- (i) Clinical psychologist.
- (ii) Clinical social worker.

(iii) Other RHC or FQHC practitioner for mental health services.

(b) *Encounters and Payment for RHCs and FQHCs that are not being paid under section 1834(o) of the Act.* (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, 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) The patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day.

(ii) The patient has a medical visit and a mental health visit on the same day.

(iii) The patient has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable cost system. Medicare pays RHCs and FQHCs that are not being paid under section 1834(o) of the Act for more than 1 visit per day when the conditions in paragraph (b) of this section are met.

■ 28. Section 405.2464 is revised to read as follows:

**§ 405.2464 Payment rate.**

(a) *Determination of the payment rate for RHCs and FQHCs that are authorized to bill on the basis of reasonable cost.* (1) An all-inclusive rate is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC or FQHC services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(4) The MAC, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits and adjusts the rate if:

(i) There is a significant change in the utilization of services;

(ii) Actual allowable costs vary materially from allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(5) The RHC or FQHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Determination of the payment rate for FQHCs billing under the prospective payment system.* (1) An encounter-based rate is calculated by CMS by dividing total FQHC costs by total

FQHC encounters to establish an average cost per encounter.

(2) The exceptions in § 405.2463(b) do not apply.

(3) The encounter-based rate is adjusted—

(i) For geographic differences in the cost of inputs according to § 405.2462(c)(1).

(ii) When the FQHC furnishes services to a new patient, as defined in § 405.2462(b)(3)(ii).

(iii) When a beneficiary receives a comprehensive initial Medicare visit (that is, an initial preventive physical examination or an initial annual wellness visit).

■ 29. Section 405.2466 is amended as follows:

■ A. By revising paragraph (a) and the paragraph (b) heading.

■ B. In paragraph (b)(1) introductory text by removing the term “intermediary” each time it appears and by adding in its place the term “MAC”.

■ C. In paragraphs (b)(1)(i), and (b)(1)(ii) by removing the term “rural health clinic” each time it appears and by adding in its place the term “RHC”.

■ D. Revising paragraph (b)(1)(iii).

■ E. In paragraph (b)(1)(iv) by removing the term “rural health clinics” and by adding in its place the term “RHCs”.

■ F. In paragraphs (b)(1)(i), and (b)(1)(ii) by removing the term “Federally qualified health center” and by adding in its place the term “FQHC”.

■ G. In paragraphs (b)(1) introductory text, (b)(2), (c)(1), and (c)(2) by removing the word “clinic” each time it appears and by adding in its place the term “RHC”.

■ H. In paragraphs (b)(1) introductory text, (b)(2), (c)(1), (c)(2), and (d)(2) by removing the word “center” each time it appears and by adding in its place the term “FQHC”.

■ I. Revising paragraphs (c) introductory text, and (d)(1).

■ J. In paragraph (d)(2) by removing the term “intermediary” each time it appears and by adding in its place the term “MAC”.

The revisions read as follows:

**§ 405.2466 Annual reconciliation.**

(a) *General.* Payments made to RHCs or FQHCs that are authorized to bill under the reasonable cost system during a reporting period are subject to annual reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation for RHCs or FQHCs that are authorized to bill under the reasonable cost system.*

(1) \* \* \*

(iii) The total payment due the RHC is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to RHC services from the cost of these services. FQHC services are not subject to a deductible and the payment computation for FQHCs does not include a reduction related to the deductible.

\* \* \* \* \*

(c) *Notice of program reimbursement.* The MAC notifies the RHC or FQHC that is authorized to bill under the reasonable costs system:

\* \* \* \* \*

(d) \* \* \*

(1) *Underpayments.* If the total reimbursement due the RHC or FQHC that is authorized to bill under the reasonable cost system exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC or FQHC to bring total payments into agreement with total reimbursement due the RHC or FQHC.

