DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 491, and 493

[CMS–1443–FC]

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: Final rule with comment period.

SUMMARY: This final rule with comment period implements 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. In addition, it establishes a policy which allows rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and makes other technical and conforming changes to the RHC and FQHC regulations. Finally, this final rule with comment period implements changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing (PT) referrals.

DATES: *Effective Dates:* The provisions of this final rule with comment period are effective on October 1, 2014, except for amendments to § 405.2468(b)(1), § 491.8(a)(3), § 493.1, § 493.2, § 493.1800, and § 493.1840 which are effective July 1, 2014.

Comment Period: We will consider comments on the subjects indicated in sections II.B.1., E.2. and E.4. of this final rule with comment period received at one of the addresses provided below, no later than 5 p.m. on July 1, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1443–FC. 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–FC, 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–FC, 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.

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.

SUPPLEMENTARY INFORMATION:

Acronyms

ACS American Community Survey
AI/AN American Indian/Alaskan Native
AIR All-Inclusive Rate
APCP Advanced Primary Care Practice
BLS Bureau of Labor Statistics
CCM Chronic Care Management
CCN CMS Certification Number
CCR Cost-To-Charge Ratio
CFR Code of Federal Regulations
CLIA Clinical Laboratory Improvement Amendments of 1988
CMP Civil Monetary Penalty
CMS Centers for Medicare & Medicaid Services
CNM Certified Nurse Midwife
CP Clinical Psychologist
CR Change Request
CSW Clinical Social Worker
CY Calendar Year
DSMT Diabetes Self-Management Training
EHR Electronic Health Record
E/M Evaluation and Management
FQHC Federally Qualified Health Center
FSHCAA Federally Supported Health Centers Assistance Act
FTCA Federal Tort Claims 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
MSA Metropolitan Statistical Area
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
RIA Regulatory Impact Analysis
RHC Rural Health Clinic
SNF Skilled Nursing Facility
UDS Uniform Data System
UPL Upper Payment Limit

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111–148 and Pub. L. 111–152) added section 1834(o) of the Social Security Act (the Act) to establish a new system of payment for the costs of federally qualified health center (FQHC) services under Medicare Part B (Supplemental Medical Insurance) based on prospectively set rates. According to section 1834(o)(2)(A) of the Act, the FQHC prospective payment system (PPS) is to be effective beginning on October 1, 2014. The primary purpose of this final rule with comment period is to implement a methodology and payment rates for the new FQHC PPS.

This rule also implements our proposal to allow RHCs to contract with non-physician practitioners, consistent with statutory requirements in section 1861(aa) of the Act that require at least one nurse practitioner (NP) or physician assistant (PA) be employed by the RHC, and makes other technical and conforming changes to the RHC and FQHC regulations.

The ''Taking Essential Steps for Testing Act of 2012'' (TEST Act) (Pub. L. 112–202) was enacted on December 4, 2012. The TEST Act amended section 353 of the Public Health Service Act (PHS Act) to provide the Secretary with discretion as to which sanctions may be applied to cases of intentional violation of the prohibition on proficiency testing (PT) referrals. This final rule with comment period adopts changes to the CLIA regulations to implement the TEST Act.

2. Summary of the Major Provisions

a. FQHC PPS

In accordance with the provisions of the Affordable Care Act, we proposed in the September 23, 2013 **Federal Register** (78 FR 58386) to establish a national, encounter-based prospective payment rate for all FQHCs, to be determined based on an average of reasonable costs of FQHCs in the aggregate, and pay FQHCs the lesser of their actual charges for services or a single encounter-based rate for professional services furnished per beneficiary per day. As required by section 1834(o)(1)(A) of the Act, we proposed to establish payment codes based on an appropriate description of FQHC services, and taking into account the type, intensity, and duration of services provided by FQHCs. We also proposed adjustments to the encounter-based payment rate for geographic differences in the cost of inputs by applying an adaptation of the geographic practice cost indices (GPCIs) used to adjust payments under the Physician Fee Schedule (PFS). These provisions are being finalized as proposed. We also proposed adjustments when a FQHC furnishes care to a patient who is new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit (that is, an initial preventive physical examination (IPPE) or an initial annual wellness visit (AWV)). These provisions have been revised based on comments received and are being finalized to allow the proposed adjustments as well as an adjustment for subsequent AWVs.

We also proposed not to include adjustments or exceptions to the single, encounter-based payment when an illness or injury occurs subsequent to

the initial visit, or when mental health, diabetes self-management training/medical nutrition therapy (DSMT/MNT), or the IPPE are furnished on the same day as the medical visit. These provisions have been revised based on the comments received and are being finalized to allow an exception to the single, encounter-based payment when an illness or injury occurs subsequent to the initial visit, or when a mental health visit is furnished on the same day as the medical visit.

We also proposed that coinsurance would be 20 percent of the lesser of the actual charge or the PPS rate. Most preventive services are exempt from beneficiary coinsurance in accordance with section 4104 of the Affordable Care Act. Accordingly, for FQHC claims that include a mix of preventive and non-preventive services, we proposed 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 to use provider-reported charges to determine the amount of coinsurance that should be waived for payments based on the provider's charge. This provision has been revised based on comments received and is being finalized to allow a simpler method for calculating coinsurance when there is a mix of preventive and non-preventive services.

The statute requires implementation of the FQHC PPS for FQHCs with cost reporting periods beginning on or after October 1, 2014. We proposed that FQHCs would transition into the PPS based on their cost reporting periods and that the claims processing system would maintain the current system and the PPS until all FQHCs transitioned to the PPS. We also proposed to transition the PPS to a calendar year update for all FQHCs, beginning January 1, 2016, to be consistent with many of the PFS rates that are updated on a calendar year basis. We are finalizing these provisions as proposed.

b. Other FQHC and RHC Changes

In addition to our proposals to codify the statutory requirements for the FQHC PPS, we proposed to allow RHCs to contract with non-physician practitioners, consistent with statutory requirements that require at least one NP or PA be employed by the RHC. We also proposed edits to correct terminology, clarify policy, and make other conforming changes for existing mandates and the new PPS.

c. 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 are amending the CLIA regulations to add 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 payment rates (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 upper payment limits (UPL) or productivity standards. In the proposed rule, we estimated the overall impact, based on the estimated PPS rate, would increase total Medicare payments to FQHCs by approximately 30 percent, with an annualized cost to the federal government between $183 million and $186 million, based on 5 year discounted flows using 3 percent and 7 percent factors. Based on current data, our final estimate is an overall impact of increasing total Medicare payments to FQHCs by approximately 32 percent, based on payment at the FQHC PPS. (Note that this does not take into account the application of ''lesser of'' provision in section 1833(a)(1)(Z) of the Act. For more information, see sections II.E.2 and VII.D.1 of this final rule with comment period). The annualized cost to the federal government associated with the final FQHC PPS is estimated to be between $200 million and $204 million, based on 5 year discounted flows using 3 percent and 7 percent factors. These estimates also reflect the policy modifications that are noted in section I.A.2 and discussed in more detail in sections II.B. and II.C. of this preamble.

b. For Other FQHC and RHC Changes

We estimated that there would be no costs associated with the removal of the contracting restrictions for RHCs or for technical and conforming regulatory changes that would be made in conjunction with the establishment of the FQHC PPS.

c. For the CLIA Enforcement Actions for Proficiency Testing Referral Provisions

We estimated that an average of 6 cases per year may have fit the terms described in the proposed rule to have alternative sanctions applied. Based on experience with laboratories that engaged in proficiency testing referral in the past, we estimated that the average cost experienced by laboratories for which we imposed a revocation of the CLIA certificate as a result of a PT referral violation was $578,000 per laboratory. We estimated that the average cost of alternative sanctions, based on comparable violations for which alternative sanctions have been imposed, would be $150,000 per laboratory. Therefore, we projected that the aggregate annual savings would be approximately $2.6 million per year ($578,000 minus $150,000 for 6 laboratories), resulting in net average savings per affected certificate holder of $428,000 ($578,000 minus $150,000). We continue to consider these to be reasonable estimates.

B. Overview and Background

1. FQHC Description and General Information

FQHCs are facilities that furnish services that are typically furnished in an outpatient clinic setting. They are currently paid an all-inclusive rate (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).

FQHCs are also entities that were treated by the Secretary for purposes of Medicare Part B as a comprehensive federally funded health center as of

January 1, 1990 (see section 1861(aa)(4)(C) of the Act).

Section 330 Health Centers are the most common 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 1,200 health centers operating approximately 9,000 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 or medically underserved population 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 with discounts adjusted on the basis of the patient's ability to pay and being governed by a board of directors that represent the individuals being served by the FQHC and a majority of whom receive their care at the FQHC. According to HRSA's Uniform Data System (UDS),[1] approximately 8 percent of FQHC patients were Medicare beneficiaries, 41 percent were Medicaid recipients, and 36 percent were uninsured in 2012. The remaining 15 percent were privately insured or had other public insurance. Medicare and Medicaid accounted for approximately 9 percent and 47 percent of their total billing in dollars, respectively.

The 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 furnish other services. All FQHCs are eligible to participate in the 340B Drug Pricing Program which is a program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. 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 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 health centers receiving grant funds under section 330). HRSA administers the Health Center grant program and other programs that assist FQHCs in increasing access to primary and preventive health care in underserved communities.

[1] 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.

2. Medicare's FQHC Coverage and Payment Benefit

The FQHC coverage and payment benefit under Medicare began on October 1, 1991. It was authorized by section 1861(aa) of the Act (which amended 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 Part 405 and Part 491.

FQHC covered services and supplies include the following:

- Physician, NP, PA, Certified Nurse-Midwife (CNM), Clinical Psychologist (CP), and Clinical Social Worker (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 DSMT and 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 the UPL and productivity standards that were established in 1978 and 1982 for RHCs (43 FR 8260 and 47 FR 54165, respectively) and adopted for FQHCs in 1992 and 1996 (57 FR 24967 through 24970 and 61 FR 14650 through 14652, respectively), 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 section 1842(i)(3) of the Act. Authority to apply productivity standards is found in section 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 also 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. 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 wrap-around 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 for cost reporting periods beginning on or after 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.5. of this final rule with comment period.

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 (§ 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 our regulations at § 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 continue to be eligible to be certified as provider-based FQHCs. Provider-based designations are not made for FQHCs that do not already have this status.

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. 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 2014 payment limits per visit for urban and rural FQHCs are $129.02 and $111.67, respectively. FQHCs with multiple sites may elect to file a consolidated cost report (CMS Pub. 100–04, Medicare Claims Processing Manual, chapter 9, section 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)(4) 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.

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.

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 for specific payment codes 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 Healthcare Common Procedure Coding System (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) of the Act.

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 furnished 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 furnished 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 furnished 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 and others in the development of the proposed rule. We are aware of the challenges facing FQHCs in increasing access to health care for underserved populations and the importance of Medicare payments to the overall financial viability of FQHCs. Our goal for the FQHC PPS is to implement a system in accordance with the statute whereby FQHCs are fairly paid for the services they furnish to Medicare patients in the least burdensome manner possible, so that they may continue to furnish primary and preventive health services to the communities they serve.

We have evaluated our approach based on the comments we received to the proposed rule in the context of balancing payment requirements, regulatory burden, and the need for appropriate accountability and oversight. We received approximately 100 timely comments on the proposed FQHC PPS. The following sections describe the comments we received, our response to the comments, and the final decisions on our proposals.

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 section 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. The statute also requires us to ''establish payment rates for specific payment codes based on . . . appropriate description of services.'' 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 fewest reporting requirements and least 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 we believe could encourage excess utilization in the long-term, and could 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 (with a few adjustments as discussed in section II.C. of this final rule with comment period), for the FQHC PPS would provide appropriate payment while remaining administratively simple.

Also, our analysis of Medicare claims data supported an encounter-based payment rate. As discussed in section II.A.3 of this final rule with comment period, our analysis determined that FQHC Medicare claims listed a single HCPCS code that defined the overall type of encounter (for example, a mid-level office visit (HCPCS code 99213)). The vast majority of FQHC encounters were defined as evaluation and management (E/M) office visits (HCPCS codes 99201 through 99215). Other codes were used more sporadically, and we believe that the administrative burden associated with developing and maintaining a payment system composed of multiple rates (for example, a fee schedule) far outweighs the minor variations in reimbursement. Therefore, we developed an encounter-based rate, with a few adjustments, as the basis for payment under the FQHC PPS. We believe the description of FQHC services that we proposed in the proposed rule, and the development of payment codes that are based on the costs of groups of FQHC services (as discussed in section II.E.2. of this final rule with comment period), meets the requirement of the statute.

Comment: A large number of commenters were strongly supportive of a single, bundled encounter-based PPS rate, and many noted that this approach encourages comprehensive and

integrated care. Some of the commenters who supported a bundled encounter-based rate also recommended that CMS develop multiple rates to reflect additional payment adjustments.

Response: We agree with the commenters that a bundled encounter-based rate would provide appropriate payment while remaining administratively simple. We will address the recommendations for additional payment adjustments in section II.C.4. of this final rule with comment period.

After consideration of the public comments received, we are finalizing our proposal to pay FQHCs using an encounter-based rate.

2. Medicare FQHC Cost Reports

As required by section 1834(o)(2)(B)(i) of the Act, initial payment rates (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 for the proposed rule, 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, and we identified cost reports with cost reporting periods that ended between June 30, 2011, and June 30, 2012. We stated in the proposed rule that we would use the most recent available data for the final rule. Therefore, in estimating 100 percent of reasonable costs for this final rule with comment period, we used cost report data from December 31, 2013, HCRIS quarterly update, and we supplemented this with data from the three prior HCRIS quarterly updates (that is, September 30, 2013, June 30, 2013, and March 31, 2013). We also obtained HCRIS data for hospital-based FQHCs (Form 2552–10) and HHA-based FQHCs (Form 1728–94), which added data from provider-based FQHCs. In the expanded sample that we used for this final rule with comment period, we identified cost reports with cost reporting periods ending between June 30, 2011, and June 30, 2013. 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. (A cost reporting entity is a FQHC delivery site that files either an individual or a consolidated cost report.) For 63 percent of cost reporting entities, there were either multiple cost reports available or the cost reporting period was not exactly 1 year. For the remaining 37 percent of cost reporting entities, the only available cost report covered 1 full year. Compared to the characteristics of the cost report data used for the proposed rule, the significant increase in the percentage of FQHCs with multiple cost reports is due mostly to the expanded time period that we used for the final rule to identify cost reports available for analysis. 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. We also note that, under section 1833(c) of the Act, effective January 1, 2014, outpatient mental health services are paid on the same basis as other Part B services. 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.

For this final rule with comment period, we used the methodology described in the proposed rule to estimate 100 percent of reasonable costs. After eliminating the current payment limits, outpatient mental health limitations, and productivity 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.

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 of cost reports used for the proposed rule. 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. We believe that removing statistical outliers is consistent with standard practice and results in a more accurate estimation of costs overall. In this final rule with comment period, we used the same approach to exclude statistical outliers from the cost report sample.

Comment: Several commenters objected to the exclusion of outlier cost reports and claims in calculating the base rate. Some of these commenters opined that the authority in section 1834(o)(1)(A) of the Act, to ''include adjustments . . . determined appropriate by the Secretary'' cannot override the requirement in section 1834(o)(2)(B) of the Act that the aggregate amount of initial PPS rates equal ''100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen).'' Commenters suggested that the exclusion of outliers results in a lower base rate and would not represent all appropriate costs, such as higher costs of visits furnished to complex Medicare patients, or for furnishing costly, but necessary items, such as expensive drugs and biologicals, whose costs may be beyond a FQHC's control. Some of the commenters also urged CMS to compute the base PPS rate without the exclusion of outliers.

Response: We respectfully disagree with the assertion that the exclusion of outliers is inconsistent with statutory authority. Under section 1834(o)(2)(B) of the Act, we are required to set the initial payment rates to equal ''100 percent of the estimated amount of reasonable costs.'' The statute does not require us to set initial payment rates based on the inclusion of every cost report or claim submitted. We analyzed the most current available FQHC cost report and claims data, and consistent with standard practice, trimmed the data for outliers so that the estimates are not skewed by unusual data. Outliers were defined based on two criteria: (1) Cost reports with an average cost per visit value more than 3 standard deviations from the geometric mean of all average costs per visit; and (2) encounters with an adjusted charge value more than 3 standard deviations from the geometric mean of all adjusted charges. This trim methodology of three standard deviations from the geometric mean is a relatively conservative approach, and the two trims together exclude less than 3 percent of the overall sample. We believe that removing statistical outliers results in a more accurate estimation of costs overall.

Comment: Several commenters from tribal organizations recommended that CMS not exclude outliers in calculating the base rate, as they believe that they may be disproportionately impacted because their costs are unusually high.

Response: Of the approximately 69 tribal FQHCs furnishing services at approximately 114 separate sites, there were 8 tribal FQHCs whose costs were considered statistical outliers. Although tribal FQHCs have a higher rate of statistical outliers than non-tribal FQHCs, the number of tribal FQHCs whose costs were more than three standard deviations from the geometric mean is still quite low. As previously noted, the statute does not require the rate to reflect actual costs for each individual FQHC. The per diem rate that is established reflects the national average cost of a FQHC visit.

Comment: A commenter noted that FQHCs count multiple visits per day on their cost reports, and FQHCs should be given a one-time opportunity to adjust their reported FQHC visits to a per diem to avoid an undue reduction in the estimated cost per FQHC visit.

Response: As stated in the proposed rule, we used the adjusted claims data to calculate an average cost per diem in order to accurately capture all costs and did not rely solely on cost report data. We used the same approach for this final rule with comment period.

Comment: Some commenters were concerned that costs related to electronic health record (EHR) implementation would not be adequately reflected in 2012 cost report data as many FQHCs adopted EHRs in 2012.

Response: We used the most recent available data for this final rule, and we updated our sample to include cost reports with reporting periods ending June 30, 2013. We do not believe it is appropriate to adjust the calculation of reasonable cost based on anticipated future costs.

