Settlement Part where the issues are particularly complex even if specific dollar thresholds are not met? Should the Chief ALJ be able to adjust the dollar thresholds for cases eligible for mandatory settlement part processes based upon the Review Commission's case load?

7. Should cases be permitted to remain in mandatory settlement part proceedings for more than 18 months without the approval of the Chief ALJ?

8. Should the parties be allowed to elect to not participate in a mandatory settlement part proceeding and, instead, request that the case proceed directly to a hearing on the merits?

The Review Commission welcomes any other comments or suggestions regarding Settlement Part.

Dated: May 1, 2012.

Debra Hall,

Acting Executive Director.

[FR Doc. 2012–11080 Filed 5–10–12; 8:45 am]

BILLING CODE 7600–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0345; FRL–9671–2]

State of Hawaii; Regional Haze Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public hearing.

SUMMARY: EPA is announcing that public hearings will be held on May 31, 2012 and June 1, 2012 for the proposed rule, ''State of Hawaii; Regional Haze Federal Implementation Plan'', which will be posted on EPA's Web site by May 16, 2012.

DATES: The public hearings will be held on May 31, 2012 and June 1, 2012. See **SUPPLEMENTARY INFORMATION** section for further details about the public hearings.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for hearing locations.

FOR FURTHER INFORMATION CONTACT: If you have questions about the public hearings, please contact Gregory Nudd, EPA Region 9, 415–947–4107, *nudd.gregory@epa.gov.* If you are a person with a disability under the ADA and require a reasonable accommodation for this event, please contact Philip Kum at *kum.philip@epa.gov* or at (415) 947–3566 by May 16, 2012.

SUPPLEMENTARY INFORMATION: Section 169A of the Clean Air Act (CAA) establishes as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution.'' Hawaii has two Class I areas: Hawaii Volcanoes National Park on the Big Island and Haleakala National Park on Maui.

Regional haze is visibility impairment caused by the cumulative air pollutant emissions from numerous sources over a wide geographic area. EPA's proposed Regional Haze Federal Implementation Plan (FIP) for Hawaii will address the requirements of the CAA and EPA's regulations regarding regional haze. The proposed rule, ''State of Hawaii; Regional Haze Federal Implementation Plan'', will be available by May 16, 2012 on the following Web site: *http://www.epa.gov/region9/air/actions/hawaii.html* and will subsequently be published in the **Federal Register**.

The proposed rule and information on which the proposed rule relies will also be available in the docket for this action. Generally, documents in the docket for this action will be available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

Public hearings: EPA will hold two public hearings at the following dates, times and locations to accept oral and written comments into the record:

Date: May 31, 2012.
Time: Open House: 5:30–6:30 p.m.
Public Hearing: 6:30–8:30 p.m.
Location: The University of Hawaii, Maui College in the Pilina Multipurpose Room, 310 W. Kaahumanu Ave., Kahului, Hawaii 96732.

Date: June 1, 2012.
Time: Open House: 4:30–5:30 p.m.
Public Hearing: 5:30–7:30 p.m.
Location: Waiakea High School in the Cafeteria, 155 W. Kawili St., Hilo, Hawaii 96720.

To provide opportunities for questions and discussion, EPA will hold open houses prior to the public hearings. During these open houses, EPA staff will be available to informally answer questions on our proposed action and this supplemental proposed rule. Any comments made to EPA staff during the open houses must still be provided formally in writing or orally during a public hearing in order to be considered in the record.

The public hearings will provide the public with an opportunity to present data, views, or arguments concerning the proposed Regional Haze FIP for Hawaii. EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Please consult the proposed rule for guidance on how to submit written comments to EPA.

At the public hearing, the hearing officer may limit the time available for each commenter to address the proposal to five minutes or less if the hearing officer determines it is appropriate. Any person may provide written or oral comments and data pertaining to our proposal at the public hearing. We will include verbatim transcripts, in English, of the hearing and written statements in the rulemaking docket.

Dated: May 1, 2012.

Elizabeth Adams,

Acting Air Division Director, Region IX.

