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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; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 491, and 493

[CMS–1443–P]

RIN 0938–AR62

Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral

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

ACTION: Proposed rule.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

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

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

Acronyms

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

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

The Affordable Care Act (Pub. L. 111–148) 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 rule is to propose a methodology and payment rates for the new FQHC PPS.

This rule also proposes to allow RHCs to contract with non-physician practitioners, consistent with statutory requirements that require at least one nurse practitioner (NP) or physician assistant (PA) be employed by the RHC.

The "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 PT referral. The purpose of this proposal is to amend the CLIA regulations to be in alignment with the statutory change and to propose the regulatory changes needed to fully implement the TEST Act.

2. Summary of the Major Provisions

a. Basis for Payment Under the FQHC PPS

Under the PPS, we are proposing to establish a national, encounter-based rate for all FQHCs and pay FQHCs a single encounter-based rate for professional services furnished per beneficiary per day. The encounter-based rate would be calculated based on an average cost per visit (that is, total FQHC cost divided by total FQHC encounters) using Medicare cost report and claims data. We believe an encounter-based payment rate for the FQHC PPS will both provide appropriate payment while remaining administratively simple. An encounter-based payment rate is consistent with our commitment to greater bundling of services, and gives FQHCs the flexibility to implement efficiencies to reduce over-utilization of services. FQHCs are accustomed to billing for a single encounter and being paid through an all-inclusive rate (AIR). An encounter-based payment is also similar to Medicaid payment systems, and Medicaid is the predominant payer for FQHCs.

We are also proposing a few simple adjustments to the encounter-based payment rate. We are proposing to adjust the encounter-based rate for geographic differences in the cost of inputs by applying an adaptation of the geographic practice cost indices (GPCI) used to adjust payment under the Physician Fee Schedule (PFS). Also, we are proposing to adjust the encounter-based rate when a FQHC furnishes care to a patient that is new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit (that is, an initial preventive physical examination (IPPE) or an initial annual wellness visit (AWV)). We believe this adjustment would account for the greater intensity and resource use associated with these types of services. For additional information on the design of the FQHC PPS and risk adjustment, see section II. of this proposed rule.

b. Addressing Payment for Multiple Visits on the Same Day

Under the current reasonable cost based payment methodology, FQHCs are paid an AIR for all services furnished on the same day to the same beneficiary, with the following exceptions: (1) The FQHC can bill for an additional visit on the same day when an illness or injury occurs subsequent to the initial visit; and (2) the FQHC can bill for additional visits when mental health, diabetes self-management/medical nutrition therapy (DSMT/MNT), or the IPPE are furnished on the same day as the medical visit. However, there are no statutory requirements that we pay separately for these services, and an analysis of FQHC claims data submitted in 2011 and 2012

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

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

c. Beneficiary Coinsurance

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

d. Waiving Coinsurance for Preventive Services

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

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

e. Transition Period and Annual Adjustment

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

f. Other FQHC/RHC Provisions

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

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

g. CLIA Enforcement Actions for Proficiency Testing Referral

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

3. Summary of Cost and Benefits

a. For the FQHC PPS

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

b. For Other FQHC and RHC Changes

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

c. CLIA Enforcement Actions for Proficiency Testing Referral Changes

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

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

III. Additional Proposed Changes Regarding FQHCs and RHCs

A. Rural Health Clinic Contracting

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

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

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

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

B. Technical and Conforming Changes

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

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

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

A. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. The purpose of CLIA is to ensure the accuracy and reliability of laboratory testing for all Americans. Under this authority, which was codified at 42 U.S.C. 263a, the Secretary issued regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). The regulations specify the standards and specific conditions that must be met to achieve and maintain CLIA certification. CLIA certification is required for all laboratories, including but not limited to those that participate in Medicare and Medicaid, which test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings.

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

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

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

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

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

In the February 7, 2013 **Federal Register** (78 FR 9216), we published a proposed rule titled Part II—Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (hereafter referred to as the Burden Reduction proposed rule) to propose reforms to the Medicare and CLIA regulations that we had identified as unnecessary, obsolete, or excessively burdensome. In that rule, we proposed changes to the CLIA PT regulations to establish policies under which certain PT referrals by laboratories would generally not be subject to revocation of their CLIA certificate or a 2 year prohibition on laboratory ownership or operation. To do this, we proposed a narrow exception in our longstanding interpretation of what constitutes an "intentional" PT referral.