\* \* \* \* \*

■ 30. Add § 405.2467 to read as follows:

**§ 405.2467 Requirements of the FQHC PPS.**

(a) *Cost reporting.* For cost reporting periods beginning on or after October 1, 2014, FQHCs are paid on a PPS basis that does all of the following:

(1) Includes a process for appropriately describing the services furnished by FQHCs.

(2) Establishes payment rates for specific payment codes based on such appropriate descriptions of services.

(3) Takes into account the type, intensity and duration of services furnished by FQHCs.

(4) May include adjustments (such as geographic adjustments) determined by the Secretary.

(b) *HCPCS coding.* FQHCs are required to submit HCPCS codes in reporting services furnished.

(c) *Initial payments.* (1) Beginning October 1, 2014, for the first fifteen months of the PPS, the estimated aggregate amount of PPS rates is equal to 100 percent of the estimated amount of reasonable costs that would have occurred for that period if the PPS had not been implemented.

(2) Payment amount is calculated prior to any FQHC payments based on the reasonable cost system.

(d) *Payments in subsequent years.* (1) Beginning January 1, 2016, PPS payment rates will be increased by the percentage increase in the Medicare economic index.

(2) Beginning January 1, 2017, PPS rates will be increased by the percentage

increase in a market basket of FQHC goods and services as established through regulations, or, if not available, the Medicare economic index.

■ 31. Section 405.2468 is amended:

■ A. In paragraph (a) by removing the word “intermediary”, and by adding in its place the word “MAC”.

■ B. In paragraphs (b) introductory text and (c) by removing the term “rural health clinic” and by adding in its place the term “RHC”.

■ C. In paragraph (b) introductory text by removing the term “Federally qualified health center” and by adding in its place the term “FQHC”.

■ D. In paragraphs (b)(4), (b)(5), (d)(2)(iv), and (d)(2)(v) by removing the word “clinic” each time it appears and by adding in its place the term “RHC”.

■ E. In paragraphs (b)(4), (b)(5), (d)(2)(iv), (d)(2)(v) by removing the word “center” each time it appears and by adding in its place the term “FQHC”.

■ F. Revising paragraphs (b)(1), (c), and (d)(1).

The revisions read as follows:

**§ 405.2468 Allowable costs.**

\* \* \* \* \*

(b) \* \* \*

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

\* \* \* \* \*

(c) *Tests of reasonableness of cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the MAC with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. For RHCs and FQHCs that are authorized to bill under the reasonable cost system, these tests include, but are not limited to, screening guidelines and payment limits.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the RHC or FQHC that is authorized to bill under the reasonable cost system provides reasonable justification satisfactory to the MAC.

\* \* \* \* \*

■ 32. Section 405.2469 is revised to read as follows:

**§ 405.2469 Federally qualified health centers (FQHCs) supplemental payments.**

(a) *Eligibility for supplemental payments.* FQHCs under contract

(directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive either:

(1) Under the reasonable cost payment system if the FQHC is authorized to bill under the reasonable cost payment system, or

(2) The PPS rate if the FQHC is authorized to bill under the PPS.

(b) *Calculation of supplemental payment.* The supplemental payment for FQHC covered services provided to Medicare patients enrolled in MA plans is based on the difference between—

(1) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHCs all-inclusive cost-based per visit rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act, or

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

(c) *Financial incentives.* Any financial incentives provided to FQHCs under their MA contracts, such as risk pool payments, bonuses, or withholds, are prohibited from being included in the calculation of supplemental payments due to the FQHC.

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter occurs between a MA enrollee and a practitioner as set forth in § 405.2463.

**§ 405.2470 [Amended]**

■ 33. Section 405.2470 is amended by:

■ A. In paragraphs (a)(1), (b)(1), and (c)(3) through (5) by removing the word “intermediary”, and by adding in its place the word “MAC”.

■ B. In paragraphs (b)(2), by removing the word “intermediary’s” and adding in its place the word “MAC’s”.

■ C. In paragraphs (a) introductory text, (c)(1), and (c)(2)(i) and (ii) by removing the term “rural health clinic” and by adding in its place the term “RHC”.