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. The requirement for FQHCs to submit HCPCS codes was implemented through program instructions (CMS Change Request (CR) 7038).

Beginning with dates of service on or after January 1, 2011, FQHCs are required to report all pertinent services furnished and list the appropriate HCPCS code for each line item along with revenue code(s) for each FQHC visit when billing Medicare. 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 currently used to determine current Medicare payment to FQHCs. We proposed 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 for the proposed rule, 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. To model potential adjustments for this final rule with comment period, we obtained final action Medicare FQHC claims from the CMS IDR with dates of service between January 2011 and December 2013. Of these claims, only those with dates of service between January 1, 2011, and June 30 2013, were retained for analysis and linking with Medicare cost reports, as described further in section II.A.4. of this final rule with comment period. 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 Medicare 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 Medicare claims. For this final rule with comment period, we updated our analysis of HCPCS reporting trends and found they are relatively similar in 2013 FQHC Medicare 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 by 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.

Comment: Commenters supported the use of 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. Some commenters recommended that we incorporate additional payment adjustments based on the HCPCS codes in the FQHC claims data.

Response: We agree with the commenters that it is appropriate 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 PFS. We will address the recommendations for additional payment adjustments in section II.C.4. of this final rule with comment period.

Comment: Some commenters were concerned that services that were more recently recognized as payable to FQHCs would not be reflected in the claims sample as it did not include claims with dates of service beyond June 30, 2012.

Response: We used the most recent available data for this final rule with comment period. We updated our sample to include claims with dates of service through June 30, 2013, to the extent that an associated cost report was included in our cost report sample (as discussed previously and in section II.A.2. of this final rule with comment period).

Comment: A commenter was concerned that a FQHC market basket of goods and services would not reflect the variety of non-billable ancillary services furnished during a FQHC visit.

Response: Market baskets developed for other Medicare payment systems typically utilize cost report data, and the costs of covered services provided incident to a billable visit may be included on the FQHC cost report.

Comment: Some commenters opined that the implementation of HCPCS reporting for FQHCs was confusing, resulting in claims with significant errors in line item reporting, and questioned the credibility of analyses based on claims submitted in 2011 and 2012.

Response: Since data used for the proposed rule included final action claims with dates of service through June 2012 that were obtained from the IDR in 2013, we believe that any initial errors in the coding or adjustment of claims were corrected or were not present in the majority of the claims used for modeling adjustments in the proposed rule. (see CMS CRs 7038 and 7208, which updated CMS Pub 100–04, Claims Processing Manual, Chapter 9). For this final rule with comment period, we updated our sample to include final action claims with dates of services through June 2013, which are even less likely to have significant coding or adjustment errors.

After consideration of the public comments received, we are finalizing our proposal 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 PFS.

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

In this final rule with comment period we used the same methodology described in the proposed rule 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. In the sample used for the proposed rule, cost reports with reporting periods that began on or after January 1, 2011, accounted for 81 percent of the sample. In the updated sample used for this final rule with comment period, cost reports with reporting periods that began on or after January 1, 2011, accounted for 98 percent of the sample. 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 (Medicare and non-Medicare) 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, and that this information is not currently available on the free-standing FQHC cost report, Form CMS–222–92.

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 used for the proposed rule. 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. We believe that removing statistical outliers is consistent with standard practice and results in a more accurate estimation of costs overall. For this final rule with comment period, we used the same approach to exclude statistical outliers from the linked claims sample.

After trimming the linked claims data for outliers, the final data set used for this final rule with comment period included 5,468,852 visits from 5,458,632 distinct claims encompassing 6,533,716 claim lines. This included visits furnished to 1,297,013 beneficiaries at 3,778 delivery sites under 1,215 cost-reporting entities. For this final rule with comment period, we modified the definition of a daily visit to be consistent with our revised policy to allow an exception to the per diem PPS payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit. Separately payable encounters for the same beneficiary at the same FQHC were combined into a single daily visit, while allowing for a separate medical visit, mental health visit, and subsequent illness/injury visit, which could result in up to three encounters per beneficiary per day. The final data set yielded 5,462,670 daily visits.

Comment: A commenter suggested that using CCRs to measure the cost of furnishing FQHC services is not appropriate for FQHCs because certain types of FQHC care management services are not captured in the billed charges; the CCRs would not be uniform among medical and mental health services; and the CCRs would be affected by the pricing strategies of FQHCs that keep their charges low to minimize the copayment impact on uninsured and indigent patients. The commenter recommended that CMS use PFS relative value units or other metrics to adjust FQHC average cost per visit.

Response: We used Medicare cost report data to measure the aggregate reasonable cost of furnishing FQHC services. However, as discussed in the proposed rule, the cost report data is insufficient for modeling the types of adjustments considered for the FQHC PPS. The CCRs for each cost-reporting entity were used to approximate data not available on the cost report and to convert each FQHC's charge data, as found on its claims, to costs. The use of the CCRs was primarily for modeling the adjustments and does not substantially impact our measure of the aggregate reasonable cost of furnishing FQHC services. Therefore, in this final rule with comment period, we plan to continue to use the CCR to adjust charges in order to estimate costs.

Comment: A commenter requested that CMS clarify whether a statistically significant number of outlier visits were for FQHCs in a particular state or for a particular service.

Response: The average range of outliers based on the adjusted charge for the encounter was approximately 1.3 percent of FQHC visits, with higher rates in U.S. territories (4 percent) and the Pacific census division (3 percent). Slightly more than 1 percent of all office visits were outliers.

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

In developing the FQHC PPS rates and adjustments, we considered existing payment policies regarding payment for multiple visits on the same day, preventive laboratory services and technical components of other preventive services, and vaccine costs to

determine potential interactions with the implementation of the FQHC PPS.

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 all-inclusive payment system was also designed to minimize reporting requirements, and as such, it reflects all the services that a FQHC furnishes 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 includes 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 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 69624) subsequently revised the regulations to allow FQHCs to receive separate payment for DSMT/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.

To determine if these exceptions should be included, updated, or revised in the new PPS, in the September 23, 2013 proposed rule (78 FR 58386) we discussed that 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.

In the September 23, 2013 proposed rule (78 FR 58386) proposed rule, we discussed that an analysis of data from Medicare FQHC claims with dates of service between January 1, 2011 and June 30, 2012, indicated 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 we stated that eliminating the ability to do so would not significantly impact either the FQHC payment or a beneficiary's access to care. We also suggested this policy would also simplify billing by removing the need for modifier 59, which signifies that the conditions being treated are totally unrelated and services are furnished 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 rarely occur 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, in the proposed rule, we proposed to revise § 405.2463(b) to remove the exception to the single encounter payment per day for FQHCs paid under the proposed PPS and we stated that 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 reflected a daily (per diem) rate and resulted in a slightly higher payment than one calculated based on multiple encounters on the same day.

Based on the Medicare claims data furnished by FQHCs that indicates minimal incidence of multiple visits billed on the same day, we concluded in the proposed rule that not including these exceptions in the PPS would not significantly impact total payment or access to care. However, because 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 furnish integrated, patient-centered health care services in a variety of ways, we asked for comments to address whether there are factors that we have not considered, particularly in regards to the provision of mental health services, and whether this change would impact access to these services or the integration of services in underserved communities.

We received many comments on our proposal not to include these exceptions in the new PPS for FQHCs. None of the commenters were supportive of the proposal.

Comment: Some commenters said that we should continue to allow mental health or other visits to be furnished on the same day as a medical visit because their patients have transportation, mobility, work, or childcare issues.

Response: We wish to clarify that we did not propose to prohibit mental health visits from occurring on the same day as a medical visit. We did propose not to include an exception to the per diem payment system to allow for multiple billing when mental health (or subsequent illness/injury, DSMT/MNT or IPPE) is furnished on the same as a medical visit, as discussed later.

Comment: Some commenters suggested that if we do not allow separate billing for mental health services that are furnished on the same day as a medical service, we should instead develop an adjustment that would increase the PPS per diem base payment rate when a mental health visit occurs on the same day as another billable visit. Other commenters suggested an adjustment for mental

health, behavioral health, DSMT, and MNT.

Response: As we discussed in earlier, we did not propose to include adjustments to the PPS per diem payment rate except for new patient and initial Medicare visits. While we considered an adjustment for mental health services and DSMT/MNT, our analysis of the claims data did not support such adjustments. Also, including additional adjustments would result in a lower PPS rate, which would impact FQHC payments for all visits.

Comment: Some commenters acknowledged that the incidence of Medicare billing for more than 1 visit per beneficiary per day in FQHCs is extremely low, but argued that their FQHC often billed multiple visits on the same day, particularly for mental health visits that occur on the same day as a medical visit, and that this proposal would have a significant impact on their FQHC payments and their patient's access to care.

Response: Based on our analysis of national Medicare claims data, we believe there would be a very minimal impact if the exception allowing multiple billing on the same day was to be eliminated, especially for mental health services. We analyzed the claims data of the FQHCs that provided the most detailed comments that they would be significantly or disproportionately impacted if they could not bill separately for mental health visits that occur on the same day as a medical visit. A commenter from a large FQHC in the southeastern part of the U.S. with more than 23,000 total visits per year described how they are a fully integrated primary care FQHC and every patient has a team of professionals that includes behavioral health. Yet a review of the Medicare claims data for this FQHC showed that out of a yearly total of more than 23,000 total visits, only 74 mental health visits, or 0.32 percent, were billed on the same day as a medical visit. A review of Medicare claims data for a large FQHC in the western part of the U.S. showed that 2.0 percent had a mental health visit on the same day as another visit, but of those 2.0 percent, only 0.5 percent of these were billable visits. A large multisite FQHC in the southern part of the U.S. stated that as a result of their integrated model of behavioral care and same day billing, there was a reduction in visits to the emergency room. The claims data for this FQHC showed a rate of same day billing for mental health visits of 0.5 percent, and no evidence was provided to link this to a reduction in emergency room visits. While this is slightly higher than the average of 0.3 percent, it is still a very low rate.

We do not know why these and other FQHCs believe that they are billing more same-day mental health visits than indicated by their claims data. Perhaps the FQHC may be considering all their patients, not just Medicare beneficiaries who comprise an average of 8 percent of all FQHC patients. Another possibility is that the FQHC may be considering some behavioral health services that are beyond the scope of Medicare-covered services, or are including services furnished by non-FQHC practitioners. Based on the claims data and the information provided in the comments, we do not agree that removal of the exceptions to allow for multiple billing would have a significant impact on the financial viability of these FQHCs or reduce access to care for Medicare beneficiaries.

Comment: Several commenters acknowledged that their use of the exception for multiple billing on the same day was low or non-existent for Medicare beneficiaries, but wanted us to retain this exception so that they could use this to leverage Medicaid in their state to pay separately for mental health.

Response: We do not believe that Medicare policy should be determined in order to influence state Medicaid policies.

Comment: Some commenters disputed our data which showed that only 0.5 percent of all claims were for multiple same day visits. The commenters suggested the following reasons for the low number of multiple same day visits: FQHCs did not code correctly; FQHCs did not know they could bill for multiple visits; FQHC billing systems are not set up for multiple billing because other payment systems do not reimburse for it; and that the MACs do not allow it.

Response: Section 1834(o)(1)(B) of the Act, as added by the Affordable Care Act required FQHCs to utilize HCPCS codes on their Medicare claims in order to inform the development of the FQHC PPS. FQHCs have also been required to use HCPCS codes for payment purposes when a preventive service for which coinsurance is waived is on the same claim as a service that has a coinsurance requirement. Other payment systems may also require HCPCS coding on claims. We are aware that some FQHCs have limited experience with coding and that the coding submitted on Medicare claims may not have been accurate or complete in all cases. However, even if the rate shown in the claims data was doubled or tripled, the rate of billing for multiple visits on the same day would still be extremely low.

As we stated in the September 23, 2013 proposed rule, the ability to bill for multiple visits on the same day for subsequent illness or injury has been allowed since the beginning of the FQHC program. We also noted that the ability to bill for multiple visits on the same day for mental health services has been allowed since 1996, and the ability to bill for multiple visits on the same day has been allowed for DSMT/MNT since 2007. While it is possible that some FQHCs were not aware that this option existed, we know from the claims data that mental health, IPPE, and DSMT/MNT services constitute a small percentage of a FQHC's total Medicare services.

We understand that billing systems vary among FQHCs and that some billing systems are more adept at managing tasks such as multiple same-day billing. However, we believe that if the inability to bill for multiple visits presented a significant loss of payment for a FQHC, the FQHC would have upgraded its system to allow for this type of billing. We are also not aware of any MACs that do not allow for multiple same day billing for the circumstances in which they are allowable.

Medicare comprises only 8 percent of FQHC patient population, and not all Medicare beneficiaries require mental health or DSMT/MNT services. Particularly for mental health services, it is often difficult to schedule appointments on the same day as a medical visit, and most mental health conditions require ongoing treatment which would likely be at a frequency that differs from the need for primary care visits. Therefore, we would expect the rate of same day billing to be low, despite the availability of the exceptions.

Comment: Some commenters requested that FQHCs be allowed to bill separately for other services such as optometry and dental care when furnished on the same day as another visit.

Response: Other services, such as optometry and dental care, cannot be billed separately on the same day as another medical visit under the current AIR system. We did not propose and we are not considering expanding the type of services that can be billed separately when furnished on the same day as another visit. The PPS rate and its adjustments reflect the total cost of furnishing services to Medicare beneficiaries.

Comment: Some commenters were concerned that removing the ability to bill separately for mental health services that are furnished on the same day as a medical visit would create an incentive

for FQHCs to schedule these encounters on separate days.

Response: Under both the all-inclusive payment system and the PPS per diem system, there is a risk that a FQHC could deliberately schedule patient visits over a period of time in order to maximize payment. We expect FQHCs and other providers of care to Medicare beneficiaries to act in the best interests of their patients, which includes scheduling visits in a manner that maximizes the health and safety of their patients.

Comment: A few commenters stated that FQHCs will not be able to continue working with community mental health centers if we do not allow separate billing for mental health services furnished on the same day as a medical visit.

Response: Commenters did not provide enough supporting information as to why this proposal would negatively or adversely affect FQHC relationships with community mental health centers to allow us to respond meaningfully to this comment.

Comment: Some commenters suggested that removing the ability to bill separately for mental health and other services is inconsistent with the Affordable Care Act's focus on value over volume.

Many commenters wrote that the ability to bill separately for mental health and other visits on the same day as a primary care visit would help them to furnish integrated and coordinated care and would benefit their patients. Many of them stated that allowing separate payment for mental health services furnished on the same day as a medical visit would provide incentives to furnish integrated care for Medicare patients with complex health conditions. Others were concerned that not allowing this exception would send a message that we do not value mental health care. Commenters also suggested that people with mental illness are less likely to return for a mental health visit if a primary care visit is not also scheduled, and that furnishing mental health visits on the same day as a medical visit helps to increase compliance with medications.

Response: We agree with commenters about the importance of promoting and furnishing coordinated and integrated care, which can be especially challenging in underserved areas. Based on Medicare claims data and the comments we received, there is no evidence that access to care would be reduced if exceptions to the per diem PPS are not allowed.

However, we agree that separate payment for mental health services furnished on the same day as a medical visit has the potential to increase access to mental health services in underserved areas and that this would help to demonstrate the value of mental health services, especially in areas where need is high and utilization is low. We acknowledge that FQHCs furnish services to underserved and vulnerable populations that often have had difficulty accessing mental health services, and that commenters overwhelmingly support separate payment for mental health services furnished on the same day as a medical visit. Therefore, in this final rule with comment period, we are modifying our original proposal to allow an exception to the per diem payment system so that FQHCs can bill separately for mental health services that are furnished on the same day as a medical visit.

We will also allow an exception to the per diem payment system to allow FQHCs to bill separately when an illness or injury occurs on the same day in which a FQHC visit has already occurred. This exception is available for situations where a Medicare beneficiary has a FQHC visit, leaves the FQHC, and later in the day has an illness or injury that was not present during the initial visit. While it does not happen often, when it does occur we believe the FQHC should be able to bill separately because it is a unique situation that could not be planned or anticipated and the FQHC would not benefit from the economies of scale that can occur when multiple medical issues are addressed in the same visit.

We do not believe that the circumstances that justify allowing same day billing for a subsequent injury or illness or a mental health visit that occurs on the same day as a medical visit also applies to DSMT/MNT. A DSMT/MNT visit is part of the broad category of primary care services that are included in the services of a FQHC and are part of the PPS per diem payment. Visits with multiple practitioners that occur on the same day, including visits for different conditions or visits with a specialist physician, are not separately payable in a FQHC under the all-inclusive payment methodology or the PPS methodology. We do not see any reason why these DSMT/MNT visits should be considered differently. Additionally, the cost of a DSMT/MNT visit is far lower than the cost of a medical or mental health visit, so it would not be justified to pay separately for those visits at the PPS rate. We also did not include IPPE as a separately billable visit, because we are already allowing an adjustment to the PPS rate for a new patient or initial Medicare visit.

We are allowing the exception to the per diem PPS payment for mental health services that occur on the same day as a medical visit to promote access to these services in FQHCs. While this may also contribute to the coordination of care, this alone will not achieve the goals of the Affordable Care Act to furnish integrated and coordinated services. Instead, we believe that these goals may be supported through an adaptation of the Chronic Care Management (CCM) services program that will be implemented for physicians billing under the PFS in 2015. We encourage FQHCs to review the CCM information in the CY 2014 PFS final rule with comment period titled, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014'' (December 10, 2013 (78 FR 74230)) and submit comments to us on how the CCM services payment could be adapted for FQHCs in CY 2015 to promote integrated and coordinated care in FQHCs. We also invite RHCs to submit comments on how CCM services could be adapted for RHCs in CY 2015 to promote integrated and coordinated care.

In this final rule with comment period, we are modifying our proposal not to allow an exception to the per diem PPS payment for subsequent injury or illness and for mental health services furnished on the same day as a medical visit, and we invite public comments on this modification. We are adopting as final our proposal not to allow an exception to the per diem PPS for DSMT/MNT or IPPE.