[FR Doc. 2012–11426 Filed 5–10–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 441, and 447

[CMS–2370–P]

RIN 0938–AQ63

Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration Under the Vaccines for Children Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement new requirements in sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Social Security Act, as amended by the Patient Protection and Affordable Care Act of 2010 (the

Affordable Care Act). It implements Medicaid payment for primary care services furnished by certain physicians in calendar years (CYs) 2013 and 2014 at rates not less than the Medicare rates in effect in those CYs or, if greater, the payment rates that would be applicable in those CYs using the CY 2009 Medicare physician fee schedule conversion factor (CF). This minimum payment level applies to specified primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine, and also applies to services paid through Medicaid managed care plans. It would also provide for a 100 percent Federal matching rate for any increase in payment above the amounts that would be due for these services under the provisions of the State plan as of July 1, 2009. In this proposed rule, we specify which services and types of physicians qualify for the minimum payment level in CYs 2013 and 2014, and the method for calculating the payment amount and any increase for which increased Federal funding is due.

In addition, this proposed rule would update the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children under the Pediatric Immunization Distribution Program, more commonly known as the Vaccines for Children (VFC) program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 11, 2012.

ADDRESSES: In commenting, please refer to file code CMS–2370–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–2370–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–2370–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: Mary Cieslicki, (410) 786–4576, or Linda Tavener, (410) 786–3838, for issues related to payments for primary care physicians.

Mary Beth Hance, 410–786–4299, for issues related to charges for the administration of pediatric vaccines.

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.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This proposed rule implements new requirements in sections 1902(a)(13), 1902(jj), 1905(dd) and 1932(f) of the Social Security Act requiring payment by State Medicaid agencies of at least the Medicare rates in effect in CYs 2013 and 2014 or, if higher, the rate using the CY 2009 conversion factor (CF) for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. Also, this proposed rule implements the statutory payment provisions uniformly across all States, defines, for purposes of enhanced Federal match, eligible primary care physicians, identifies eligible primary care services, and specifies how the increased payment should be calculated. Finally, this proposed rule provides general guidelines for implementing the increased payment for primary care services delivered by managed care plans.

This proposed rule also proposes updates to vaccine rates that have not been updated since the VFC program was established in 1994. We propose to update these rates due to inflation and we are proposing to use the Medicare Economic Index (MEI).

2. Summary of the Major Provisions

a. Payments to Physicians for Primary Care Services

This proposed rule would implement Medicaid payment for primary care services furnished by certain physicians in calendar years (CYs) 2013 and 2014 at rates not less than the Medicare rates in effect in those CYs or, if greater, the payment rates that would be applicable in those CYs using the CY 2009

conversion factor (CF). It would also provide for a 100 percent Federal matching rate for any increase in payment above the amounts that would be due for these services under the provisions of the State plan as of July 1, 2009. This proposed rule is necessary to promote access to primary care services in the Medicaid program before and during the expansion of coverage that begins in 2014. These proposals implement the Affordable Care Act.

b. Vaccine Administration Under the Vaccines for Children (VFC) Program

This proposed rule proposes to update the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children under the Pediatric Immunization Distribution Program, more commonly known as the Vaccines for Children (VFC) program. We are proposing to use the MEI which is a price index that is used by CMS to update Medicare physician payments. We believe the MEI is the best tool to update these rates because: (1) It reflects input price inflation faced by physicians inclusive of the time period when the national average was established in 1994, and (2) we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices. The MEI was most recently updated at the end of 2011.

3. Summary of the Costs and Benefits

Provision description	Total costs	Total benefits
Payments to Physicians for Primary Care Services.	The overall economic impact of this proposed rule is an estimated $5.52 billion in CY 2013 and $5.66 billion in CY 2014. In CY 2013, the Federal cost is approximately $5.74 billion with $225 million in State savings. In CY 2014, the Federal cost is approximately $5.96 billion with $300 million in State savings. Of this amount, the aggregate economic impact, as a result of this proposed rule requiring States to reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014, is estimated at an additional $970 million in Federal costs. The Federal costs for funding that increase, in State payments during CYs 2013 and 2014, are estimated at $490 million and $480 million, respectively.	The overall benefit of this rule is the expected increase in provider participation by primary care physicians resulting in better access to primary and preventive health services by Medicaid beneficiaries.
Increase in Vaccine for Children Program Maximum Ceiling.	This rule raises the maximum rate that States could pay providers for the administration of vaccines under the VFC program in subsequent years after CY 2014. States are not anticipated to raise their VFC ceilings in 2013 and 2014 because of the implementation of the primary care payment increase.	The overall benefit of this provision is that it gives States the ability to increase their VFC vaccine administration rates.