■ D. In paragraphs (a) introductory text, (c)(1), and (c)(2)(i) and (ii) by removing the term “Federally qualified health center” and by adding in its place the term “FQHC”.

■ E. In paragraphs (b)(1) and (2), (c)(1), (c)(2) introductory text, and (c)(3) through (6) by removing the word “clinic” and by adding in its place the term “RHC”.

■ F. In paragraphs (b)(1) and (2), (c)(1), (c)(2) introductory text, and (c)(3) through (6) by removing the word “center” each time it appears and by the term “FQHC”.

■ 34. Section 405.2472 is amended by revising paragraph (a) to read as follows:

**§ 405.2472 Beneficiary appeals.**

\* \* \* \* \*

(a) The beneficiary is dissatisfied with a MAC’s determination denying a request for payment made on his or her behalf by a RHC or FQHC;

\* \* \* \* \*

**PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES**

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

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

■ 36. Section 491.8 is amended by revising paragraph (a)(3).

**§ 491.8 Staffing and staff responsibilities.**

(a) \* \* \*

(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 clinic or center. In the case of a clinic, at least one physician assistants or nurse practitioner must be an employee of the clinic.

\* \* \* \* \*

**PART 493—LABORATORY REQUIREMENTS**

■ 37. The authority citation for Part 493 is revised to read as follows:

**Authority:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)), and the Public Law 112–202 amendments to 42 U.S.C 263a.

■ 38. Section 493.1 is amended by revising the second sentence to read as follows:

**§ 493.1 Basis and scope.**

\* \* \* It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act, as amended by section 2 of the Taking Essential Steps for Testing Act of 2012. \* \* \*

■ 39. Section 493.2 is revised by adding the definition of “Repeat proficiency testing referral” in alphabetical order to read as follows:

**§ 493.2 Definitions.**

\* \* \* \* \*

*Repeat proficiency testing referral* means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory’s proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organizations).

\* \* \* \* \*

■ 40. Section 493.1800 is amended by revising paragraph (a)(2) introductory text to read as follows:

**§ 493.1800 Basis and scope.**

(a) \* \* \*

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA 1988, as amended by section 2 of the Taking Essential Steps for Testing Act of 2012.

\* \* \* \* \*

■ 41. Section 493.1840 is amended by revising paragraph (b) to read as follows:

**§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.**

\* \* \* \* \*

(b) *Adverse action based on improper referrals in proficiency testing.* If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS does one of the following:

(1) Revokes the laboratory’s CLIA certificate for at least 1 year, prohibits the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and may also impose a civil money penalty in accordance with § 493.1834(d), if CMS determines that—

(i) A proficiency testing referral is a repeat proficiency testing referral as defined at § 493.2; or

(ii) On or before the proficiency testing event close date, a laboratory reported proficiency testing results obtained from another laboratory to the proficiency testing program.

(2) Suspends or limits the CLIA certificate for less than 1 year based on the criteria in § 493.1804(d), and also impose alternate sanctions as appropriate, in accordance with §§ 493.1804(c) and (d), 493.1806(c), 493.1807(b), 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i) or (ii) of this section does not apply but that the laboratory obtained test results for the proficiency testing samples from another laboratory on or

before the proficiency testing event close date. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

(3) Imposes alternate sanctions in accordance with §§ 493.1804(c) and (d), 493.1806(c), 493.1807(b), 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1) or (2) of this section do not apply, and a PT referral has occurred, but no test results are received prior to the event close date by the referring laboratory from the laboratory that received the referral. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

\* \* \* \* \*

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

Dated: September 5, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: September 10, 2013.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

**Note:** The following Addendum will not appear in the Code of Federal Regulations.

**Addendum: Proposed Geographic Adjustment Factors (GAFs) for the FQHC PPS**

As described in section I.I.C.2. of this proposed rule, the proposed GAFs for the FQHC PPS are based on the proposed CY 2014 work and practice expense GPCIs and the proposed cost share weights for the CY 2014 GPCI update, as published in the CY 2014 PFS proposed rule. These GAFs are subject to change in the final FQHC PPS rule based on more current data, including the finalized PFS GPCI and cost share weight values.