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 § 405.2448, which may be paid for when furnished 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 § 405.2449, include laboratory tests 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 did not propose a change in billing procedures, and we did not propose to include payment for these services under the FQHC PPS. We noted this payment structure simplifies billing procedures as laboratory tests and technical components of diagnostic services are always billed separately to Part B and are not 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 all-inclusive rate 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.

Comment: Most commenters were supportive of our intent to clarify appropriate billing procedures through program instruction, and some commenters suggested that we also use rulemaking to resolve issues concerning Medicare billing. Many of these commenters requested greater clarity on billing for the technical components of FQHC services separately under Part B.

Response: As we stated in the proposed rule, we plan to clarify the appropriate billing procedures for technical components of FQHC services and other billing issues through program instruction, and we do not believe that clarifications to billing procedures require rulemaking.

Comment: A commenter disagreed with our conclusion that laboratory services and diagnostic tests are by definition excluded from the FQHC benefit. The commenter noted that preventive primary health services and preventive services, as defined in section 1861(aa)(3) of the Act and codified in § 405.2448 and § 405.2449 of the regulations, include a variety of screening tests, and neither the statute nor the regulations exclude the technical components of these tests from the FQHC benefit.

Response: We respectfully disagree with this commenter and maintain that 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)(3) of the Act. We also maintain that both the professional and technical components of FQHC primary preventive services and preventive services, as defined in section 1861(aa)(3) of the Act and codified in § 405.2448 and § 405.2449 of the regulations, are covered under the FQHC benefit. Laboratory tests and diagnostic services that do not meet the statutory and regulatory definitions of FQHC primary and preventive services, and are not otherwise specified in the statute or regulations as within the scope of the FQHC benefit, are not covered under the FQHC benefit. We agree with the commenter that neither the statute nor the regulations specifically exclude the technical components of these tests. We also note that the FQHC regulations do not distinguish between the technical and professional components of primary or preventive services. As a matter of our payment policy, we believe that laboratory tests and diagnostic services that do not meet the statutory and regulatory definitions of FQHC primary preventive and preventive services, and are not otherwise specified in the statute or regulations as within the scope of the FQHC benefit, are not covered under the FQHC benefit. As a matter of policy, we believe the 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. We note that this payment structure does not change the scope of the FQHC benefit.

Comment: A commenter recommended that FQHCs be allowed to bill all Medicare Part B services on an institutional claim, including 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.

Response: To distinguish services that are not paid as part of the encounter rate, we believe that the current billing requirements for billing services separately to Medicare Part B on a Part B practitioner claim are more appropriate for most services. We note that the telehealth originating site facility fee will continue to be billed separately on an institutional claim.

After consideration of the public comments received, we plan to clarify the appropriate billing procedures through program instruction, as proposed.

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 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 did not propose any changes to this payment structure, rather, we stated that 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 continue paying for these services under the FQHC PPS when furnished as part of an otherwise qualifying encounter.

Comment: A few commenters requested clarification regarding coverage and payment for vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) that are typically covered and paid under Medicare Part D. They believe that these vaccines, when furnished by FQHCs, should be covered and paid separately by Part D plans and should not be covered and paid for as part of a FQHC encounter.

Response: Under section 1862(a)(7) of the Act, as codified at 42 CFR 411.15(e) of our regulations, immunizations other than pneumococcal, influenza, and HBV are generally excluded from Medicare Part B coverage. Section 4161(a)(3)(C) of OBRA '90 (Pub. L. 101–508) amended section 1862(a) of the Act to specify that the FQHC benefit can include preventive primary health services, as described in section 1861(aa)(3)(B) of the Act, that would otherwise be excluded from Part B under section 1862(a)(7) of the Act. Preventive primary services, as defined in § 405.2448, describes which services may be paid for when furnished by FQHCs. (See the June 12, 1992 (57 FR 4980) and April 3, 1996 (61 FR 4657) final rules). These preventive primary services include immunizations (see § 405.2448(b)(8)). This means that when FQHCs furnish ACIP-recommended vaccines, they are covered and paid for under Part B as part of the FQHC benefit, and are excluded from Part D.

Except for pneumococcal and influenza vaccines and their administration, which are paid at 100 percent of reasonable cost, payments to FQHCs for covered FQHC services furnished to Medicare beneficiaries are made on the basis of an AIR per covered visit. The charges for other Medicare-covered vaccines and their administration when furnished by a FQHC can be included as line items for an otherwise qualifying encounter, and payment for these other Medicare-covered vaccines would be included in the AIR. However, an encounter cannot be billed if vaccine administration is the only service the FQHC provides. For more information on how to bill under the AIR for services furnished incident to a FQHC encounter, see CMS Pub. 100–04, Medicare Claims Processing Manual, chapter 9.

Section 10501(i)(3)(A) of the Affordable Care Act did not amend the coverage requirements applicable to the FQHC benefit. We did not propose to remove immunizations from the preventive primary services set out at § 405.2448, and immunizations furnished by FQHCs after implementation of the PPS will continue to be covered under Part B as part of the FQHC benefit. We proposed to 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. As part of the implementation of the FQHC PPS, we plan to update the appropriate billing procedures through program instruction.

We note that under 1860D–2(e)(2)(B) of the Act, a drug prescribed to a Part D eligible individual that would otherwise be a covered Part D drug is excluded from Part D coverage if payment for such drug, as so prescribed and dispensed or administered, is available under Part A or B for that individual. Consequently, vaccines furnished by FQHCs and covered under Part B as part of the FQHC benefit in accordance with § 405.2448(b)(8) are not covered or payable under Part D. For more information on the exclusion from Part D of drugs covered under Part B, see CMS Pub. 100–18, Medicare Prescription Drug Benefit Manual, Chapter 6. Section 20.2.

Comment: A few commenters recommended that CMS apply a consistent approach to payment for vaccines covered under Part B, which commenters asserted would ensure broad access for Medicare beneficiaries. These commenters recommended that CMS pay for the cost and administration of the HBV at 100 percent of reasonable cost through the cost report. A commenter recommended that influenza and pneumococcal vaccines should be billed at time of service, either with or without an encounter, and be paid using the national MAC fees, with an annual reconciliation on the cost report between the payments and the reasonable costs of these vaccines. This commenter wished to reduce the time between vaccine administration and payment and to document on individual patient claims that these vaccines were furnished. However, most commenters supported our proposal to continue to reimburse influenza and pneumococcal vaccines through the cost report.

Response: As discussed in the preamble to the April 3, 1996 FQHC final rule (61 FR 14651), section 1833(a)(3) of the Act specifies that services described in section 1861(s)(10)(A) of the Act are exempt from payment at 80 percent of reasonable costs and payment to RHCs and FQHCs for influenza and pneumococcal vaccines and their administration is at 100 percent of reasonable cost. Consistent with section 1833(a)(3) of the Act, we used our regulatory authority to codify at § 405.2466(b)(1)(iv) that for RHCs and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost paid as part of the annual reconciliation through the cost report (61 FR 14657, April 3, 1996). Payment for all other Medicare-covered vaccines is included in the AIR, and we proposed to continue to pay for all other Medicare-covered vaccines as part of the encounter rate under the FQHC PPS. We note that HBV is described in section 1861(s)(10)(B) of the Act, and we do not believe that the statute directs us to change the payment structure to pay for HBV at 100 percent of reasonable cost through the cost report.

We considered the commenter's request to pay for influenza and pneumococcal vaccines billed at time of service with an annual reconciliation between these payments and reasonable costs and we do not believe this would be necessary. FQHCs are accustomed to reporting and receiving payment for the reasonable costs for these vaccines and their administration through the annual cost report, and we believe that an annual reconciliation between vaccine fee amounts and reasonable costs would create an additional administrative burden for FQHCs and MACs. We also note that as of January 1, 2011, FQHCs have been required to report pneumococcal and influenza vaccines and their administration on a patient claim with the appropriate HCPCS and revenue codes when furnished during a billable visit.

After consideration of the public comments received, we are finalizing these provisions as proposed. We will continue to pay for the administration and payment of influenza and pneumococcal vaccines at 100 percent of reasonable costs through the cost report, and we will continue to pay for other Medicare-covered vaccines under the FQHC PPS as part of the encounter rate 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 proposed the following adjustments.

1. Alternative Calculations for Average Cost per Visit

For the 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).

Proposed average cost per daily visit = $788,547,531/5,223,512 = $150.96

For this final rule with comment period, we modified the definition of a daily visit, as discussed in section II.A.4. of this final rule with comment period and consistent with the policy discussed in section II.B.1. of this final rule with comment period, which allows an exception to the per diem PPS payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit. Separately payable encounters for the same beneficiary at the same FQHC were combined into a single daily visit, while allowing for a separate medical visit, mental health visit, and subsequent illness/injury visit, which allows for up to three encounters for beneficiary per day.

For this final rule with comment period, we used the updated claims data to calculate an average cost per visit by dividing the total estimated costs ($846,058,100) by the total number of daily visits (5,462,670).

Final average cost per daily visit = $846,058,100/5,462,670 = $154.88

In the proposed rule, 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.

Proposed average cost per visit = $788,547,531/5,245,961 = $150.32

For this final rule with comment period, we used the updated final data set to examine how the average cost per visit would differ under current policy. While the total estimated cost was the same ($846,058,100), the total number of visits in the denominator (5,468,852) did not combine multiple visits on the same day of service.

Final average cost per visit = $846,058,100/5,468,852 = $154.70

In the proposed rule, 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 noted 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.

Proposed average cost per visit from cost report data = $832,387,663/5,374,217 = $154.89

For this final rule with comment period, we used the current data set to update the average cost per visit derived from the cost reports by dividing the total estimated Medicare costs (excluding vaccines) reported ($897,330,363) by the total number of Medicare visits reported (5,634,602).

Final average cost per visit from cost report data = $897,330,363/5,634,602 = $159.25

Consistent with our proposal to remove the exception to the single encounter payment per day, we proposed 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 noted that the alternative calculations yield an average cost per visit that differs from $150.96 by less than 3 percent. We also noted that these calculations were derived based on the cost report and claims data available during our development of the proposed rule and were subject to change in the final rule based on more current data.

For this final rule with comment period, consistent with our policy to allow an exception to the per diem PPS payment for subsequent injury and mental health services furnished on the same day as a medical visit, we will use the average cost per daily visit of $154.88, as calculated above based on adjusted claims data, as the final PPS rate prior to any risk adjustment. We note that the alternative calculations yield an average cost per visit that differs from $154.88 by less than 3 percent.

2. FQHC Geographic Adjustment Factor

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

Since 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 FQHC geographic adjustment factor (FQHC 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 on July 19, 2013 (78 FR 43282).

For modeling geographic adjustments for the 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 noted that the FQHC 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 FQHC 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 FQHC GAF as follows:

Geographic adjustment factor = (0.53149 × Work GPCI) + (0.46851 × PE GPCI)

We included the FQHC GAF adjustment when modeling all other potential adjustments. We proposed to apply the FQHC GAF based on where the services are furnished, and we noted the FQHC GAF may vary among FQHCs

that are part of the same organization. The list of proposed FQHC GAFs by locality was included in the Addendum of the proposed rule and as a downloadable file at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html.*

Comment: Commenters were supportive of a FQHC GAF adjustment, but some suggested changes to the proposed FQHC GAFs. Some commenters suggested that the rural FQHC GAFs may not reflect the actual cost of furnishing FQHC services in rural areas, and they requested that we increase the rural FQHC GAFs. Some of these commenters believe that the factors influencing costs for urban versus rural providers are not identical for FQHCs and physician practices. Among the concerns raised by these commenters are that a rural FQHC's operating costs (such as utilities and transportation costs) may be higher than similar costs of FQHCs in urban areas; predominantly rural FQHCs often have fewer sites than urban FQHCs and benefit less from economies of scale; and FQHCs located in rural areas may incur additional costs if they offer payment incentives in order to recruit and retain qualified physicians and non-physician practitioners.

Response: Since FQHCs furnish services that are analogous to those furnished by physicians in outpatient clinic settings, we proposed to adapt the PFS GPCIs to calculate the FQHC GAFs, as we believe it would be consistent to apply geographic adjustments similar to those applied to services furnished under the PFS. As discussed in the CY 2014 PFS final rule with comment period, we used updated Bureau of Labor Statistics (BLS) Occupational Employment Statistics data to calculate the work GPCI and purchased services index of the PE GPCI and updated U.S. Census Bureau American Community Survey (ACS) data to calculate the rent component (which includes utilities) of the PE GPCI. Given their reliability, public availability, level of detail and national scope with sufficient data coverage in both urban and rural areas, we believe that the ACS and BLS data are the most appropriate sources for measuring geographic cost differences in operating a medical practice. (See our discussion in the CY 2014 PFS final rule with comment period (78 FR 74380 through 74381)). We believe that the data used to develop the PFS GPCIs are reflective of the costs of furnishing FQHC services, including the geographic variation in the costs of furnishing FQHC services in rural areas. Moreover, we do not have a comprehensive national source that would provide us with a basis for adjusting the FQHC GAFs for rural areas independently of the PFS GPCIs while meeting data selection criteria similar to the criteria used for selecting the PFS GPCI sources. We also note that as discussed later in this section, many rural areas would see a substantial decrease in payment amounts if they were no longer grouped with urban areas.

Comment: A commenter was concerned that FQHCs with multiple delivery sites with different costs may be penalized if accommodation for these different sites is not taken into account.

Response: We proposed to apply the FQHC GAF based on where the services are furnished. Therefore, for FQHCs with multiple delivery sites in different areas, the FQHC GAF may vary depending on the delivery site.

Comment: A commenter was concerned that application of the FQHC GAF reduces its PPS rate below the proposed base rate, which is below its cost of furnishing FQHC services.

Response: Under the FQHC PPS, Medicare payment for FQHC services is based on 100 percent of aggregate reasonable costs, not on an individual FQHC's costs. While the FQHC GAF will vary by locality, we note that the fully implemented, geographically adjusted PPS rate for all FQHCs will be approximately 32 percent higher, based on payment at the FQHC PPS rate, when compared to current payments to FQHCs.

Comment: A commenter noted that FQHC lookalikes do not have access to malpractice coverage under the Federal Tort Claims Act (FTCA) and therefore incur malpractice expense. The commenter requested that CMS incorporate a malpractice adjustment in the FQHC GAFs for FQHC lookalikes, or otherwise recognize malpractice expense under the FQHC PPS.

Response: FQHCs that receive section 330 grant funds are the predominant type of FQHC, with more than 1,100 centers operating approximately 8,900 delivery sites. These FQHCs are eligible to apply for medical malpractice coverage under the FTCA. In comparison, there were 93 look-alikes in 2012, according to HRSA's UDS. The PPS rate is based on aggregate costs, and assumes that not all FQHCs have the same costs. It would not be feasible to develop separate PPS rates for FQHCs based on differences in malpractice or any other costs. We excluded the PFS malpractice GPCI from the calculation of the FQHC GAF as the geographic variation in malpractice costs is not relevant for the majority of FQHCs that are eligible to apply for medical malpractice coverage under the FTCA. We note that FQHCs are required to report professional liability insurance on Worksheet A of the FQHC cost report (Form CMS–222), and malpractice expense was recognized as a component of the reasonable costs used to calculate the FQHC PPS rates.

Comment: A commenter disagreed with our adaptation of the PFS GPCIs and recommended that we adjust the FQHC PPS rate for geographic differences based on Metropolitan Statistical Areas (MSAs). The commenter believes that use of the current PFS locality structure would result in underpayment for FQHC services furnished in several California counties.

Response: As previously noted, 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. Moreover, by adapting the PFS GPCIs for the FQHC PPS, the accuracy of FQHC payments also benefits from the ongoing assessment, evaluation, and updates to the PFS GPCIs, including the periodic review and adjustment of GPCIs as mandated by section 1848(e)(1)(C) of the Act.

We note that adjusting the FQHC PPS rate for geographic differences based on MSAs could result in significant reductions in payment for rural FQHCs when compared to geographically adjusted payments using the current PFS locality configuration. As discussed in the CY 2014 PFS final rule with comment period, published in the **Federal Register** on December 10, 2013 (78 FR 74230), a MSA-based locality structure would expand the number of PFS payment localities, and many rural areas would see substantial decreases in their GPCI values given that they would no longer be grouped together with higher cost counties (78 FR 74380 through 74391). If the PFS locality structure or GPCI values changed, we would make corresponding changes to the FQHC localities and FQHC GAFs. As other methodologies emerge for geographic payment adjustment under the PFS, they may also eventually apply to the new FQHC PPS.

Comment: A commenter recommended that after the first year of implementation, we use a market basket approach to adjust payments based on geographic locations. The commenter suggested that we revise the FQHC cost report to capture additional wage data that, in conjunction with HRSA's UDS data, could be used to develop a wage

index to adjust the PPS rate based on reported salary differentials.

Response: We appreciate the commenter's interest in developing a wage index for the FQHC PPS. We believe that a FQHC GAF based on the PFS GPCIs is appropriate for FQHC services, as an FQHC's employment mix and scope and delivery of services are generally similar to a physician's practice. We note that a FQHC GAF based solely on a wage index, which is a relative measure of geographic differences in wage levels, would not reflect the relative cost difference in the full mix of goods and services comprising the PFS practice expense GPCIs (for example, purchased services, office rent, equipment, supplies, and other miscellaneous expenses). We do not believe that the additional reporting burden suggested by the commenter, or the additional administrative burden of collecting and validating the type of data needed for a reliable FQHC wage index, would justify the potential incremental benefit of using a FQHC-specific wage index in calculating the FQHC GAFs.

Comment: A commenter asked why we did not use the CY 2015 GPCI values to calculate the FQHC GAFs.

Response: For modeling geographic adjustments for the FQHC PPS proposed rule, we used the CY 2014 work and practice expense GPCIs published in the CY 2014 PFS proposed rule. We noted that the FQHC GAFs could be subject to change in the final FQHC PPS rule based on more current data, including the finalized PFS GPCI and cost share weight values.