C. Background

1. Payments to Physicians for Primary Care Services: Statutory and Regulatory Framework

a. Improving Primary Care

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) was enacted; together they are known as the Affordable Care Act. This proposed rule would implement the new requirements in sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Act, as amended by the Affordable Care Act. Section 1902(a)(13) of the Act requires payment by State Medicaid agencies of at least the Medicare rates in effect in calendar years (CYs) 2013 and 2014 or, if higher, the rate that would be applicable using the CY 2009 Medicare conversion factor (CF), for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine.

Primary care for any population is critical to ensuring continuity of care, as well as to providing necessary preventive care, which improves overall health and can reduce health care costs. The availability of primary care is particularly important for Medicaid enrollees to establish a regular source of care and to provide care to a population that is more prone to chronic health conditions that can be appropriately managed by primary care physicians. Primary care physicians provide services that are considered to be a core part of the Medicaid benefit package. Additionally, these physicians can perform the vital function of coordinating care, including specialty care.

As we move towards CY 2014 and the expansion of Medicaid eligibility, it is critical that a sufficient number of primary care physicians participate in the program. Section 1902(a)(13) of the Act will encourage primary care physicians to participate in Medicaid by increasing payment rates.

b. Medicaid Payment to Providers

Section 1902(a)(30)(A) of the Act requires that Medicaid payments be consistent with efficiency, economy, and quality of care and be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. In meeting these requirements, States have broad discretion in establishing and updating Medicaid service payment rates to primary care providers. For instance, many States reimburse based on the cost of providing the service, a review of the amount paid by commercial payers in the private market, or as a percentage of rates paid under the Medicare program for equivalent services. States may update

rates based on specific trending factors such as the MEI or a Medicaid specific trend factor that incorporates a State-determined inflation adjustment rate. Increasingly, States are providing medical assistance through managed care plans under contracts with managed care organizations (MCOs) and other organized delivery systems, such as prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). The contract between the State and the managed care plan requires the plan to provide access to and make payments to primary care physicians using the funds the State pays to the managed care plan. Indeed, according to the Medicaid and CHIP Payment and Access Commission (MACPAC), 49 million Medicaid beneficiaries receive care through some form of Medicaid managed care.

Section 1902(a)(13)(C) of the Act requires that States pay a minimum payment amount for certain primary care services delivered by designated primary care physicians. Primary care services are defined in new section 1902(jj) of the Act and include certain specified procedure codes for evaluation and management (E&M) services and certain vaccine administration codes. Under this provision, States must reimburse at least as much as the Medicare physician fee schedule (MPFS) rate in CYs 2013 and 2014 or, if greater, the payment rate that would apply using the CY 2009 Medicare CF. The requirement for payment at the Medicare rate extends to primary care services paid on a fee-for-service (FFS) basis, as well as to those paid by Medicaid managed care plans. This proposed regulation would specify which services and physicians qualify for the increased payment amount in CYs 2013 and 2014, and the method for calculating that payment.

Section 1905(dd) of the Act provides for a higher FMAP for the required increase in physician payment. For FFS expenditures, the FMAP rate will be 100 percent of the difference between the Medicaid State plan rate in effect on July 1, 2009, and the amount required to be paid under section 1902(a)(13)(C) of the Act. That means that States will be fully reimbursed for these increased payments by the Federal government.

One goal of this proposed rule is to define the payment provisions further so that States may uniformly identify the rate differential. Specifically, we propose a payment methodology that would take into account potential changes in Medicare rates between CYs 2013 and 2014 and CY 2009 that is independent of the legislatively required payment reductions caused by Medicare's sustainable growth rate mechanism. Furthermore, this proposed rule would address Medicare's use of different fee schedules that take into account the site of service (for example, physician's office, or outpatient department of a hospital) and geographical location of the provider.