	Locality name	GAF
1	Alabama .....	0.933
2	Alaska .....	1.306
3	Arizona .....	0.984
4	Arkansas .....	0.919
5	Anaheim/Santa Ana, CA .....	1.122
6	Los Angeles, CA .....	1.095
7	Marin/Napa/Solano, CA .....	1.154
8	Oakland/Berkeley, CA .....	1.152
9	San Francisco, CA .....	1.215
10	San Mateo, CA .....	1.209
11	Santa Clara, CA .....	1.203
12	Ventura, CA .....	1.104
13	Rest of California .....	1.053
14	Colorado .....	1.002
15	Connecticut .....	1.066

Locality name	GAF	Locality name	GAF	Locality name	GAF
16 DC + MD/VA Suburbs .....	1.120	47 Rest of Missouri .....	0.905	77 Fort Worth, TX .....	0.995
17 Delaware .....	1.024	48 Montana .....	0.974	78 Galveston, TX .....	1.009
18 Fort Lauderdale, FL .....	1.013	49 Nebraska .....	0.938	79 Houston, TX .....	1.009
19 Miami, FL .....	1.016	50 Nevada .....	1.026	80 Rest of Texas .....	0.952
20 Rest of Florida .....	0.973	51 New Hampshire .....	1.021	81 Utah .....	0.945
21 Atlanta, GA .....	1.005	52 Northern NJ .....	1.108	82 Vermont .....	0.991
22 Rest of Georgia .....	0.940	53 Rest of New Jersey .....	1.070	83 Virginia .....	0.986
23 Hawaii/Guam .....	1.075	54 New Mexico .....	0.954	84 Virgin Islands .....	1.000
24 Idaho .....	0.935	55 Manhattan, NY .....	1.107	85 Seattle (King Cnty), WA .....	1.083
25 Chicago, IL .....	1.032	56 NYC Suburbs/Long I., NY .....	1.123	86 Rest of Washington .....	1.003
26 East St. Louis, IL .....	0.962	57 Poughkpsie/N NYC Suburbs, NY .....	1.038	87 West Virginia .....	0.901
27 Suburban Chicago, IL .....	1.040	58 Queens, NY .....	1.122	88 Wisconsin .....	0.972
28 Rest of Illinois .....	0.944	59 Rest of New York .....	0.965	89 Wyoming .....	0.989
29 Indiana .....	0.947	60 North Carolina .....	0.953		
30 Iowa .....	0.929	61 North Dakota .....	0.982		
31 Kansas .....	0.933	62 Ohio .....	0.959		
32 Kentucky .....	0.925	63 Oklahoma .....	0.913		
33 New Orleans, LA .....	0.983	64 Portland, OR .....	1.024		
34 Rest of Louisiana .....	0.929	65 Rest of Oregon .....	0.975		
35 Southern Maine .....	0.998	66 Metropolitan Philadelphia, PA ...	1.043		
36 Rest of Maine .....	0.940	67 Rest of Pennsylvania .....	0.957		
37 Baltimore/Surr. Cntys, MD .....	1.058	68 Puerto Rico .....	0.808		
38 Rest of Maryland .....	1.023	69 Rhode Island .....	1.035		
39 Metropolitan Boston .....	1.081	70 South Carolina .....	0.945		
40 Rest of Massachusetts .....	1.037	71 South Dakota .....	0.974		
41 Detroit, MI .....	1.009	72 Tennessee .....	0.936		
42 Rest of Michigan .....	0.957	73 Austin, TX .....	1.001		
43 Minnesota .....	1.005	74 Beaumont, TX .....	0.941		
44 Mississippi .....	0.916	75 Brazoria, TX .....	1.002		
45 Metropolitan Kansas City, MO ..	0.968	76 Dallas, TX .....	1.013		
46 Metropolitan St Louis, MO .....	0.974				

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