As discussed in the CY 2014 PFS final rule with comment period (78 FR 74380 through 74391), the CY 2015 PFS GPCI values reflect our most current updates of the underlying data sources and represent our best estimates of the geographic variation in the costs of furnishing physician services. In contrast, the CY 2014 GPCI values partially reflect the updates to the underlying data and MEI cost weights. Therefore, we will use the CY 2015 GPCI values, as published in the CY 2014 final rule with comment period, to model the geographic adjustments for the FQHC PPS rates as they represent the most current data. We note that the PFS cost share weights were finalized as proposed, and we will use the relative weights of the PFS work and PE GPCIs, as proposed and finalized, to calculate each locality's FQHC GAF.

For payments under the FQHC PPS, we believe it most appropriate to apply geographic adjustments consistent with those applied to services furnished under the PFS during the same period. Therefore, the FQHC GAFs and cost share weights will be updated in conjunction with updates to the PFS GPCIs, which would maintain consistency between the geographic adjustments applied to the PFS and the FQHC PPS in the same period. We note that the FQHC GAFs for October 1 through December 31, 2014, will be adapted from the CY 2014 PFS GPCIs applicable during that same period. Subsequent updates to the FQHC GAFs will be made in conjunction with updates to the PFS GPCIs for the same period.

We have considered the public comments we received, and are finalizing the FQHC GAF provisions as proposed, with some modifications. As proposed, we are revising § 405.2462 to require that payments under the FQHC PPS will be adjusted for geographic differences by applying an adaptation of the work and practice expense GPCIs used to adjust payment under the PFS. We are modifying § 405.2462 to specify that the FQHC GAFs used for payment will be adapted from the GPCIs used to adjust payment under the PFS for that same period.

For modeling geographic adjustments for the FQHC PPS proposed rule, we did not use the proposed CY 2014 work and practice expense GPCIs that were published in the CY 2014 PFS proposed rule. Instead, for modeling the geographic adjustments for this FQHC PPS final rule, we used the final CY 2015 work and practice expense GPCIs and cost shares that were published in the CY 2014 PFS final rule with comment period as the CY 2015 GPCI values represent the most recent fully implemented GPCI update and therefore more current data. More information on how we modeled the FQHC PPS geographic adjustment is discussed in section II.D. of this final rule with comment period.

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 AWV). We proposed 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 was 1.3333.

Comment: Commenters supported the proposed adjustments, but some recommended that we also apply the adjustment factor to subsequent AWVs. Commenters recommended that we allow an adjustment for subsequent AWVs in addition to initial AWVs in order to support the goal of improving health outcomes and increasing access to subsequent AWVs. Commenters also believe that the subsequent AWV is similar to the increased intensity of the IPPE and initial AWV, in terms of both the duration of the visits and the number of ancillary services furnished.

Response: Subsequent AWV is a very small percent of total FQHC visits (approximately 0.25 percent), but the claims data suggest that subsequent AWV is significantly more costly than most other FQHC visits. The claims data also suggest that subsequent AWV is somewhat less costly than an IPPE or initial AWV, which is consistent with the comparatively reduced level of required physician work associated with the subsequent AWV. As previously noted, our goal for the FQHC PPS is to implement a system in accordance with the statute whereby FQHCs are fairly paid for the services they furnish to Medicare patients in the least burdensome manner possible. Rather than establish a separate adjustment for subsequent AWV, we will add the subsequent AWV to the proposed adjustment for new patient or initial Medicare visit. Based on current FQHC data, the composite group of new patient visits, IPPEs, initial AWVs, and subsequent AWVs is associated with 34.16 percent higher estimated costs than other visits.

In this final rule with comment period, we are modifying our proposal, and we will adjust the encounter rate to reflect the 34.16 increase in costs when FQHCs furnish care to new patients or when they furnish an IPPE, initial AWV, or subsequent AWV, which could account for the greater intensity and resource use associated with these types of services. Our composite risk adjustment factor for these types of visits is 1.3416.

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 calculated whether there were differences in resource use for mental health visits and preventive care visits when compared to medical care visits

using mathematical modeling techniques. 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 declined to an 8 percent higher estimated cost per visit after adjusting for the FQHC 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 AWV), indicating that a significant amount of preventive care visits were IPPEs or initial AWVs. We did not propose a payment reduction for preventive care encounters and we noted 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 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, and that 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 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 AWV, 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.

Comment: Several commenters recommended that CMS address the special circumstances facing Indian health providers by considering the inclusion of a low-volume upward adjustment, a population-density adjustment, and a service-mix adjustment to the PPS rate. These commenters stated that a volume adjustment is necessary because low-volume tribal FQHCs find it more difficult to spread their costs across their patient base, and are less likely to obtain volume discounts and benefit from economies of scale. They also stated that many tribal FQHCs in rural areas furnish less complex or lower intensity services than urban providers, resulting in different payment-to-cost ratios that result in reimbursement inequities.

Response: We appreciate the challenges that tribal FQHCs face in furnishing services, especially in rural and isolated areas, and the significant health disparities that remain for AI/AN populations. We also understand that providers in isolated and rural areas, including tribal FQHCs, may have fewer patients than providers in more densely populated areas, and may not be able to offer as full of a range or level of complexity in their services as other providers, or benefit from the economies of scale that providers with higher volume or in more densely populated areas may have. In developing the PPS rate, we considered various possible adjustments, including a low-volume adjustment. When analyzing Medicare claims data, lower overall FQHC volume was found to be associated with higher estimated costs (see ''Results of Research on the Design of a Medicare Prospective Payment System for Federally Qualified Health Centers'' by Arbor Research Collaborative for Health). However, we did not propose to include a low-volume adjustment, because we believe that the PPS rate, along with adjustments for new and initial visits and AWV, will provide appropriate reimbursement for the costs of services provided.

Comment: Commenters were generally supportive of a single base rate with a geographic adjustment and an adjustment for new patients and initial Medicare visits. Some commenters recommended additional adjustments, such as: high acuity of patients; visit characteristics; multiple chronic conditions; encounters with more than two HCPCS codes on the claim; unique geographical differences among FQHCs; and dual eligible beneficiaries.

Response: As discussed in the proposed rule, FQHC claims data regarding secondary diagnoses and ancillary services appears to be limited. As a result, there is a risk that the recommended adjustments, such as increased payments for high acuity, multiple chronic conditions, or encounters with multiple HCPCS, could be based on incomplete information. Our analyses of clinical conditions, encounter duration, and types of service, which considered the same or similar types of adjustments, found that these adjustments had limited impact on costs or were too complex for the FQHC PPS. Our analysis of more current data continues to support these conclusions. As discussed in section II.C.2. of this final rule with comment period, we believe it is appropriate to adjust for geographic differences among FQHCs using the GAF.

We tested for an association between dual eligibility and the estimated cost per visit. On average, the estimated cost of a FQHC visit was 4 percent higher among dual eligible beneficiaries. After applying the GAF and the new patient/initial visit adjustment to the model, the estimated cost of a FQHC visit was, on average, 0.4 percent higher among dual eligible beneficiaries. We do not believe that this slight variation in estimated cost justifies the added complexity of an additional payment adjustment for dual eligible beneficiaries.

Comment: A commenter recommended that CMS include an upward adjustment for FQHCs that provide significant ''enabling services.'' The commenter believes that non-clinical services provided to patients to support care delivery, enhance health literacy, or facilitate access to care can reduce health disparities and improve outcomes for FQHC patients.

Response: While FQHCs, including look-alikes, are required by section 330 of the PHS Act to provide services that enable individuals to use the required primary health services that they provide, these services are not part of the Medicare FQHC benefit.

Comment: Some commenters believe that the PPS payment methodology removes incentives to provide fewer, more intensive visits and recommended that CMS increase payments to high-performing FQHCs that furnish efficient, integrated care. Some commenters recommended that CMS encourage expanded access to care, the development of medical homes, and horizontal networks of care by applying upward adjustments to FQHCs that offer value-added services, such as a broader scope of services, expanded hours, or teaching health centers.

Response: While we appreciate the suggestions, neither the cost report nor the claims data contains sufficient information to assess the validity of commenters' claims with respect to these types of adjustments. Moreover, the types of adjustments suggested by these commenters are beyond the scope of the FQHC PPS methodology. However, we are taking steps to foster innovation in how FQHCs deliver services to Medicare beneficiaries. For example, the FQHC Advanced Primary Care Practice (APCP) Demonstration, operated by CMS in partnership with HRSA, is designed to evaluate the effect of the advanced primary care practice model in improving care, promoting health, and reducing the cost of care provided to Medicare beneficiaries served by FQHCs. This demonstration is being conducted in accordance with the Secretary's demonstration authority under section 1115A, which facilitates the development and expansion of successful payment models. For more information on the FQHC APCP, see *http://www.fqhcmedicalhome.com/*.

Comment: A commenter noted that CMS did not include data from provider-based FQHCs in its costs calculations, asserted that provider-based FQHCs experience higher costs than freestanding FQHCs, and urged CMS to add an adjustment to ensure payments to provider-based FQHCs recognize their differential costs.

Response: As discussed in section II.A.2. of this final rule with comment period, in developing the rates for this final rule with comment period, we included data from provider-based FQHCs in calculating the PPS rate. Under the FQHC PPS, Medicare payment for FQHC services is not based on an individual FQHC's costs. The cost report and claims data do not support an adjustment for provider-based FQHCs. While the average cost per visit is somewhat higher for provider-based FQHCs than for freestanding FQHCs, none of the provider-based FQHCs were identified as outliers based on the average cost per visit from the cost reports, and only 0.4 percent of the encounters in the claims were identified as outliers based on estimated costs.

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 was made available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html*.

D. Base Rate Calculation

We calculated a proposed base rate for the FQHC PPS by adjusting the average cost per visit to account for the proposed adjustment factors. We calculated a proposed average payment multiplier using the average FQHC 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 FQHC 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):

Proposed average payment multiplier = 0.9721(1.00)(0.9944) + 0.0279(1.3333)(0.9944) = 1.0036

We calculated a proposed 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:

Proposed base rate per daily visit = $150.96 × (1/1.0036) = $150.42

The proposed base rate per daily visit of $150.42 reflected costs through June 30, 2012, and did not include an adjustment for price inflation. As the FQHC PPS is to be implemented beginning October 1, 2014, we proposed to update the base rate to account for the price inflation through September 30, 2014, as measured by 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 proposed 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 proposed 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. We also proposed 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—PROPOSED 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

Proposed MEI-adjusted base payment rate = $150.96 × (1/1.0036) × 1.0364 = $155.90

Thus, we proposed a base payment rate of $155.90 per beneficiary per visit for the proposed FQHC PPS. We noted that this base rate is subject to change in the final rule based on more current data.

Proposed payments to FQHCs were calculated as follows:

Proposed base payment rate × FQHC GAF = Proposed PPS payment

In calculating the proposed payment, the proposed base payment rate was $155.90, and the FQHC GAF was based on the locality of the delivery site.

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

Proposed base payment rate × FQHC GAF × 1.3333 = Proposed PPS payment

In calculating the proposed payment, 1.3333 represented 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.

To calculate the FQHC base rate for this final rule with comment period, we used updated data, the finalized adjustment factors, the finalized definition of a daily visit (as discussed in sections II.A.4. and II.B.1. of this final rule with comment period), and the finalized adjustment for a new patient, IPPE, initial AWV, and subsequent AWV (as discussed in section II.C.3. of this final rule with comment period). We calculated a final base rate for the FQHC PPS by adjusting the average cost per visit to account for the finalized adjustment factors. We calculated a final average payment multiplier using the average final FQHC GAF (0.9961) multiplied by the average risk adjustment for non-new patient/IPPE/AWV (1.0), as weighted by the percent of encounters that represented non-new patient/IPPE/AWV (0.9683), and we added this to the average final FQHC GAF (0.9961) multiplied by the average risk adjustment for new patient/IPPE/AWV (1.3416), as weighted by the percent of encounters that represented new patient/IPPE/AWV (0.0317):

Final average payment multiplier = 0.9683(1.00)(0.9961) + 0.0317(1.3416)(0.9961) = 1.0069

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

Final base rate per daily visit = $154.88 × (1/1.0069) = $153.82

We did not receive any comments on our use of the MEI to update the FQHC base rate. Our final data set reflects cost reporting periods ending between June 30, 2011, and June 30, 2013. Given that the updated cost data typically has a midpoint that is close to the middle of 2012, we are continuing to use June 30, 2012, as the starting point for inflating prices forward. We are finalizing our proposal to update the FQHC base rate per daily visit for inflation using the growth as measured by the MEI from July 2012 through December 2015. The estimated base rate of $153.82 per diem is inflated through FY 2014 using the historical MEI market basket increase of 1.8 percent. For the 15-month period October 1, 2014 through December 31, 2015, we apply an update of 1.3 percent as measured by the 4th quarter 2013 forecast of the MEI, the most recent forecast available at the time. The adjusted base payment that reflects the MEI historical updates and forecasted updates to the MEI is $158.85. This payment rate incorporates a combined MEI update factor of 1.0327 that trends dollars forward from July 1, 2012 through December 31, 2015.

TABLE 2—FINAL 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
$846,058,100	5,462,670	1.0069	$154.88	$153.82	1.0327	$158.85

Final MEI-adjusted base payment rate = $154.88 × (1/1.0069) × 1.0327 = $158.85

Thus, we are finalizing a base payment rate of $158.85 per beneficiary per day for the FQHC PPS, based on current data and the finalized policies.

Payments to FQHCs were calculated as follows:

Base payment rate × FQHC GAF = PPS payment

In calculating the payment, the base payment rate was $158.85, and the FQHC GAF was based on the locality of the delivery site.

If the patient is new to the FQHC, or the FQHC is furnishing an IPPE, initial AWV, or subsequent AWV, payment would be calculated as follows:

Base payment rate × FQHC GAF × 1.3416 = PPS payment

In calculating the payment, 1.3416 represents the risk adjustment factor applied to the PPS payment when FQHCs furnish care to new patients or when they furnish an IPPE, initial AWV, or subsequent AWV (see discussion in section II.C.3. of this final rule with comment period).

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 usually do not 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 noted that a change in cost reporting periods that is made primarily to maximize payment would not be acceptable under established cost reporting policy (see § 413.24(f)(3) of the regulations 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 proposed to transition the PPS to a calendar year update for all FQHCs, beginning January 1, 2016, because many of the PFS files we proposed 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 proposed to defer the first MEI statutory adjustment to the PPS rate from October 1, 2015 to December 31, 2016, because the proposed base payment rate incorporates a forecasted percentage increase in the MEI through December 31, 2015.

Comment: Many commenters requested that FQHCs be permitted to transition into the FQHC PPS beginning on October 1, 2014, even if that is not the beginning of their cost reporting period.

Response: As we stated in the proposed rule, a change in cost reporting periods that is made primarily

to maximize payment would not be acceptable under established cost reporting policy. This principle has been applied uniformly to the implementation of all new prospective payment systems in Medicare. The MACs do not have the discretion to transition a FQHC at a time other than their cost reporting period except when a FQHC has a change of ownership resulting in a different cost reporting period, or otherwise has good cause. Good cause is not met if it is determined that the reason is to maximize reimbursement.

Comment: Many commenters requested that we create a FQHC-specific market basket beginning in 2016 for the annual update to the PPS rate. These commenters opined that a FQHC-specific market basket would more accurately reflect the actual costs of FQHC services than using the MEI. A commenter requested that the FQHC market basket take into account changes in the scope of services that FQHC furnish.

Response: We will continue to assess the feasibility of developing a FQHC-specific market basket and will provide notification of our intentions in subsequent rulemaking.

We did not receive any comments on our proposal to transition the PPS to a calendar year update for all FQHCs, beginning January 1, 2016. Therefore, we are finalizing this provision as proposed.

2. Medicare Claims Payment

We noted that 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 shall be 80 percent of the lesser of the provider's actual charge or the PPS rate. In the proposed rule, we stated that we were considering several revisions to the claims processing system. These include revisions to reject claims in which the qualifying visit described a service that is outside of the FQHC benefit, such as inpatient hospital E/M services or group sessions of DSMT/MNT; revisions to 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; and revisions to 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.

Comment: Commenters identified the ''lesser of'' provision in section 1833(a)(1)(Z) of the Act as their most significant concern with the proposed rule. This provision requires that Medicare payment for FQHC services furnished under the PPS to equal ''80 percent of the lesser of the actual charge or the amount determined under'' section 1834(o) of the Act. Many commenters were concerned that paying FQHCs the lesser of the actual charge or the PPS rate will routinely underpay FQHCs and undermine the purpose of the PPS. These commenters believe the PPS would be inappropriately comparing a per diem rate for a typical bundle of services with a charge or sum of charges for individual services. Some FQHCs also claim that they keep their charges low across all payers because they serve an underserved population, which will cap their Medicare FQHC payments at these low charge rates. Commenters recommended that if the ''lesser of'' provision must be implemented, it would be more appropriate for Medicare to compare the PPS rate to the FQHC's average charge per visit from the prior year, trended forward by the MEI or a FQHC-specific inflationary factor.

Response: We appreciate the information and perspectives provided by the commenters and will address each of these points individually.

Comment: Commenters opined that CMS lack the statutory authority to implement the ''lesser of'' provision because section 1833(a)(1) of the Act generally excludes FQHC services, and that even if we determine that CMS has the authority to apply the ''lesser of'' provision, the statutory deficiencies would allow CMS to be flexible in implementing this provision.

Response: We respectfully disagree with commenters that the statutory basis of the ''lesser of'' provision is not clear. We find the language in section 1833(a)(1)(Z) of the Act, which states ''with respect to Federally qualified health center services for which payment is made under section 1834(o) of the Act, the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section'' to be clear, and we believe that placement of this provision in section 1833(a)(1) of the Act does not undermine its authority.

Comment: Commenters noted that due to the ''lesser of'' provision, initial payments under the PPS would be less than 100 percent of the estimated amount of reasonable costs, and this does not meet the budget neutrality requirement in the Affordable Care Act.