The Affordable Care Act amended section 1932(f) of the Act to clarify that States must incorporate the requirement for increased payment to primary care providers into contracts with managed care organizations. We propose general guidelines for States to follow when identifying the amounts by which MCOs must increase existing payments to primary care providers, and any additional capitation costs to the State attributable to such required increases in existing payments. We are also proposing to extend this same treatment to PIHPs and PAHPs through regulations at part 438, to the extent that primary care provider payments are made by these entities.

We seek comments on how best to implement through regulation the requirement that managed care plans (whether capitated, partially capitated or on a FFS basis) pay primary care providers at the Medicare rate for primary care services, consistent with those paid on a FFS basis. Additionally, we seek comments from States and others on the best way to adequately identify the increase in managed care capitation payments made by the State that is attributable to the increased provider payment, for the purpose of claiming 100 percent FFP. We are particularly interested in ensuring that primary care physicians receive the benefit of the increased payment. Section 1932(f) of the Act, as amended by the Affordable Care Act, requires that the managed care contracts pay providers at the applicable Medicare rate levels. We propose to review managed care contracts to ensure that this requirement is imposed on managed care plans by the State. We also propose to require managed care plans to report to the State the payments made to physicians under this provision to justify any adjustments to the capitation rates paid by the State under the contract. In proposing this approach, we are mindful of balancing the need for adequate documentation of the payment with the administrative burden it places on States and managed care plans. We are requesting comment on these provisions and additional suggestions on how to ensure that managed care plans provide the necessary data to the State, as well as how to ensure and monitor that managed care plans appropriately pass on to physicians the portion of the increased capitation rate that is attributable to the primary care rate increase.

This proposed rule also addresses identification of the rate differential eligible for 100 percent Federal matching funds for vaccine administration, as set forth in section 1905(dd) of the Act. In 2011, the vaccine administration billing codes were changed so it is not possible to track the Medicaid State plan rate in CY 2009 directly to the rates applicable in CYs 2013 and 2014. We are requesting comment on our proposal for imputing the CY 2009 rate.

c. Medicare Payment to Primary Care Providers

Medicare provides health insurance coverage to people who are aged 65 and over, or who meet other special criteria, under title XVIII of the Act. For institutional care, such as hospital and nursing home care, Medicare makes payments to providers using prospective payment systems. Payment for physicians' services under Medicare is based on the MPFS. The MPFS assigns relative value units (RVUs) for each procedure, as well as practice cost indices (GPCIs) for geographic variations in payments, and a global CF, which converts RVUs into dollars. Individual fee schedule amounts for the MPFS are the product of the geographic adjustment, RVUs, and CF. Site of service (for example, physician office or outpatient hospital) is reflected as an adjustment to the RVUs. We generally issue the MPFS final rule for the subsequent calendar year on or before November 1st each year. The MPFS final rule includes the RVUs and CF for the upcoming calendar year, which permits the calculation of rates. Updates may occur throughout the year, but normally occur quarterly.

2. Vaccine Administration Under the Vaccines for Children (VFC) Program

The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), (Pub. L. 103–66), created the Vaccines for Children (VFC) Program), which became effective October 1, 1994. Section 13631 of OBRA 1993 added section 1902(a)(62) to the Act to require that States provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children in accordance with section 1928 of the Act. Section 1928 of the Act requires each State to establish a VFC Program (which may be administered by the State Department of Health) under which certain specified groups of children are entitled to receive qualified

pediatric immunizations without charge for the cost of the vaccine.