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

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

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

B. Proposed Changes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. Other Required Information

A. Requests for Data From the Public

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

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

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

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

B. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

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

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

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

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

VI. Response to Comments

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

VII. Regulatory Impact Analysis

A. Statement of Need

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

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

2. Effects on RHCs

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

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

3. Effects on Other Providers and Suppliers

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

4. Effects on the Medicare and Medicaid Programs

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

TABLE 3—ESTIMATED INCREASE IN ANNUAL MEDICARE PAYMENTS TO FQHCS

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

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

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

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

5. Effects on Medicare Beneficiaries

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

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

E. Effects of Other Policy Changes

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

a. Effects of RHC Contracting Changes

In section III.A. of this proposed rule we discuss our proposal to remove the restrictions on RHCs contracting with nonphysician practitioners when the statutory requirement to employ an NP or a PA is met would provide RHCs with greater flexibility in meeting their staffing requirements. The ability to contract with NPs, PAs, CNMs, CP, and CSWs would provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners, which may result in increasing access to care in rural areas. There is no cost to the Federal government and we cannot estimate a cost savings for RHCs.

b. Effects of the FQHC and RHC Conforming Changes

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

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

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

rule. If the expense of alternative sanctions averaged $150,000 per laboratory, we estimate the annual fiscal savings of the changes to average $2.6 million ($578,400 minus $150,000 for 6 laboratories). While the total savings may not be large, the savings to the individual laboratory or hospital that is affected can be significant. However, we note that the $2.6 million estimate may overstate or understate the provision's savings to laboratories. For example, if under current regulations the prior management is fired instead of being reassigned to other duties for the 2-year period, some of the costs of paying for the new management's salaries, benefits and training may be able to be drawn from funding that had previously been earmarked to pay those expenses for their predecessors. That is, the costs associated with the new employee could be offset by the savings gained when the former employee is terminated. Any such offset will result in lower savings than is estimated earlier. However, there are also unknowns that may result in larger savings than estimated earlier. For example, we have no data on whether terminated management historically received severance packages. If they did, those savings would have to be added to the savings we noted earlier. Such changes in severance payments would represent transfer effects of the proposed rule, rather than net social costs or benefits. In general, it is only to the extent that new laboratory directors put forth more effort than temporarily-banned laboratory directors (due, for example, to the need to familiarize themselves with laboratories they have not previously operated) or that support staff put forth more effort to make the new management arrangements than they would addressing alternative sanctions that society's resources would be freed for other uses by the proposed provision; thus, a comprehensive estimate of laboratory savings would represent some combination of transfers and net social benefits. While we recognize these potential inaccuracies in our estimates, we lack data to account for these considerations.

F. Alternatives Considered

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

G. Accounting Statement and Table

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

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

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

H. Conclusion

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

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

List of Subjects

42 CFR Part 405

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

42 CFR Part 491

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

42 CFR Part 493

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

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

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

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

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833—Amounts of payment for supplementary medical insurance services. Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program. Section1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

■ 3. In § 405.2401, paragraph (b) is amended as follows:

■ A. Removing the definition of "Act".

■ B. Revising the definition of "Allowable costs".

■ C. Removing the definition of "Carrier".

■ D. Adding the definitions of "Certified nurse midwife (CNM)," "Clinical psychologist (CP)", and "Clinical social worker (CSW)".

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

■ F. Adding the definition of "Employee" and "HRSA.

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

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

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

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

§ 405.2472 Beneficiary appeals.

* * * * *

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

* * * * *

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

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

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

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

§ 491.8 Staffing and staff responsibilities.

(a) * * *

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

* * * * *

PART 493—LABORATORY REQUIREMENTS

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

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

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

§ 493.1 Basis and scope.

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

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

§ 493.2 Definitions.

* * * * *

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

* * * * *

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

§ 493.1800 Basis and scope.

(a) * * *

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

* * * * *

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

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

* * * * *

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

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

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

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

(2) Suspends or limits the CLIA certificate for less than 1 year based on the criteria in § 493.1804(d), and also impose alternate sanctions as appropriate, in accordance with §§ 493.1804(c) and (d), 493.1806(c), 493.1807(b), 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i) or (ii) of this section does not apply but that the laboratory obtained test results for the proficiency testing samples from another laboratory on or before the proficiency testing event close date. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

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

* * * * *

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

Dated: September 5, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 10, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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

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

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

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