Response: We respectfully disagree with commenters that we should have factored the ''lesser of'' provision into our budget neutrality calculations. Section 1834(o)(2)(B)(i) of the Act requires us to calculate a PPS rate that, when multiplied by our estimates of services, will yield 100 percent of estimated reasonable costs. Although we must apply the ''lesser of'' provision in section 1833(a)(1)(Z) of the Act when paying FQHCs under the PPS, section 1834(o)(2)(B)(i) of the Act specifies that the estimated aggregate amount of prospective payment rates is to be determined prior to the application of section 1833(a)(1)(Z) of the Act.

Comment: Commenters asserted that CMS did not provide sufficient information about the ''lesser of'' provision in the proposed rule, such as defining the term ''charge'' or providing an analysis of the effect of the ''lesser of'' provision on FQHC payments under the PPS. Commenters urged CMS to clarify implementation details in the final rule and to give the public another opportunity to comment after publishing this information. Commenters requested that CMS grant a 2- to 3-year moratorium on the ''lesser of'' provision, while beginning to pay the PPS rates as of October 1, 2014.

Response: We believe the statutory language in section 1833(a)(1)(Z) of the Act requiring a comparison with the provider's ''actual charge'' is straightforward. Moreover, the regulatory principles of reasonable cost reimbursement in § 413.53(b) already defines ''charges'' as ''the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services.'' We did not include all the implementation details in the proposed rule because claims processing instructions are not typically subject to regulatory notice and comment.

The proposed rule modeled the impact of the PPS using the estimated PPS rate, and did not model the overall impact of the ''lesser of'' provision because FQHCs control their own pricing structures, and we have limited information to accurately project actual FQHC charges. Therefore, we believe it would have been inappropriate to publish an analysis demonstrating the impact of the ''lesser of'' provision.

Comment: Some commenters claimed that FQHCs keep their charges low across all payers because they serve an underserved population. A few commenters asserted that the costs of

integrated care furnished to beneficiaries are not adequately reflected in the HCPCS codes and charges billed to Medicare. Commenters were concerned that, in order to receive the higher payments under the PPS, FQHCs would be forced to raise their charges, which would increase the coinsurance liability for patients who do not qualify for a sliding fee schedule discount.

Response: Most FQHCs are subject to the requirements in the section 330(k)(3)(G) of the PHS Act, which states that FQHCs prepare ''a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay.''

FQHCs can adjust their charges within the broad parameters established by the PHS Act and HRSA guidance, and the application of a sliding fee scale can subsidize an eligible patient's out-of-pocket liability. The commenter is correct that coinsurance liability generally increases when charges increase, and that this is a consideration for FQHCs when setting charges. We also note that, under certain circumstances, FQHCs may waive coinsurance amounts for Medicare and Medicaid beneficiaries (see for example, section 1128B(b)(3)(D) of the Act and § 1001.952(k)(2) of the regulations). Also, most FQHCs are subject to the statutory and regulatory requirements of the Health Center Program (section 330 of the PHS Act; 42 CFR Part 51c; and 42 CFR 56.201 through 56.604), which, among other requirements, mandates that they may collect no more than a ''nominal fee'' from individuals whose annual income is at or below 100 percent of the Federal Poverty Level.

Comment: A few commenters recommended that we apply the ''lesser of'' provision at the aggregate level through an annual reconciliation on the Medicare cost report of aggregate payments with aggregate charges. These commenters noted that this aggregate approach averages out lower charges for low intensity services with higher charges for high intensity services. Some commenters suggested that we conduct an annual reconciliation on the Medicare cost report to determine whether aggregate PPS payments exceeded or fell short of aggregate allowable costs, using costs as a proxy for actual charges.

Response: We believe that the statutory language in section 1833(a)(1)(Z) of the Act requiring a comparison with the provider's ''actual charge'' is straightforward, and a comparison of aggregate payments with aggregate charges would be inconsistent with the plain reading of the statutory language that implies a claims level comparison. We also were not persuaded that costs are a reasonable proxy for charges. We note that in general, a Medicare PPS is a method of paying providers based on a predetermined, fixed amount that is not subject to annual reconciliation. Payments under a Medicare PPS for other provider types are not subject to annual reconciliation with a provider's charge, and an annual reconciliation of costs for providers paid under a Medicare PPS is generally limited to amounts paid outside the applicable PPS.

Comment: Many commenters believe that the proposed PPS would inappropriately compare a per diem rate for a typical bundle of services with a charge or sum of charges for individual services furnished on the same day, which commenters described as an ''apples to oranges'' comparison. Commenters asserted that comparing the bundled rate to the sum of individual charges would routinely yield underpayment and make it difficult for FQHCs to meet their obligation under section 330 of the PHS Act that requires health centers to collect adequate payment from government programs, including Medicare. Commenters recommended that if the ''lesser of'' provision must be implemented, it would be more appropriate for CMS to implement the ''lesser of'' provision in a way that ensures parity between the rate(s) and charges to which they are compared. Commenters suggested that CMS compare the PPS rate to the FQHC's average charge per visit, as determined on an annual basis and trended forward by an applicable inflation factor (for example, the MEI or a FQHC-specific inflationary index).

A commenter suggested that FQHCs should be allowed to bill all-inclusive rate charges under the FQHC PPS. This commenter noted that the proposed PPS rate is based on cost report data that are not adequately reflected in the HCPCS codes and charges billed to Medicare, and the commenter believes it would be appropriate for FQHCs to bill an all-inclusive rate. The commenter suggested that it would be appropriate for FQHCs to set the charge for a Medicare visit at the higher of its Medicare or Medicaid PPS rate to avoid a reimbursement loss from application of the ''lesser of'' provision. This commenter also suggested that ancillary services should be billed and paid by Medicare over and above the all-inclusive PPS rates.

Response: Most Medicare payment systems that have a ''lesser of'' provision in section 1833(a)(1) of the Act are paid on a fee basis for each item or service. While unbundling the PPS rate to pay separately for individual services would address the ''apples-to-oranges'' concern, we note that most of the commenters recommending that we compare the PPS rate with the FQHC's average charge also supported our proposal to offer a single, bundled, encounter-based rate for payment with some adjustments, as discussed earlier. We believe that the proposed FQHC PPS encounter-based rate, which would be similar across all encounters, is a significantly different payment structure than other payment systems subject to a ''lesser of'' comparison with actual charges. We acknowledge that a comparison of a service-specific charge to an encounter-based payment does not apply the ''apples-to-apples'' comparisons of similar ''lesser of'' provisions included in section 1833(a)(1) of the Act.

We considered modifying our proposal and adopting the recommendation of many commenters to pay FQHCs based on the lesser of the FQHC's average Medicare charge per diem or the PPS rate. We agree that such an approach would be responsive to commenters seeking parity in the comparison between the bundled PPS rate and the charges. However, we believe that the statutory language in section 1833(a)(1)(Z) of the Act requiring a comparison with the provider's ''actual charge'' is straightforward, and a comparison with the FQHC's average charge from a prior period would be inconsistent with the plain reading of the statutory language.

We believe we can be responsive to commenters seeking parity in the comparison between the bundled PPS rate and the charges, while allowing direct interpretation of the statutory requirements of section 1833(a)(1)(Z) of the Act, by establishing a new set of HCPCS G-codes for FQHCs to report an established Medicare patient visit, a new or initial patient visit and an IPPE or AWV. As authorized by section 1834(o)(2)(C) of the Act, we shall establish and implement by program instruction the payment codes to be used under the FQHC PPS. We would define these G-codes in program instruction to describe a FQHC visit in accordance with the regulatory definitions of a Medicare FQHC visit. Each FQHC would establish a charge to

the beneficiary with which to bill Medicare for the encounters. Consistent with longstanding policy, the use of these payment codes does not dictate to providers how to set their charges. A FQHC would set the charge for a specific payment code pursuant to its own determination of what would be appropriate for the services normally provided and the population served at that FQHC, based on the description of services associated with the G-code. The charge for a specific payment code would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary. We would continue to require detailed HCPCS coding with the associated line item charges for data gathering (for example, providing information about the ancillary services furnished), to support the application of adjustments for new patients, IPPE, and AWV, and to facilitate the waiving of coinsurance for preventive services.

FQHCs will be required to use these payment codes when billing Medicare under the PPS. Medicare would pay FQHCs based on 80 percent of the lesser of the actual charge reported for the specific payment code or the PPS rate on each claim (and beneficiary coinsurance would be 20 percent of the lesser of the actual charge for the G-code or the PPS rate), which allows for direct interpretation of the statute by comparing the PPS rate to the FQHC's actual charge for a Medicare visit. In order to ease administrative burden and in compliance with § 413.53, the FQHC may choose to use these specific payment codes for its entire patient base. We acknowledge that other payors may have requirements that would preclude FQHCs from using these payment codes, and we suggest that FQHCs be mindful of the differences in required billing methodologies and coding conventions when submitting claims to other payors.

Although we did not propose to establish HCPCS G-codes for FQHCs to report and bill for Medicare visits, we believe that comparing the PPS per diem rate to a FQHC's charge for a per diem visit (as defined by the specific payment codes) would be responsive to commenters seeking parity in the comparison between the bundled rate and the charges, and would also be responsive to commenters concerns regarding meeting the requirements of section 330(k)(3)(F) of the PHS Act, which requires section 330 grantees to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services from government programs, including Medicare. Establishment of these G-codes would also be responsive to the commenter that suggested that FQHCs should be allowed to bill all-inclusive rate charges under the FQHC PPS. Since the G-codes would describe FQHC visits as a per diem, encounter-based visit in accordance with Medicare regulations, we also note that the charges established for these Medicare visits might not directly affect the charges for non-Medicare patients.

In setting its charges for these Medicare FQHC visits, a FQHC would have to comply with established cost reporting rules in § 413.53 which specify that charges must reflect the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. We anticipate that each FQHC would establish charges for the Medicare FQHC visits that would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that the FQHC would furnish per diem to a Medicare beneficiary. We note that establishing Medicare per diem rates that are substantially in excess of the usual rates charged to other paying patients for a similar bundle of services could be subject to section 1128(b)(6) of the Act, as codified in § 1001.701.

We disagree with the commenter's suggestion that ancillary services should be billed and paid by Medicare over and above the all-inclusive PPS rate because the costs of these ancillary services were included in the reasonable costs used to calculate the PPS rates.

After consideration of the public comments received, we are finalizing our proposal and the revised regulations at § 405.2462 to pay FQHCs based on the lesser of the PPS rate or the actual charge. In response to the public comments, we will also establish HCPCS G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS. Appropriate billing procedures for the G codes will be made through program instruction. As we did not propose the establishment of G-codes in the proposed rule, nor did we receive public comments specifically requesting such codes, we invite comments on the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS.

3. Beneficiary Coinsurance

Section 1833(a)(1)(Z) of the Act requires that FQHCs be paid ''80 percent of the lesser of the actual charge or the amount determined under such section''. 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 Medicare claims data for dates of service between January 1, 2011 through June 30, 2013 indicated that beneficiary coinsurance based on 20 percent of the FQHCs' charges was approximately $29 million higher, or 20 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. Accordingly, we proposed 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 sections 1866(a)(2)(A) and 1833(a)(3)(A) of the Act and elsewhere that addresses coinsurance amounts and Medicare cost principles. If finalized as proposed, total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the FQHC's charge or the PPS rate (whichever was less).

Comment: Several commenters recommended that if CMS makes changes to the coinsurance provisions in the payment regulation at § 405.2462(d) in response to comments on the ''lesser of'' provision, CMS should make corresponding revisions to the coinsurance regulation at § 405.2410.

Response: The coinsurance provisions in § 405.2462(d) and § 405.2410 have been updated in this final rule with comment period.

Comment: Commenters noted that calculating the amount of coinsurance to be charged a patient is a significant administrative responsibility for FQHCs. Commenters were concerned that a comparison of the PPS rate with charges at the point of service would be administratively complex and unnecessarily burdensome for FQHCs, and FQHCs would have difficulty calculating the beneficiary's coinsurance liability at point of service.

Response: We respectfully disagree that FQHCs would have difficulty calculating a beneficiary's coinsurance liability at point of service. A FQHC will set its own charge, and we believe the charge amount is likely to be available at point of service. We also believe that

FQHCs will be able to estimate the PPS rate at time of service. We proposed to apply a FQHC GAF based on where the services are furnished, and we proposed to adjust the encounter rate when FQHCs furnish care to new patients or when they furnish a comprehensive initial Medicare visit. We are finalizing our proposal to apply a FQHC GAF, and we are modifying our proposal and will adjust the encounter rate when FQHCs furnish new patient visits, IPPEs, or AWVs. Therefore, each delivery site would have two geographically adjusted PPS rates for each period: One rate for a visit furnished to a patient who is not new to the FQHC and is not receiving an IPPE or AWV, and one rate for a new patient visit, IPPE or AWV that is eligible for an adjustment. At the point of service, a FQHC could determine whether its own charge or its estimate of the applicable PPS rate (which would be one of two discrete values) is lower, and the FQHC could estimate beneficiary coinsurance at point of service based on 20 percent of the lesser amount. We note that the remittance advice issued by the MAC will continue to include the coinsurance amount and will reflect the amount of coinsurance recognized by Medicare.

Comment: A few commenters wanted coinsurance to be based on charges, even when the charges are higher than the PPS rate. Some also questioned our legal authority to assess coinsurance at 20 percent of the lesser of the charge or the PPS rate.

Response: Under the current reasonable cost payment system, beneficiary coinsurance for FQHC services is assessed based on the FQHC's charge, and we acknowledge that the statute makes no specific provision to revise the coinsurance to be 20 percent of the lesser of the FQHC's charge or the PPS rate, although it does state clearly that CMS is limited to paying 80 percent of the FQHC's charge or the PPS rate, whichever is less. We continue to 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 sections 1866(a)(2)(A) and 1833(a)(3)(A) of the Act and elsewhere that addresses coinsurance amounts and Medicare cost principles. These sections were not repealed by the Affordable Care Act and continue to provide legal authority for FQHCs to seek coinsurance payments from Medicare beneficiaries.

After consideration of the public comments received, we are finalizing these provisions as proposed and revising the regulations at § 405.2462(d) and § 405.2410(b)(2) that beneficiary coinsurance for payments under the FQHC PPS would generally be 20 percent of the lesser of the FQHC's charge or the PPS rate. We note that the proposed revision to § 405.2410(b)(1)(ii)(A) regarding the deductible and coinsurance amount for RHCs is not being finalized as proposed as it inadvertently changed the intent of the regulation and will therefore remain as stated in the current regulation.

4. Waiving Coinsurance for Preventive Services

As provided by section 4104 of the Affordable Care Act, 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 proposed 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, as a proxy, 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 proposed 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 Part B drugs that are physician-administered and routine venipuncture will be paid under the FQHC PPS rate, we noted 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 proposed that 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 furnished 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 proposed that 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, and that total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the lesser of 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. We acknowledged that this calculation is fairly complex for the claims processing systems and may also be difficult for providers to replicate, and that 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, excluding these types of claims from calculation of the FQHC base encounter rate, and 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, because the cost of these services is generally lower that other services,

payment for preventive services under the PFS will be less, in many cases, than the FQHC 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 date of service.

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 discussed whether using the proportionality of PFS payments to determine the coinsurance waiver would facilitate the waiving of coinsurance for preventive services while preserving the all-inclusive nature of the encounter-based rate with the least billing complexity. Therefore, we proposed 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, and we invited public comment on how this proposal would impact a FQHC's' administrative procedures and billing practices.

Comment: Commenters noted that we did not specify that Medicare will pay for the coinsurance waiver, and some were concerned that our proposals to waive coinsurance for preventive services would require FQHCs to forego 20 percent of the total payment amount. Commenters requested that we clarify that Medicare will pay 100 percent for preventive services, with payment for a visit with a preventive and non-preventive component equal to the total payment less the coinsurance assessed. Commenters also urged us to specify the rules for waiving coinsurance in the regulations text.

Response: Under § 410.152, Medicare Part B pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the service setting. In the CY 2011 Medicare PFS final rule (75 FR 73417 through 73419, November 29, 2010) we included a detailed discussion regarding preventive services covered under the FQHC benefit, and we clarified that we would apply the coinsurance waiver in the FQHC setting. We implemented the billing requirements for waiving coinsurance in the FQHC setting through program instruction (CMS Pub. 100–04, Medicare Claims Processing Manual, Chapter 9, Section 120).

Our discussion and proposals in the FQHC PPS proposed rule were not intended to change the general requirements with respect to waiving coinsurance for preventive services in the FQHC setting. Medicare will continue to pay 100 percent for preventive services furnished in the FQHC setting as part of a FQHC visit. Rather, we proposed revisions to the methodology used to waive coinsurance for preventive services to ensure that our operational approach would be compatible with payments under an all-inclusive FQHC PPS encounter-based system.

We agree that it would be appropriate to codify the general rules for waiving coinsurance in the regulations text, and we will modify the proposed regulatory text at § 405.2410 and § 405.2462 to reflect existing requirements that apply the coinsurance waiver in the FQHC setting, subject to the billing requirements of the applicable payment methodology. However, we believe that the details of implementation would be more appropriate to include in program instruction, and we plan to implement the procedures for waiving coinsurance for preventive services furnished by FQHCs as an update to the billing requirements for preventive services.

Comment: Commenters requested that we add information to the Medicare Claims Processing Manual clarifying the list of services to which the coinsurance waiver requirement applies.

Response: A table of services subject to the coinsurance waiver is available in CMS Pub. 100–04, Medicare Claims Processing Manual, Chapter 18, Section 1.2.

Comment: Commenters were concerned that it would be too complex and burdensome for FQHCs to calculate the coinsurance at point of service using the proposed methodology for claims with a mix of preventive and non-preventive services that would be paid using the PPS rate. Most commenters requested that CMS rethink this calculation to simplify how coinsurance would be assessed for these types of claims. Commenters recommended that CMS completely waive coinsurance and pay 100 percent of the PPS rate for any FQHC encounter that includes a preventive service, whether the preventive service represented the face-to-face portion of the visit or an ancillary service. Commenters asserted that this would be easier to administer and more consistent with the Congress's intent to eliminate barriers to the provision of preventive services.