Under the VFC Program, a provider, in administering a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine. Section 1928(c)(2)(C)(ii) of the Act allows a provider to impose a fee for the administration of a qualified pediatric vaccine as long as the fee, in the case of a federally vaccine-eligible child, does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration). However, a provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

II. Provisions of the Proposed Regulation

A. Payments to Physicians for Primary Care Services

1. Primary Care Services Furnished by Physicians With Specified Specialty and Subspecialty (§ 447.400)

a. Specified Specialties and Subspecialties

Section 1902(a)(13)(C) of the Act specifies that physicians with a specialty designation of family medicine, general internal medicine, and pediatric medicine qualify as primary care providers for purposes of increased payment. This proposed rule provides that services provided by subspecialists related to the primary care specialists designated in the statute would also qualify for higher payment. These subspecialists would be recognized in accordance with the American Board of Medical Specialties designations. For example, a pediatric cardiologist would qualify for payment if he or she rendered one of the specified primary care services by virtue of that physician's subspecialty within the qualifying specialty of internal medicine. Additionally, this proposed rule would specify a method for States to use in identifying practitioners who may receive the increased payment.

The inclusion of subspecialists is based on three factors. We first considered that many primary care subspecialists render the primary care services specified in this rule. Stakeholders, including physicians, States, and independent policy makers strongly emphasized this point in their engagement with CMS on this proposed rule. Many stressed the importance of subspecialists, particularly pediatric subspecialists, in the provision of primary care and strongly recommended that they be eligible for the higher payment. Additionally, we see no justification for including only subspecialists in one specialty designation and, therefore, we are proposing that all subspecialists within the three specialty designations be eligible for increased payment for primary care services. Finally, we believe the statute provides the latitude to include related subspecialists within these specialty designations.

Therefore, we are proposing that all subspecialists recognized by the American Board of Medical Specialties within the three specialty designations be eligible for increased payment for primary care services. That is, we propose that all subspecialists within the specialty designations of family medicine, general internal medicine, and pediatric medicine as recognized by the American Board of Medical Specialties be eligible for increased payment. In this rule, we propose to specify how States would identify the specialists and subspecialists eligible for increased payment. Identification of eligible physicians is critical to ensure that only specified physicians receive increased payment.

Under our proposal, States would be required to establish a system to require physicians to identify to the Medicaid agency their specialty or subspecialty before an increased payment is made. For program integrity purposes, the State will be required to confirm the self-attestation of the physician before paying claims from that provider at the higher Medicare rate. We propose that this be done either by verifying that the physician is Board certified in an eligible specialty or subspecialty or through a review of physician's practice characteristics.

Specifically, for a physician who attests that he or she is an eligible primary care specialist or subspecialist but who is not Board certified (including those who are Board-eligible, but not certified), a review of the physician's billing history must be performed by the Medicaid agency. We are proposing that at least 60 percent of the codes billed by the physician for all of CY 2012 must be for the E&M codes and vaccine administration codes specified in this regulation. For a new physician who enrolls during either CY 2013 or CY 2014 and who attests that he or she is within one of the eligible specialties or subspecialties and who is not Board certified, we propose that following the end of the CY in which enrollment occurs, the State would review the physician's billing history to confirm that 60 percent of codes billed during the CY of enrollment were for primary care services eligible for payment under sections 1902(a)(13)(C) and 1902(jj) of the Act.

To summarize, we would not limit specified providers to physicians who are Board certified. States would be required to verify the eligibility of non-Board certified physicians through a review of the physician's practice characteristics.

We developed this proposal for the use of a supporting history of codes billed to qualify physicians for increased payment after reviewing the statutory requirements for the Medicare Incentive Payments for Primary Care Services payments authorized by section 5501(a) of the Affordable Care Act, which amended section 1833 of the Act. That provision specifically requires that primary care services account for at least 60 percent of the allowed charges billed by a practitioner for services to be eligible for increased payment. We propose that the same standard be applied to the Medicaid payments under section 1902(a)(13)(C) of the Act although we propose that verification would be based on the number of codes billed for the specified primary care services, rather than charges. The use of billing codes rather than allowed charges helps to assure that physicians providing a certain volume of primary care services are uniformly recognized for higher payment across States, regardless of variations in service charges.

We are seeking comment on whether 60 percent or some other percentage threshold would be more appropriate to determine whether a non Board certified physician qualifies for increased payment.