Response: While a complete coinsurance waiver for these types of claims would be a simple approach, we do not believe that we have the authority to waive coinsurance completely whenever a preventive service is furnished during a FQHC encounter without regard to the value of the preventive service relative to all other services furnished during the same encounter.

We agree that the proposed approach is complex and might be difficult for providers to replicate. Our own analysis subsequent to publication of the proposed rule led us to conclude that the benefits of the proposed methodology would be outweighed by the complexity of the systems changes and ongoing systems interactions that would be needed to implement the methodology as proposed.

We reconsidered the other methodologies for waiving coinsurance presented in the proposed rule. However, we believe that these options would also be difficult for providers to replicate at point of service.

We proposed that 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. We believed that the current approach to waiving coinsurance for preventive services, which relies solely on FQHC reported charges, would be insufficient under the FQHC PPS for payments based on the FQHC PPS rate.

In response to commenters that requested that CMS rethink this calculation to simplify how coinsurance would be assessed for these types of claims, we reconsidered whether the current approach to waiving coinsurance for preventive services when payments are based on the FQHC's charge could be adapted to payments based on the FQHC PPS rate. After reconsideration of how coinsurance could be assessed, we now believe that the current approach is

feasible and relatively simple to apply to payments based on the FQHC PPS rate, with certain modifications.

If we were to apply the current approach of waiving coinsurance for preventive services under the new FQHC PPS, we would subtract the dollar value of the FQHC's reported line-item charge for the preventive service from the full payment amount, whether payment is based on the FQHC's charge or the PPS rate. Medicare would pay the FQHC 100 percent of the dollar value of the FQHC's reported line-item charge for the preventive service, up to the total payment amount. Medicare also would pay a FQHC 80 percent of the remainder of the full payment amount, and we would assess beneficiary coinsurance at 20 percent of the remainder of the full payment amount. If the reported line-item charge for the preventive service equals or exceeds the full payment amount, we would pay 100 percent of the full payment amount and the beneficiary would not be responsible for any coinsurance.

We believe that the relative simplicity of this revised methodology is responsive to commenters that requested a simpler calculation that would be easier to replicate at point of service, and a coinsurance waiver based on the reported line item charges will be more transparent to beneficiaries. We also believe that the similarity to the current approach for waiving coinsurance for preventive services will be simpler for Medicare claims processing systems to implement.

After consideration of the public comments received, we will not finalize the process for calculating the coinsurance as proposed, and instead will modify the proposed regulatory text at § 405.2410 and § 405.2462 based on the comments received. Specifically, we will use the current approach to waiving coinsurance for preventive services, whether total payment is based on the FQHC's charge or the PPS rate, by subtracting the dollar value of the FQHC's reported line-item charge for the preventive services from the full payment amount. We will issue further guidance on the billing procedures through program instruction. We invite comments on this approach to waiving coinsurance for preventive services based on the dollar value of the FQHC's reported line-item charge for preventive services.

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 Part 405, Subpart X.

Currently, 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 the lesser of a predetermined national rate or the FQHC charge. For services included in the FQHC per diem payment, 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 noted that we are 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, and 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 noted that we are also exploring whether we have audit resources to include FQHCs in the pool of institutional providers that are subject to periodic cost report audits.

Comment: A commenter requested that CMS consider suspending the required submission of annual cost reports once all FQHCs have transitioned to the FQHC PPS.

Response: The statute does not exempt FQHCs from submitting cost reports. In addition, we continue to need cost reports for payments to FQHCs that are outside of the PPS, to update our cost estimates, and to facilitate the potential development of a FQHC market basket.

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 (see § 422.316). 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 proposed to revise § 405.2469 to reflect this provision.

Comment: A few commenters requested clarification that wrap-around payments will be established based on the PPS rate, as modified by any applicable adjusters, and not based on the FQHC's charge, if such charge is less than the PPS rate.

Response: FQHCs that have a written contract with a MA organization are paid by the MA organization at the rate that is specified in their contract, and the rate must reflect rates for similar services furnished outside of a FQHC setting. If the contracted rate is less than the Medicare PPS rate, Medicare will pay the FQHC the difference, referred to as a wrap-around payment, less any cost sharing amounts owed by the beneficiary. The PPS rate is subject to the FQHC GAF, and may also be adjusted for a new patient visit or if a IPPE or AWV is furnished. The supplemental payment is only paid if the contracted rate is less than the adjusted PPS rate.

Comment: Commenters requested that CMS issue guidance discouraging MA plans from applying any deductible under the MA plan to FQHC services.

Response: MA plans are not subject to section 1833(b)(4) of the Act and therefore are not required to waive application of the Medicare deductible to beneficiaries in FQHCs. Guidance on this topic is beyond the scope of this final rule with comment period.

After consideration of the public comments received, we are finalizing this provision as proposed.

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 using physicians who are either RHC employees or contractors. However, in order to promote stability and continuity of care, the Rural Health Clinic Services Act of 1977 required RHCs to employ a nurse practitioner (NP) or physician assistant (PA) (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 proposed 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-physician practitioners 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 NP or PA employed at all times (subject to the waiver provision for existing RHCs set forth at section 1861(aa)(7) of the Act), a RHC would be free to enter into contracts with other NPs, PAs, CNM, CPs or CSWs.

We received approximately 14 comments from individuals, hospitals, rural health clinics, national associations, and tribal organizations on this proposal. Commenters agreed that this would provide RHCs with additional flexibility and improve access to care. Some commenters also noted that this would reduce certain costs.

Comment: A commenter requested that CMS allow all PAs and NPs who work at a RHC to do so as contractors to allow maximum flexibility in the clinic's staffing operations.

Response: As previously noted, section 1861(aa)(2)(iii) of the Act requires RHCs to employ at least one NP or PA. We do not have the authority to remove this requirement. However, we note that as long as the statutory requirement that at least one NP or PA is employed is met, the RHC can contract with other NPs or PAs.

Comment: A commenter recommended that we interpret the word ''employ'' to mean ''utilize, use, or engage the services of'' so that independent contractors could meet the statutory requirement that at least one NP or PA be employed.

Response: We appreciate the suggestion but since we did not propose to change our interpretation of the word ''employ'', this comment is beyond the scope of this rule. We note however, that as of the effective date of this provision of this final rule with comment period, only one PA or NP will be required to be in a W–2 relationship with the RHC, and that all other RHC practitioners can be either employees or contractors.

After consideration of the public comments received, we are finalizing this provision as proposed.

B. Technical and Conforming Changes

1. Proposed Technical and Conforming Changes

In addition to proposing to codify the statutory requirements for the FQHC PPS and to allow RHCs to contract with non-physician practitioners, we proposed edits to correct terminology, clarify policy, and make conforming changes for existing mandates and the new PPS. Some of the proposed 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 resident of a 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, Section 20.1.1).

We did not receive any comments on these technical proposals and we are finalizing these provisions as proposed.

2. Additional Technical and Conforming Changes

We did not propose the following changes, but based on our review of the rule, we make the following clarifying and editorial changes:

- Updating § 405.501 and § 410.152 to clarify that this provision on the determination of reasonable charges continues to apply to FQHCs that are authorized to bill under the reasonable cost payment system, and does not apply to FQHCs that are authorized to bill under the PPS.
- Updating § 410.152 to clarify that this provision continues to apply to FQHCs that are authorized to bill under the reasonable cost payment system, and does not apply to FQHCs that are authorized to bill under the PPS.
- Updating § 405.2468 (f)(4) to reflect the change in name from ''Medicare + Choice'' organization to ''Medicare Advantage'' organization.
- Updated § 405.2415(a)(2) and (b) to clarify that these provisions apply to FQHCs.
- Updated § 405.2404(b) to make the references to the Secretary gender neutral.

C. Comments Outside of the Scope of the Proposed Rule

Comment: Many commenters requested that all FQHCs be assigned to one MAC instead of each FQHC being assigned to a MAC based on their geographic location. Commenters believe that assigning FQHCs to multiple MACS results in confusion and inconsistency as each MAC can issue different instructions concerning the FQHC benefit and associated billing requirements.

Response: Section 421.404 describes how FQHCs as well as other providers

and suppliers are assigned to a MAC; changes to the MAC assignments are beyond the scope of this rule.

Comment: A few commenters requested that CMS revise the definition of telehealth so that FQHCs could be distant site providers of telehealth services.

Response: Distant site providers of telehealth services are defined in section 1834(m) of the Act. We made no provision relating to telehealth and this topic is beyond the scope of this rule.

Comment: A commenter requested that PAs be allowed to individually enroll as Medicare and Medicaid providers and bill for their services.

Response: Section 1842(b) of the Act prohibits PAs from directly billing Medicare. This topic is beyond the scope of this rule.

Comment: A commenter requested that CMS mandate that states pay FQHCs their full Medicaid encounter rate for any Medicare-Medicaid enrollees.

Response: This is currently a state option and this topic is beyond the scope of this rule.

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

A. Background

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 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 (see 42 CFR part 493) on February 28, 1992 (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 PT program that covers all of the specialties and subspecialties for which the laboratory is certified and all analyses listed in part 493 Subpart I. 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. Rept. 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. Rept. 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 analyses 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 analyses 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 inter-laboratory 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 (§ 493.1840(a)(8) and (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, the Congress enacted the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112–202, (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 February 7, 2013 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 we determine PT samples were intentionally referred to another laboratory.

Subsequently, in the September 23, 2013 (78 FR 58386) proposed rule addressing the FQHC PPS and other topics, we proposed additional changes to the CLIA regulations to implement the TEST Act.

The regulatory changes in this final rule with comment period will add the remaining policies and regulatory changes needed to fully implement the TEST Act.

B. Proposed and Final Regulatory 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.

As discussed later in this section, we are finalizing the regulatory changes proposed in the September 23, 2013 proposed rule, which will divide the sanctions for PT referral into three categories based on severity and extent of the referrals. The first category is for the most 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 alone would be appropriate. Therefore, we proposed to revoke the CLIA certificate for at least 1 year, ban the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and possibly impose a civil monetary penalty (CMP).

In keeping with the February 7, 2013 proposed rule (78 FR 9216), we proposed 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, adhere to regulation and 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 proposed, 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 noted that PT programs place heavy reliance on each laboratory and laboratory director's ability to self-police the laboratory's analysis of PT samples to ensure that the testing is performed in accordance with the CLIA requirements. PT scores must reflect an individual laboratory's performance-reporting results from another laboratory is deceptive to the public. These 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 its 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 PT would be undermined. Further, as stated in the CLIA regulations at § 493.801(a)(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 A 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 up to 2 years. Prior to the TEST Act, revocation of a CLIA certificate for a PT violation always triggered a 2-year ban on the owner and operator. Given the severity of violations involving repeat PT referrals or the reporting of another laboratory's results, we proposed 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 this first category of sanctions.

We also proposed a second category of sanctions under which the CLIA certificate would be suspended or limited (rather than revoked), in combination with the imposition of alternative sanctions. We proposed 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 proposed to suspend or limit the CLIA certificate for less than 1 year rather than revoke the CLIA certificate, and proposed 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 proposed 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. If surveyors determine that, in the previous 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 proposed that when the certificate is suspended or limited, alternative sanctions would be applied in addition to the principal sanctions of suspension or limitation. We proposed 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 proposed to also impose state on-site monitoring of the laboratory.

A third category of sanctions was proposed for 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 proposed that in such scenarios, at a minimum, the laboratory would always be required to pay a CMP as calculated using the criteria set forth in § 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 proposed to impose only alternative sanctions. In determining whether to impose particular alternative sanctions, we proposed 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. Therefore, we expressed our belief that these same criteria will be effective in the imposition of alternative sanctions for PT referral cases.

In summary, we proposed to amend § 493.1840 by revising paragraph (b) to specify three categories for the imposition of sanctions for PT referrals. We believed that 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 proposed to make three conforming changes to the CLIA regulations at the authority citation for § 493 and at § 493.1 and § 493.1800(a)(2) to include references to the PHS Act as amended by the TEST Act.

We received 14 timely public comments on the proposed changes to the CLIA regulations to implement the enforcement discretion for PT referral cases as provided by the TEST Act. The comments came from a variety of sources, including laboratory accreditation organizations, laboratory professional organizations, medical societies, health care systems, and a professional corporation. In general, commenters supported and favored the changes to the regulations governing enforcement actions for PT referral. The majority of commenters agreed that the three categories were reasonable and would allow CMS to respond to PT referrals in a measured approach. However, a few commenters expressed concern that our proposed approach to enforcement was too prescriptive and would not allow for full use of the discretion afforded by the TEST Act. Because of the nature and consequences of the enforcement actions for PT referral, the seriousness of a PT referral violation, and the 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, we developed a prescriptive framework for enforcement actions in order to apply sanctions in a comprehensive, reasonable, and consistent approach. We respond to specific comments as follows:

Comment: A few commenters stated that waived laboratories should be exempt from penalties associated with PT referral since they are not required by law to participate in PT.

Response: While this comment is outside the scope of this rule, we would like to clarify that the CLIA statute (42 U.S.C. 263a) states that laboratories holding a certificate of waiver are only exempt from subsections (f) and (g) of the statute. All other subsections apply, including the prohibition against PT referral and the statutory consequences established in subsection (i), which refers to ''any laboratory'' that the Secretary determines has intentionally referred its PT samples. Therefore, the statutory requirements under subsection (i) do apply to waived laboratories that participate in PT and waived laboratories are not exempt from the ban against the referral of PT samples and the penalties required when PT referral has been substantiated.

Comment: A commenter questioned how CMS will ensure regional offices and state surveyors are consistent in the application of these changes and the associated enforcement.

Response: We will continue using the current process that requires all suspected PT referral cases to be reviewed by the CMS Regional Office and also forwarded to CMS Central Office for additional review by a team of experts. The team will continue to thoroughly review every case to determine whether the facts support a determination of PT referral and, if so, which category of sanctions will be applied. Written survey and enforcement guidance and training will be provided to the regional offices and

state agencies and will be made publicly available.

Comment: Several commenters stated that CMS should develop and adopt a definition for ''intentional'' as it applies to PT referral and add the definition to § 493.2 in the CLIA regulations.

Response: While this comment is outside the scope of this rule, we point the commenter to the Burden Reduction proposed rule (78 FR 9216). From the onset of the CLIA program, we have consistently interpreted the phrase ''intentionally refers'' to mean general intent, as in intention to act. We proposed the first exception to our longstanding interpretation of ''intentionally refers'' in the Burden Reduction proposed rule. Under that proposal, a referral would not be considered ''intentional'' if our investigation reveals PT samples were sent to another laboratory for reflex or confirmatory testing, the referral is not a repeat PT referral, and the referral occurred while acting in full conformance with the laboratory's written, legally accurate, and adequate standard operating procedure.

Comment: Several commenters questioned if a repeat PT referral included multiple analyses on a referred PT sample or multiple PT samples in the same PT event.

Response: As stated in the definition of ''repeat proficiency testing referral,'' to be considered a repeat PT referral, the referral must be a second instance in which a PT sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's PT 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). A single instance of referral for multiple analyses on a single PT sample set, or referral for analyses of multiple samples from the same PT event, would not be considered a ''second instance.'' A second instance of referral would arise when referral is made from an entirely different set of PT samples from an entirely different PT event sent on a date that is different from the date of the earlier PT event.

Comment: A commenter recommended that CMS not revoke a certificate for a repeat PT referral unless CMS could determine that the repeat referral occurred in similar or the same circumstances to the initial referral.

Response: As stated previously, except in the most egregious instances of PT referral 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, the laboratory's CLIA certificate will not be revoked for a single instance of PT referral. Such an instance of PT referral will result in alternative sanctions. This provides the laboratory an opportunity to review all policies and procedures and an opportunity to thoroughly train all staff to mitigate all chances of a second instance of PT referral. The timeframe included in the definition of a repeat referral has been defined as the two survey cycles prior to the time of the PT referral in question. Two survey cycles generally equates to a 4-year period on average. This is not a precise calendar time period but, with respect to a given laboratory, is carefully recorded as a matter of actual and documented survey event dates. We believe that it is reasonable to expect laboratories to maintain a heightened vigilance for this timeframe to ensure that they do not have any repeated referrals of PT samples. The narrow exception to the determination of an intentional referral described in the Burden Reduction proposed rule will, once finalized, be considered a single instance and will be incorporated in the determination of whether a repeat PT referral has taken place.

Comment: Several commenters questioned whether CMS will finalize the Burden Reduction proposed rule which proposed reforms to the Medicare and CLIA regulations that we identified as unnecessary, obsolete or excessively burdensome and questioned how the September 23, 2013 proposed rule relates to the Burden Reduction proposed rule.

Response: In the Burden Reduction proposed rule, we proposed a narrow exception to our longstanding interpretation of what constitutes an ''intentional'' PT referral. The proposed narrow exception in the Burden Reduction rule would work in concert with the framework described in this final rule for enforcement for PT referral to ensure the severity of the sanctions fits the nature and extent of the PT referral violation.

Comment: Several commenters expressed concern with the first category of sanctions against the laboratory and the owner and operator for the most egregious forms of PT referral. While the commenters agreed that the most egregious forms of PT referral warrant the most serious sanctions and that the laboratory director should also be sanctioned, there was concern about the automatic prohibition against the laboratory owner. Each commenter who raised this issue expressed concern that a mandatory 1 year prohibition for owners, that applies to all laboratories of that owner, is not reasonable for large health systems that often own a large number of laboratories in many locations. The commenters expressed concern that patient care may be impacted if such an owner is prohibited from obtaining or maintaining a CLIA certificate for any laboratory that tests human specimens for health care purposes. The commenters suggested that the one year ban for the owner should be limited to the single laboratory where the PT referral occurred.

Response: It is incumbent upon laboratories to organize in a manner that allows them to mitigate circumstances so that when one or more laboratories are sanctioned, the rest of the laboratory network is not unduly impacted. However, we also recognize that there are benefits to large health systems organizing in ways to promote efficiency of care with the least cost to their patients. We agree that there should be some discretion in the regulation to allow for flexibility in the mandatory 1-year ban against owners of laboratories that, if barred from ownership, would create access issues in the communities in which they serve. However, when the CLIA certificate is revoked for the most egregious violations, encompassing cases of repeat PT referral or cases where a laboratory reports another laboratory's test results as its own, we believe that the owner and operator should be banned from owning or operating a laboratory for at least 1 year, so we will retain that sanction. However, in response to comments, we are adding a provision to limit the reach of the owner ban for certain laboratories under the same ownership as the revoked laboratory if we find, after review of relevant facts and circumstances, that patients would not be at risk if the laboratory were exempted from the ban, and that there is no evidence that a laboratory to be exempted from the ban participated or was complicit in the PT referral, except that any laboratory of the owner that received a PT sample from another laboratory, and failed to timely report such receipt to CMS or to a CMS-approved accrediting organization, may not be exempted from the owner ban. In assessing whether patients would be potentially at risk if the laboratory were exempted from the ban, we will consider factors including, but not limited to, the following: The extent to which staff of the laboratory or

laboratories that may be exempted from the owner ban have been adequately trained, and will promptly have such training reinforced, regarding PT; the history of compliance with the CLIA regulations; evidence of any systemic quality issues for the laboratory or laboratories that seek to be exempted from the owner ban; and the potential for access to care problems for patients if the laboratory or laboratories are not granted an exemption from the owner ban. We are revising our regulations at § 493.1840(b)(1) to incorporate this exception.

Comment: Several commenters requested further clarification of when CMS will limit the suspension or limitation to the individual laboratory where the PT referral occurred rather than suspending or limiting the CLIA certificate of all of the laboratories under the control of the owner or operator. The commenters recommended that we use a centralized process to determine whether suspension or limitation is appropriate in each case rather than leaving the decision up to an individual surveyor.

Response: As stated in the September 23, 2013 proposed rule, the CLIA certificate will be suspended or limited (rather than revoked), in combination with alternative sanctions, 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. 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. Suspension or limitation will always apply to the laboratory that sent the PT sample to another 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. We may also suspend or limit the CLIA certificate of other laboratories operating under the same owner depending upon the facts and circumstances of the individual case. For example, if such a laboratory received PT samples from another laboratory and did not report the receipt of those PT samples to us, suspension or limitation will also be considered for that laboratory. As stated previously, it is incumbent upon laboratories to organize in a manner to mitigate circumstances so that enforcement against a CLIA certificate does not unduly impact other laboratories operating under the same CLIA number. An exhaustive list of scenarios cannot be provided since each case of PT referral is unique and there is no way to predict every possible scenario. In determining whether to suspend or limit the CLIA certificate, we will examine the extent of the PT referral practice as well as its duration and apply the criteria of § 493.1804(d). We will develop further written surveyor guidance for the imposition of the suspension and limitation in PT referral cases. This guidance will be publicly available.

Comment: Several commenters expressed concern that a CMP will always be applied to laboratories in 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. Some stated that no sanctions should be applied in these cases because they are minor infractions and this category has no flexibility where it is most needed.

Response: While PT referrals may differ in severity and scope, we consider a PT referral infraction one of the most serious violations of the CLIA statute and regulations. PT is a major component of the CLIA regulations and plays an integral role in the overall quality assurance of a laboratory. We emphasize that there is no on-site, external proctor for PT in laboratories, and 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. Because of these factors, we have determined that a CMP is always appropriate in those cases where PT referral has been substantiated. However, there is no ''one size fits all'' CMP for these cases and there is flexibility in the determination of the amount of the CMP. The severity and scope of each case will be evaluated closely to determine appropriate CMP amounts in accordance with the regulation at§ 493.1834, which specifies the procedures that CMS follows to impose a CMP and the range of the penalty amount.

We also note that we received other comments that were outside the scope of the September 23, 2013 proposed rule; and therefore, are not addressed in this final rule with comment period.

After consideration of the comments received, we are finalizing the proposed definitions for ''repeat proficiency testing referral'' at § 493.2 and the changes to § 493.1840, and the three proposed conforming changes at the authority citation for Part 493 and at § 493.1 and § 493.1800(a)(2) to include references to the TEST Act. In response to comments, we are also finalizing the addition of a new provision at § 493.1840(b)(1)(ii) to allow us to except certain laboratories from the owner ban, on a laboratory by laboratory basis, if certain circumstances are met.

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 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 the Addendum of this final rule with comment period. 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 us 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 30-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 solicited public comment on the information collection requirements (ICRs) regarding the proposed FQHC rates and adjustments in § 405.2470.

The data that are used in computing the FQHS PPS rates and adjustments 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 noted that while we were not proposing any new ICRs, there is currently an OMB approved information collection request associated with the RHC/FQHC cost report which has an OMB control number of 0938–0107 and an expiration date of August 31, 2014.

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In section III.B.2. of this final rule with comment period, we present additional technical and conforming changes. These changes include specifying that the determination of reasonable charges continues to apply to FQHCs under the reasonable cost payment system and changing the term ''Medicare +Choice'' to ''Medicare Advantage.'' We believe that these regulatory changes are technical and conforming in nature, do not change our payment policies, and provide clarifications all of which are in the public's interest. We note that these changes do not change our policy and are technical in nature. As such, we believe it unnecessary to provide an opportunity for public comment on these non-controversial ministerial changes.

In section II.E.2. of this final rule with comment period, we are establishing a new set of HCPCS G-codes by which FQHCs are to report their actual charges to beneficiaries. Consistent with longstanding policy, the use of these payment codes does not dictate to FQHCs how to set their charges. We are permitting FQHCs to utilize a G-code that would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary. Because section 1834(o)(2)(A) of the Act requires implementation of the FQHC PPS beginning on October 1, 2014, it is both impracticable and contrary to the public interest to provide an additional period for public comment before this methodology is implemented. Nonetheless, we are soliciting an additional round of comments with respect to the G-codes, and will consider further action if comments received from the public indicate a need to amend or revise this component of implementation.

Therefore, for the reasons stated previously, we find good cause to waive the notice of proposed rulemaking for these technical and conforming changes to our regulations at §§ 405.501, 405.2468(f)(4), and 410.152, and for our implantation structure for reporting charges to Medicare as described in section II.E.2. of the preamble to this final rule with comment period.

VII. 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.

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period 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 final rule with comment period is also 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: (1) 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 final rule with comment period 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 final rule result in an increase of approximately 32 percent in the Medicare payment to FQHCs, without taking into account the application of the ''lesser of'' provision discussed earlier, 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. 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 have not prepared an analysis for section 1102(b) of the Act because we have determined that this final rule with comment period 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 2014, that is approximately $141 million. This 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 final rule with comment period would not have a substantial effect on state and local governments, preempt state law, or otherwise have Federalism implications.

This final rule with comment period 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 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 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 IPPE and AWVs 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 3 (Impact of the PPS on Payments to FQHCs). In addition, because we have limited information to accurately project actual FQHC charges, Table 3 does not take into account the application of ''lesser of'' provision in section 1833(a)(1)(Z) of the Act. (For more information, see sections II.E.2 and VII.D.1 of this final rule with comment period).

D. Anticipated Effects of the FQHC PPS

1. Effects on FQHCs

As required by section 1834(o)(2)(B)(i) of the Act, initial payment rates (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. We will pay FQHCs a single encounter-based rate per beneficiary per day, while allowing for an exception to the per diem PPS payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit, 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 IPPE or AWV.

Based on comparisons of the final PPS rate to the AIRs (as listed on the FQHC cost reports), the FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 32 percent. As discussed in section II.E.2. of this final rule with comment period, while Medicare payments under the FQHC PPS shall be 80 percent of the lesser of the actual charge or the PPS rate, this impact analysis is based on payment at the PPS rate does not take into account the application of ''lesser of'' provision in 1833(a)(1)(Z) of the Act. 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.D. of this final rule with comment period for a discussion of the use of the MEI update to calculate the first year's base payment amount under the FQHC PPS.)

If we apply the ''lesser of'' provision in section 1833(a)(1)(Z) of the Act and assume that FQHCs' charge structures would remain the same, approximately 65 percent of FQHCs would be paid less under the FQHC PPS rate than they are currently paid. However, FQHCs are responsible for their own pricing structures, and we have limited information to accurately project actual FQHC charges under the new PPS. Moreover, our analysis of the potential impact of the application of the ''lesser of'' provision in section 1833(a)(1)(Z) of the Act compares the applicable per diem PPS rate with the charge or sum of charges for the individual HCPCS codes listed on the claims in our sample. As discussed in section II.E.2. of this final rule with comment period, we are establishing HCPCS G-codes for FQHCs to report their Medicare FQHC visits. We will pay FQHCs based on the lesser of the actual charge reported for the G-code or the PPS rate on each claim. FQHCs will need to establish charges for these G-codes, and we cannot accurately project the charges that FQHCs will establish for these G-codes. Because we have no means to predict behavioral response on charging by the FQHC community, in the impact table (Table 3), we continue to compare current payments to the PPS rates when discussing the impact of the FQHC PPS, which would be the maximum impact that would be expected after application

of the ''lesser of'' provision in section 1833(a)(1)(Z) of the Act.

Table 3 shows the impact on cost reporting entities and their associated delivery sites of the fully implemented FQHC PPS payment rates compared to current payments to FQHCs. The analysis is based on cost reports from freestanding and provider-based FQHCs with cost reporting periods ending between June 30, 2011, and June 30, 2013. We note that the impact analysis includes cost reporting entities and claims encounters that were excluded from the modeling as statistical outliers based on estimated costs. A FQHC with multiple sites has the option of filing a consolidated cost report, and the sample used to calculate the impacts reflects 1,240 cost reporting entities that represent 3,830 delivery sites.

The following is an explanation of the information represented in Table 3:

- 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 daily visits): This column shows the number of Medicare daily visits in the final data set that were used to model payments under the FQHC PPS. As discussed in section II.A.4. of this final rule with comment period and consistent with the policy discussed in section II.B.1. of this final rule with comment period, separately payable encounters for the same beneficiary at the same FQHC were combined into a single daily visit, while allowing for a separate medical visit, mental health visit, and subsequent illness/injury visit.
- 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 30 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 Adjustments to the Average Cost per Visit): These columns show the estimated fully implemented impacts on Medicare payments to FQHCs due to the policy changes. In developing the Medicare FQHC PPS, section 10501(i)(3)(A) of the Affordable Care Act requires us to take into account the type, intensity, and duration of FQHC services, and allows other adjustments, such as geographic adjustments. As we discussed in section II.A.4. of this final rule with comment period, the cost report data are insufficient for modeling these types of adjustments, so we used the HCPCS codes in the FQHC claims data to support the development of the FQHC PPS rate and adjustments.
- 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, while allowing an exception to the per diem PPS payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit. As it is uncommon for FQHCs to bill more than one visit per day for the same beneficiary, this adjustment would have minimal effect on most FQHCs.
- Column F (Effect of new patient/IPPE/AWV adjustment): This column shows the estimated fully implemented impact on payments to FQHCs of the proposal to adjust the encounter-based rate by 1.3416 when a FQHC furnished care to a patient that was new to the FQHC or to a beneficiary receiving an IPPE or AWV. As new patient visits, IPPEs, and AWVs 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 FQHC GAF): This column shows the estimated fully implemented impact on payments to FQHCs of adjusting 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 adjustments in columns E through G. The combined effects of these adjustments on overall Medicare payment to FQHCs would be 0.1 percent as the effects of these adjustments would be primarily redistributive and would have minimal impact on Medicare payments in the aggregate. While the effect of these various adjustments was budget neutral within the model, the impact analysis includes cost reporting entities and claims encounters that were excluded from the modeling as statistical outliers based on estimated costs.
- 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 3 reflects the impacts on cost reporting entities and their associated delivery sites. This table shows both the impact on payments to FQHCs of the statutorily required changes to the payment structure (Column D) and the redistributive effects of the adjustments to the average cost per visit (Columns E through H). Column I reflects the combined impact on cost reporting entities of the overall PPS rates and adjustments and MEI update. This table does not model application of the provision that Medicare pay FQHCs the lesser of the actual charge or the PPS payment rate; instead, is assumes payment at the full PPS rate. Actual payments to FQHCs will depend on the actual charges they establish under the PPS.

TABLE 3—IMPACT OF THE PPS ON PAYMENTS TO FQHCS

	(A) Number of cost-reporting entities	(B) Number of delivery sites	(C) Number of medicare daily visits	(D) Effect of statutorily required changes (%)	(E) Effect of daily visit (per diem) rate (%)	(F) Effect of new patient/ IPPE/AWV adjustment (%)	(G) Effect of FQHC GAF (%)	(H) Combined effect of all PPS adjustments (%)	(I) Effect of all policy changes and MEI adjustment (%)
All FQHCs	1,240	3,830	5,585,393	29.9	0.0	0.1	0.1	0.1	31.9
Urban/rural Status:									
Urban	712	1,945	2,738,585	24.3	0.0	0.1	3.2	3.3	30.2
Rural	373	900	1,447,261	41.9	0.1	0.0	−3.1	−3.1	39.4
Mixed rural-urban	155	985	1,399,547	30.1	0.0	0.0	−2.7	−2.7	28.3
Medicare Volume:									
Low (<6.9% of total visits)	413	1,102	897,136	24.8	0.0	0.4	3.5	3.9	31.4
Medium (6.9%–13.2% of total visits)	414	1,403	1,857,689	27.4	0.0	0.1	0.6	0.7	30.1
High (>13.2% of total visits)	413	1,325	2,830,568	33.4	0.0	−0.1	−1.3	−1.4	33.3
Total Volume:									
Low (<17,340 total visits)	413	555	450,262	33.6	0.0	0.2	−0.1	0.1	35.6
Medium (17,340–42,711 total visits)	414	983	1,387,779	31.8	0.0	0.2	−1.4	−1.1	32.1
High (>42,711 total visits)	413	2,292	3,747,352	28.8	0.0	0.0	0.6	0.6	31.4
Census Division:									
New England	99	255	709,020	27.4	−0.1	−0.1	2.2	2.1	32.0
Middle Atlantic	111	334	452,168	25.9	−0.1	0.2	3.6	3.7	32.5
East North Central	158	497	651,546	31.3	0.0	0.1	−3.2	−3.2	28.9
West North Central	81	214	266,360	31.6	−0.1	0.1	−5.3	−5.3	26.4
South Atlantic	200	753	1,100,268	32.1	0.1	−0.1	−3.0	−3.0	29.9
East South Central	87	340	379,357	37.3	0.0	0.0	−6.9	−6.9	29.6
West South Central	120	332	388,565	30.5	0.0	0.2	−5.0	−4.8	26.1
Mountain	107	341	392,506	31.3	0.0	0.4	−2.1	−1.6	31.0
Pacific	272	758	1,243,251	27.2	0.1	0.0	7.5	7.6	38.7
U.S. Territories	5	6	2,352	43.9	0.1	1.5	−1.1	0.5	46.5

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 4—ESTIMATED INCREASE IN ANNUAL MEDICARE PAYMENTS TO FQHCS *

Fiscal year	Estimated increase in payments ($ in millions)
2015	170
2016	250
2017	260
2018	280
2019	300

* These impacts do not take into account the application of ''lesser of'' provision in section 1833(a)(1)(Z) of the Act. (For more information, see sections II.E.2 and VII.D.1 of this final rule with comment period).

As discussed in section II.E.2. of this final rule comment period, while Medicare payments under the FQHC PPS shall be 80 percent of the lesser of the actual charge or the PPS rate, this table is based on payment at the PPS rate does not take into account the application of ''lesser of'' provision in 1833(a)(1)(Z) of the Act because we have limited information to accurately project actual FQHC charges. We intend for the estimated aggregate payment rates under the 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 FY 2015 is smaller than for subsequent years because FQHCs will be transitioning into the PPS throughout FY 2015 based on their own cost reporting periods.

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 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 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

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, 2013 indicated that beneficiary coinsurance based on 20 percent of the FQHC's charges was approximately $29 million higher, or 20 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 final PPS rate to the AIRs, the FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 32 percent, prior to taking into account the impact of the ''lesser of'' provision. This overall 32 percent increase translates to a 32 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

Removal of the restrictions on RHCs contracting with nonphysician practitioners when the statutory requirement to employ an NP or a PA is met will provide RHCs with greater flexibility in meeting their staffing requirements. The ability to contract with NPs, PAs, CNMs, CP, and CSWs will 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

There are no costs associated with the clarifying, technical, and conforming changes to the FQHC and RHC regulations.

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

As discussed in section IV. of this final rule with comment period, we have made a number of clarifications and changes pertaining to the regulations governing adverse actions for PT referral under CLIA, which, in combination with other actions implement the TEST Act and will 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 approximately 8 per year), we estimate that 28 (or approximately 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 approximately $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 was 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 new 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 final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding sections of this 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/*), we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this final rule with comment period.

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE FQHC PPS

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Transfers				
Federal Annualized Monetized Transfers (in millions)	200	2014	7	2014–2018
	204	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 our Regulatory Flexibility Analysis and 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 410

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

42 CFR Part 491

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

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 amends 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 405.501 [Amended]

■ 2. Section 405.501(b) is amended by removing the phrase ''Federally qualified health centers and'' and adding in its place the phrase ''FQHCs that are authorized to bill under a reasonable cost system, and''.

■ 3. Section 405.2400 is revised as follows:

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act:

(a) Section 1833—Amounts of payment for supplementary medical insurance services.

(b) Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program.

(c) Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

■ 4. 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)'' in alphabetical order.

■ E. Revising the definitions of ''Coinsurance'' and ''Deductible''.

■ F. Adding the definitions of ''Employee'' and ''HRSA'' in alphabetical order.

■ G. Revising paragraphs (1) through (3) of the definition of ''Federally qualified health center (FQHC)''.

■ H. Removing the definition of ''Intermittent nursing care''.

■ I. Adding the definition of ''Medicare Administrative Contractor (MAC)'' in alphabetical order.