In developing the overall requirements for verification of physician self-attestation, we considered that there are no pre-existing Federal Medicaid requirements concerning provider designation of a specialty or subspecialty. Because State practices vary on recognizing specialty or subspecialty designations for different purposes, reliance solely on self-attestation would result in a lack of uniformity in the application of minimum payment levels. Self-attestation alone would not provide an objective and auditable standard to document that a provider is one of the types of primary care physicians designated in statute. For this reason, we believe imposing the requirement for either Board certification in a nationally-recognized specialty or subspecialty or a supporting history of codes billed using the Medicare standard is merited.

When making a payment, the State would have the choice of initially reimbursing a newly enrolled physician at the Medicare rate or the Medicaid State plan rate used for services provided by physicians who do not qualify for the increased payment. If the State chooses to reimburse a physician initially at the higher Medicare rate and later finds through the review of codes billed that the physician did not qualify, increased payments to which the provider was not entitled under the State plan would be considered as overpayments. Conversely, the State could choose to reimburse the newly enrolled physician at the Medicaid State plan rate applicable to services provided by physicians who do not qualify for increased payment, and then make supplemental payments promptly upon determining qualification for the increased payments.

We are soliciting comments on whether the proposed timeframes, or something else, for establishing a supporting history of codes billed for a physician who is not Board certified is appropriate. We are attempting to minimize any implementation burden while also ensuring that proper audit controls are in place to prevent inappropriate application of this provision.

b. Furnished by a Specified Physician

Section 1902(a)(13)(c)of the Act requires increased payment for ''primary care services furnished in CYs 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine.'' This regulation would specify that the increased payment applies only for services under the ''physicians' services'' benefit at section 1905(a)(5)(A) of the Act and in regulations at § 440.50.

Increased payment would not be available for services provided by a physician delivering services under any other benefit under section 1905(a) of the Act such as, but not limited to, the FQHC or RHC benefits because, in those instances, payment is made on a facility basis and is not specific to the physician's services. Section 1902(a)(13)(c) of the Act requires payment ''for primary care services* * * furnished by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine at a rate no less than 100 percent of the payment rate that applies to such services and physicians under Part B of Title XVIII.'' Therefore, we believe that the statute limits payment to physicians who, if Medicare providers, would be reimbursed using the MPFS. The MPFS is not used to reimburse physicians in settings such as FQHCs or RHCs; therefore, we believe physicians delivering primary care services at FQHCs and RHCs are not eligible for increased payments under section 1902(a)(13) of the Act. Furthermore, we note that the Medicaid statute already provides a payment methodology for FQHCs and RHCs that is designed to reimburse those providers at cost.

In specifying that payment is made for qualified primary care services under the physicians' services benefit at § 440.50, the increased payment for primary care services would be required for services furnished ''by or under the personal supervision'' of a physician who is one of the primary care specialty or subspecialty types designated in the regulation. In Medicaid, many primary care physician services are actually furnished under the personal supervision of a physician by nonphysician practitioners, such as nurse practitioners and physician assistants. Such services are billed under the supervising physician's program enrollment number and are treated in both Medicare and Medicaid as services of the supervising physician. Consistent with that treatment, we propose that primary care services would be paid at the higher rates if properly billed under the provider number of a physician who is enrolled as one of the specified primary care specialists or subspecialists, regardless of whether furnished by the physician directly, or under the physician's personal supervision. This would align with Medicaid's longstanding practice in providing physician services, as well as Medicare's Part B FFS payment methodology for professional services. Additionally, this policy would recognize the important role that nonphysician practitioners working under the supervision of physicians have in the delivery of primary care services.

c. Eligible Primary Care Services (§ 447.400(b))

We propose that Healthcare Common Procedure Coding System (HCPCS) E&M codes 99201 through 99499 and vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474 or their successors would be eligible for higher payment and FFP. These codes are specified by the statute and include those primary care E&M codes not reimbursed by Medicare.

We believe that non-Medicare covered primary care services should be included because these services represent a core component of services commonly delivered in the Medicaid program. We reviewed Medicaid payment data from 2007, 2008, and 2009 for these services as a percentage of primary care expenditures, and found that they represent 6 percent of primary care payments (as distinguished from service volume). We believe this percentage warrants the inclusion of these non-Medicare reimbursed codes to achieve the purpose of encouraging primary care providers to serve the Medicaid population.

Where there are differences in codes reimbursed by Medicaid and Medicare we attribute this mostly to the fact that children represent a population not typically served by the Medicare program. As a result, the scope of primary care services is not equivalent between the two programs. We believe that the statute provides the latitude to include codes for which the Medicare program sets and publishes RVUs, even if Medicare payment is not actually made for the service.

Specifically, we are proposing to include as primary care services the following E&M codes that are not reimbursed by Medicare:

- New Patient/Initial Comprehensive Preventive Medicine—codes 99381 through 99387;
- Established Patient/Periodic Comprehensive Preventive Medicine—codes 99391 through 99397;
- Counseling Risk Factor Reduction and Behavior Change Intervention—codes 99401 through 99404, 99408, 99409, 99411, 99412, 99420 and 99429;
- E&M/Non Face-to-Face physician Service—codes 99441 through 99444.

2. Amount of Required Minimum Payments (§ 447.405)

Section 1902(a)(13)(C) of the Act requires payment not less than the amount that applies under the MPFS in CYs 2013 and 2014 or, if greater, the payment rate that would be applicable if the 2009 CF were used to calculate the MPFS.

a. Use of Fee Schedule Amount Applicable to the Geographic Location of Service

We are proposing that States be required to use the MPFS rate applicable to the site of service and geographic location of the service at issue. The Medicare Part B rates vary by geographic location and site of service. For example, rates are higher for services provided in an office setting as opposed to the outpatient hospital setting. We propose that States would be required to use the MPFS payment amounts applicable to the site of service and geographic location because we

believe these are integral to the MPFS payment system. Individual fee schedule amounts for the MPFS are the product of the geographic adjustment, RVUs, and CF that converts adjusted RVUs into dollar amounts. Site of service is reflected as an adjustment to the RVUs used to set the rate.

We are proposing that States be required to use the MPFS as published by CMS. Medicare primary care incentive payments made pursuant to section 5501 of the Affordable Care Act, which amended section 1833 of the Act, would not be included. Section 5501(a) provides for incentive payments for a subset of the codes covered by this regulation. The payments are not made as increases in fee schedule amounts and are not reflected in the MPFS.

b. Payment for Services Unique to Medicaid

For services reimbursed by Medicaid but not Medicare, we propose that payment would be made under a fee schedule developed by CMS and issued prior to the beginning of CYs 2013 and 2014. We propose that rates for non-Medicare reimbursed services would be established using the Medicare CF in effect in CYs 2013 and 2014 (or the CY 2009 CF, if higher) and the RVUs recommended by the American Medical Association's (AMA) Specialty Society Relative Value Update Committee (RUC) and published by CMS for CYs 2013 and 2014. We are specifically seeking comments from States and others on the most appropriate way to set payment rates for services not reimbursed by Medicare.

c. Updates to Medicare Part B Fee Schedule

We recognize the potential for multiple updates to the MPFS in CYs 2013 and 2014. Those rates are published by CMS on or before November 1st of the preceding calendar year, but are subject to periodic adjustments or updates throughout the calendar year. In addition, the Medicare Part B rates vary by geographic location and site of service.

We propose to permit States the option of complying with the requirements of section 1902(a)(13)(C) of the Act by either adopting annual rates or by using a methodology to update rates to reflect changes made by Medicare during the year. That is, States could adopt the MPFS in effect at the beginning of CYs 2013 and 2014 (or, if the CY 2009 CF is higher, the CY 2013 or CY 2014 RVUs multiplied by the CY 2009 MPFS CF), and apply those rates throughout the applicable calendar year without adjustments or updates. Using this methodology, mid-year updates made to the MPFS during the respective calendar year would not be reflected in Medicaid payments. Alternatively, a State could elect to adjust Medicaid payments to reflect mid-year updates made to the MPFS, but the State's methodology would have to specify the timing for such adjustments.

In consulting with State Medicaid agencies and other stakeholders, we were urged not to require multiple rate adjustments based on fluctuations in the MPFS, but to identify the MPFS for each year as of a single point in time. That annual fee schedule would serve as the basis of the rates paid by Medicaid during each of the 2 years that section 1902(a)(13)(C) of the Act is in effect. Based on the feedback, we propose giving States the choice to apply or not apply mid-year updates.