■ J. Removing the definitions of ''Nurse-midwife'', ''Nurse practitioner and physician assistant'', and Part-time nursing care''.

■ K. Adding the definitions of ''Nurse practitioner (NP)'', ''Physician assistant (PA)'' and ''Prospective payment system (PPS)'' in alphabetical order.

■ 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, and other requirements of § 410.77(a) of this chapter.

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

Clinical social worker (CSW) means an individual who meets the applicable education, training, 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 the 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 Medicare 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 as described in § 421.404 of this chapter.

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

* * * * *

Physician assistant (PA) means an individual who meet the applicable education, training, 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 (RHC) 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.

* * * * *

■ 5. 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. Removing 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.

■ 6. 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), (a)(3)(i), (a)(4)(i), and (a)(4)(ii) by removing the term ''clinic'' and adding in its place the term ''RHC''.

The revision reads as follow:

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

* * * * *

■ 7. Section 405.2404 is amended as follows:

■ A. Revising the section heading.

■ B. Amending the heading of paragraph (a), and paragraphs (b)(1) introductory text, (b)(2), (b)(3), (c), and (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 paragraphs (a)(1), (a)(2)(i), (a)(2)(ii)(A), and (a)(3) 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. Amending (a)(2)(ii) introductory text by removing the phrase ''if he determines'' and adding in its place ''if the Secretary determines''.

■ F. Amending paragraph (a)(3) by removing the phrase ''that shall be deemed'' and adding in its place the phrase ''the Secretary deems it''.

■ G. Amending paragraph (b)(1) introductory text by removing the term ''he'' and adding in its place the phrase ''he or she''.

■ H. Amending paragraph (b)(1)(i) by removing ''; or'' and adding in its place '';''.

■ I. Amending paragraph (b)(2) by removing the phrase ''The Secretary will give'' and adding in its place the phrase ''The Secretary gives''.

■ J. Revising paragraph (d).

The revisions read as follows:

§ 405.2404 Termination of rural health clinic agreements.

* * * * *

(d) *Notice to the public.* Prompt notice of the date and effect of termination must be given to the public, through publication in local newspapers by either of the following:

(1) The RHC, after the Secretary has approved or set a termination date.

(2) The Secretary, when he or she has terminated the agreement.

* * * * *

■ 8. 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.* Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, a beneficiary's responsibility is either of the following:

(1) For RHCs and FQHCs that are authorized to bill on the basis of the reasonable cost system—

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

(B) For any one item or service furnished by a FQHC, a coinsurance amount 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 actual charge; or

(ii) The FQHC PPS rate for the covered service.

■ 9. 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 and FQHC 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 psychologist and clinical social worker services as specified in § 405.2450.

(b) RHC and FQHC services are—

(1) Covered when furnished in a RHC, FQHC, 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 or FQHC at the time the services are furnished; and

(3) Not covered in a—

(i) Hospital as defined in section 1861(e) of the Act; or

(ii) Critical access hospital as defined in section 1861(mm)(1) of the Act.

■ 10. 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) Outside of 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]

■ 11. Section 405.2413 is amended as follows:

■ A. Amending paragraph (a)(2) by removing the term ''rural health clinic's'' and by adding in its place the term ''RHC's or FQHC's''.

■ B. Amending paragraph (a)(6) by removing the term ''clinic's'' and by adding in its place the term ''RHC's or ''FQHC's'' and by removing the term ''clinic'' and by adding in its place the term ''RHC''.

■ 12. Section 405.2414 is amended as follows:

■ A. Revising the section heading and 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) 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.

* * * * *

■ 13. 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 or FQHC'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 in accordance with applicable State law.

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

(6) 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 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 or FQHC:

(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.

■ 14. Section 405.2416 is amended as follows:

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

■ B. In paragraph (a)(2), removing ''; '' and adding 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)(*1*) Established by a nurse practitioner, physician assistant or certified nurse midwife; and

(*2*) 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]

■ 15. 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'', and removing ''; '' and adding in its place ''.''.

■ C. In paragraph (b), removing ''; or'' and adding in its place ''.''.

■ 16. Section 405.2430 is amended as follows:

■ A. Revising paragraphs (a)(1) introductory text, (a)(1)(i), and (a)(1)(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 of this chapter, 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).

* * * * *

■ 17. 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) by removing the phrase ''Federally qualified health center'' and adding in its place the term ''FQHC'' each time it appears.

■ C. In paragraph (a)(2) by removing the term ''Centers'' and adding in its place the term ''FQHCs''.

■ D. Revising paragraphs (b), (c)(1), and (c)(4).

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

■ F. In paragraphs (d)(1), (d)(3) introductory text, (e)(1), (e)(2), and (e)(3) by removing the phrase ''Federally qualified health center'' each time it appears and adding in its place the term ''FQHC''.

■ G. 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 of this chapter.

(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 FQHC 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]

■ 18. Section 405.2436 is amended as follows:

■ A. In paragraphs (a) introductory text, (a)(2), (b)(1)(i), (b)(2)(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''.

■ 19. 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]

■ 20. Section 405.2442 is amended as follows:

■ A. In paragraph (a) introductory text by removing the phrase ''Federally qualified health center'' each time it appears 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]

■ 21. Section 405.2444 is amended as follows:

■ A. In paragraph (c) by removing the phrase ''Federally qualified health center'' and adding in its place the term ''FQHC''.

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

■ 22. 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 qualified 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.

* * * * *

■ 23. Section 405.2448 is amended as follows:

■ A. Revising paragraphs (a) introductory text, (a)(1) and (2).

■ B. Removing paragraph (a)(3).

■ C. Redesignating paragraph (a)(4) as (a)(3).

■ D. In paragraph (b) introductory text by removing the phrase ''Federally qualified health centers'' and adding in its place the term ''FQHCs''.

■ E. In paragraph (d) by 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 ''a 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 that—

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

(2) Are furnished—

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist or clinical social worker; or

(ii) 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]

■ 24. Section 405.2449 is amended as follows:

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

■ B. In paragraph (b) by removing ''; and'' and adding in its place ''.''.

§ 405.2452 [Amended]

■ 25. Section 405.2452 is amended as follows:

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

■ B. In paragraph (a)(6), removing the term ''center'' and adding in its place the term ''FQHC''.

■ C. In paragraph (b), by removing the phrase ''federally qualified health center'' and adding in its place the term ''FQHC''.

■ 26. 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 for FQHCs and not excluded by the provisions of section 1862(a) of the Act.

■ 27. 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 section 1848(e) of the Act and 42 CFR 414.2 and 414.26 are used to adjust payment under the physician fee schedule during the same period, limited to only the work and practice expense GPCIs.

(2) Furnishing of care to a beneficiary that is a new patient with respect to the FQHC, including all sites that are part of the FQHC. A new patient is one that has not been treated by the FQHC's organization within the previous 3 years.

(3) Furnishing of care to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit) or a subsequent annual wellness visit.

(d)(1) Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, Medicare pays—

(i) 80 percent of the all-inclusive rate for FQHCs that are authorized to bill under the reasonable cost system; and

(ii) 80 percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS.

(2) 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 visit, 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.

■ 28. Section 405.2463 is revised to read as follows:

§ 405.2463 What constitutes a visit.

(a) *Visit—General.* (1) For RHCs, a visit is either of the following:

(i) 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.

(ii) Qualified transitional care management service.

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

(i) A visit as described in paragraph (a)(1)(i) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

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

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

(b) *Visit—Medical.* (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

(i) Physician.

(ii) Physician assistant.

(iii) Nurse practitioner.

(iv) Certified nurse midwife.

(v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

(i) Medical nutrition therapy visit.

(ii) Diabetes outpatient self-management training visit.

(3) Visit—Mental health. 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, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) *Visit—Multiple.* (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 the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;

(ii) Has a medical visit and a mental health visit on the same day; or

(iii) 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 for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under the prospective payment system, Medicare pays for more than 1 visit per day when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or

(ii) Has a medical visit and a mental health visit on the same day.

■ 29. 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) A per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

(2) The per diem rate is adjusted as follows:

(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(c)(2).

(iii) When a beneficiary receives either of the following:

(A) A comprehensive initial Medicare visit (that is, an initial preventive physical examination or an initial annual wellness visit).

(B) A subsequent annual wellness visit.

■ 30. Section 405.2466 is amended to read as follows:

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

■ B. In paragraph (b)(1) introductory text by removing the term ''intermediary'' 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'' and by removing the term ''Federally qualified health center'' and by adding in its place the term ''FQHC''.

■ 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) introductory text, (b)(2), (c)(1), (c)(2), and (d)(2) by removing the word ''clinic'' each time it appears and by adding in its place the term ''RHC''.

■ G. 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''.

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

■ I. 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-cost 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.

* * * * *

■ 31. 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 the lesser of their actual charges or the FQHC PPS rate 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 15 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 rate is calculated based on the reasonable cost system, prior to productivity adjustments and any payment limitations.

(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.

■ 32. Section 405.2468 is amended by:

■ A. In paragraph (a) by removing the term ''intermediary'' and by adding in its place the term ''MAC''.

■ B. In the headings of paragraphs (b) and (c), by removing the term ''rural health clinic'' and by adding in its place the term ''RHC''.

■ C. In the heading of paragraph (b) 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).

■ G. In paragraph (f)(4) by removing the term ''Medicare +Choice'' and adding in its place the term ''Medicare Advantage''.

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) * * *

(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.

* * * * *

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

§ 405.2469 FQHC 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]

■ 34. Section 405.2470 is amended by:

■ A. In paragraphs (a)(1), (b)(1), (c)(3), (c)(4), and (c)(5) by removing the term ''intermediary'', and by adding in its place the term ''MAC''.

■ B. In paragraph (b)(2), by removing the term ''intermediary's'' and by adding in its place the term ''MAC's''.

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

■ E. In paragraphs (b)(1), (b)(2), (c)(1), (c)(2) introductory text, (c)(3), (c)(4), (c)(5), and (c)(6) by removing the term ''clinic'' each time it appears and by adding in its place the term ''RHC''.
■ F. In paragraphs (b)(1), (b)(2), (c)(1), (c)(2) introductory text, (c)(3), (c)(4), (c)(5) and (c)(6) by removing the term ''center'' each time it appears and by the term ''FQHC''.

■ 35. 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 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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

Authority: Sec. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 37. Section 410.152 is amended by revising paragraph (f) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(f) *Amount of payment: Rural health clinic (RHC) and Federally qualified health center (FQHC) services.* Medicare Part B pays, for services by a participating RHC or FQHC that is authorized to bill under the reasonable cost system, 80 percent of the costs determined under subpart X of part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing RHC or FQHC services or reasonable on the basis of other tests specified by CMS.

* * * * *

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 38. 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).

■ 39. Section 491.8 is amended by revising paragraph (a)(3) to read as follows:

§ 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 assistant or nurse practitioner must be an employee of the clinic.

* * * * *

PART 493—LABORATORY REQUIREMENTS

■ 40. 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 Pub. L. 112–202 amendments to 42 U.S.C. 263a.

■ 41. 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. * * *

■ 42. Section 493.2 is amended 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 organization).

* * * * *

■ 43. 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 Laboratory 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—

* * * * *

■ 44. 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)(i) 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 impose a civil money penalty in accordance with § 493.1834(d), if CMS determines that—

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

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

(ii) Following the revocation of a CLIA certificate in accordance with paragraph (b)(1)(i) of this section, CMS may exempt a laboratory owner from the generally applicable prohibition on owning or operating a CLIA-certified laboratory under paragraph (a)(8) of this section on a laboratory-by-laboratory basis if CMS finds, after review of the relevant facts and circumstances, that there is no evidence that—

(A) Patients would be put at risk as a result of the owner being exempted from the ban on a laboratory-by-laboratory basis;

(B) The laboratory for which the owner is to be exempted from the general ownership ban participated in or was otherwise complicit in the PT referral of the laboratory that resulted in the revocation; and

(C) The laboratory for which the owner is to be exempted from the general ownership ban received a PT sample from another laboratory in the prior two survey cycles, and failed to immediately report such receipt to CMS or to the appropriate CMS-approved accrediting organization.

(2) Suspends or limits the CLIA certificate for less than 1 year based on the criteria in § 493.1804(d) and imposes alternative 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)(A) or (B) 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 alternative 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)(i) 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.

* * * * *

Dated: April 3, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 9, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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

Addendum: FQHC Geographic Adjustment Factors (FQHC GAFs)

As described in section II.C.2. of this final rule with comment period, we used the CY 2015 GPCI values and cost share weights, as published in the CY 2014 PFS final rule with comment period, to model the geographic adjustments for the FQHC PPS rates. The FQHC GAFs that will be used for payment under the FQHC PPS will be adapted from the GPCIs used to adjust payment under the PFS for that same period.

The 2014 FQHC GAFs in the following table are adapted from the CY 2014 PFS GPCIs, as finalized in the CY 2014 PFS final rule with comment period. The 2014 FQHC GAFs are the values that will be used to adjust payment under the FQHC PPS for the period of October 1 through December 31, 2014. The 2014 FQHC GAFs in the following table do not reflect the 1.0 floor on the PFS work GPCI that is effective from January 1, 2014, through March 31, 2014, which was authorized by the Pathway for SGR Reform Act of 2013.

The 2015 FQHC GAFs in the following table are adapted from the CY 2015 PFS GPCIs, as finalized in the CY 2014 PFS final rule with comment period. The 2015 FQHC GAFs listed were used to model the geographic adjustments for the FQHC PPS rates. Under current law and regulation, these same values would be used to adjust payments under the FQHC PPS during CY 2015.

We note that updates to the PFS GPCIs due to changes in law or implemented through regulation would also apply to the FQHC GAFs, such as changes to the CY 2015 PFS GPCIs that may be included in the final CY 2015 PFS rule. The FQHC GAFs would be re-calculated and updated through program instruction so that they remain consistent with the PFS GPCIs.

	Locality name	2014 FQHC GAF	2015 FQHC GAF
1	Alabama	0.933	0.936
2	Alaska	1.307	1.316
3	Arizona	0.985	0.993
4	Arkansas	0.920	0.920
5	Anaheim/Santa Ana, CA	1.123	1.120
6	Los Angeles, CA	1.096	1.100
7	Marin/Napa/Solano, CA	1.154	1.165
8	Oakland/Berkeley, CA	1.152	1.154
9	San Francisco, CA	1.216	1.224
10	San Mateo, CA	1.210	1.216
11	Santa Clara, CA	1.204	1.209
12	Ventura, CA	1.105	1.100
13	Rest of California	1.053	1.053
14	Colorado	1.003	1.005
15	Connecticut	1.067	1.069
16	DC + MD/VA Suburbs	1.121	1.123
17	Delaware	1.024	1.021
18	Fort Lauderdale, FL	1.014	1.006
19	Miami, FL	1.017	1.011
20	Rest of Florida	0.973	0.971
21	Atlanta, GA	1.005	1.002
22	Rest of Georgia	0.940	0.940
23	Hawaii/Guam	1.075	1.077
24	Idaho	0.935	0.930
25	Chicago, IL	1.033	1.026
26	East St. Louis, IL	0.962	0.961
27	Suburban Chicago, IL	1.041	1.033
28	Rest of Illinois	0.944	0.944
29	Indiana	0.948	0.948
30	Iowa	0.929	0.933
31	Kansas	0.933	0.935
32	Kentucky	0.925	0.926
33	New Orleans, LA	0.983	0.986
34	Rest of Louisiana	0.930	0.935
35	Southern Maine	0.998	0.994
36	Rest of Maine	0.940	0.944
37	Baltimore/Surr. Cntys, MD	1.059	1.058
38	Rest of Maryland	1.024	1.025

	Locality name	2014 FQHC GAF	2015 FQHC GAF
39	Metropolitan Boston	1.082	1.085
40	Rest of Massachusetts	1.038	1.040
41	Detroit, MI	1.010	0.996
42	Rest of Michigan	0.957	0.954
43	Minnesota	1.005	1.006
44	Mississippi	0.916	0.914
45	Metropolitan Kansas City, MO	0.968	0.968
46	Metropolitan St Louis, MO	0.975	0.972
47	Rest of Missouri	0.905	0.903
48	Montana	0.974	0.977
49	Nebraska	0.938	0.939
50	Nevada	1.026	1.027
51	New Hampshire	1.021	1.027
52	Northern NJ	1.109	1.107
53	Rest of New Jersey	1.071	1.072
54	New Mexico	0.955	0.954
55	Manhattan, NY	1.108	1.106
56	NYC Suburbs/Long I., NY	1.124	1.122
57	Poughkpsie/N NYC Suburbs, NY	1.039	1.040
58	Queens, NY	1.123	1.121
59	Rest of New York	0.966	0.967
60	North Carolina	0.953	0.956
61	North Dakota	0.982	0.981
62	Ohio	0.959	0.953
63	Oklahoma	0.913	0.919
64	Portland, OR	1.025	1.026
65	Rest of Oregon	0.975	0.978
66	Metropolitan Philadelphia, PA	1.044	1.052
67	Rest of Pennsylvania	0.957	0.962
68	Puerto Rico	0.808	0.816
69	Rhode Island	1.035	1.037
70	South Carolina	0.946	0.946
71	South Dakota	0.974	0.976
72	Tennessee	0.937	0.936
73	Austin, TX	1.002	1.008
74	Beaumont, TX	0.942	0.947
75	Brazoria, TX	1.002	1.005
76	Dallas, TX	1.014	1.014
77	Fort Worth, TX	0.995	1.000
78	Galveston, TX	1.010	1.016
79	Houston, TX	1.009	1.013
80	Rest of Texas	0.953	0.957
81	Utah	0.946	0.946
82	Vermont	0.992	0.992
83	Virginia	0.986	0.987
84	Virgin Islands	1.001	1.001
85	Seattle (King Cnty), WA	1.084	1.086
86	Rest of Washington	1.004	1.005
87	West Virginia	0.901	0.902
88	Wisconsin	0.973	0.970
89	Wyoming	0.989	0.992

[FR Doc. 2014–09908 Filed 4–29–14; 4:15 pm]

BILLING CODE 4120–01–P