3. State Plan Requirements (§ 447.410)

Under the proposed rule, States would be required to submit a State plan amendment (SPA) to reflect the fee schedule rate increases for eligible primary care physicians under section 1902(a)(13)(A) of the Act. The purpose of this proposed requirement is to assure that when States make the increased reimbursement to physicians, they have State plan authority to do so and they have notified physicians of the change in reimbursement as required by Federal regulations.

4. Availability of Federal Financial Participation (FFP) (§ 447.415)

Section 1905(dd) of the Act allows States to receive 100 percent FFP for expenditures equal to the difference between the Medicaid State plan rate for primary care services in effect on July 1, 2009, and the Medicare rates in effect in CYs 2013 and 2014 or, if greater, the payment rate that would be applicable using the CY 2009 Medicare CF. To claim the enhanced Federal match, States must make payments to specified physicians at the appropriate MPFS rate and must develop a method of identifying both the rate differential and eligible physicians for services reimbursed on an FFS for service basis and through managed care plans. States must be able to document the difference between the July 1, 2009 Medicaid rate and the applicable Medicare rate for specified providers that is claimable at the 100 percent matching rate. This requirement applies also to services provided to individuals eligible for both Medicaid and Medicare. This means that increased FFP will be available also for higher Medicaid payments for Medicare cost sharing for individuals who are eligible for both programs.

a. FFP in Payments for Individuals Eligible for Both Medicare and Medicaid

When a service is provided to an individual who is eligible for Medicare and Medicaid, Medicare reimburses the physician 80 percent of its fee schedule rate while Medicaid pays the remaining cost. Currently, States have two options for such payments consistent with section 1902(n) of the Act. A State may pay the provider the full amount necessary to result in aggregate payment to the provider equal to the MPFS rate (the full Medicare cost sharing amount), or only the amount (if any) to result in aggregate payment equal to the State's Medicaid rate. For example, under the second option, if the Medicare allowed amount is $100 and the Medicaid rate is $75, then Medicare pays $80 and there is no additional amount paid by Medicaid. Historically, most States have chosen to pay providers only up to the lower Medicaid rate.

In CYs 2013 and 2014, the Medicaid rate for primary care services by the specified physicians will equal the Medicare rate. As a result, these physicians should receive payment up to the full Medicare rate for primary care services and 100 percent FFP will be available for the full amount of the Medicare cost sharing amount that exceeds the amount that would have been payable under the State plan in effect on July 1, 2009.

b. Identifying the July 1, 2009 Payment Rate

For the purpose of identifying the differential between the Medicaid rate and the Medicare rate, we propose to define the Medicaid ''rate'' under the approved Medicaid State plan as the final rate paid to a provider inclusive of all supplemental or increased payments paid to that provider. For example, many States currently pay physicians affiliated with academic medical centers the Medicaid State plan rate plus a supplemental amount that together equal the average amount paid by commercial third party payers. Therefore, in calculating the rate differential, these States would determine the CY 2009 rate inclusive of any supplemental payment.

c. Federal Funding for Increased Payments for Vaccine Administration

There are a number of factors affecting the identification of the cost of vaccine administration eligible for 100 percent FFP. They include the following issues:

- The structure of the billing codes for vaccine administration changed in 2011 such that four of the codes used in 2009 were replaced by two codes.

• Some States did not use the designated billing codes in effect in 2009.

• Prior to CY 2011, billing codes for vaccine administration did not permit payment for additional vaccine/toxoid components.

• Vaccines for Children (VFC) program requirements do not permit payment for each vaccine/toxoid component administered and limit provider charges to the regional VFC ceiling amount.

Prior to CY 2011 vaccine administration billing codes did not permit additional vaccine administration payments for vaccines with more than one vaccine/toxoid component. All providers, including those participating in the VFC program, received one payment per vaccine regardless of the number of vaccine/toxoid components. In this rule, we clarify that qualifying physicians, excluding those participating in the VFC program, must receive additional payments during CYs 2013 and 2014 for vaccines with multiple vaccine/toxoid components administered to Medicaid beneficiaries.

The vaccine administration billing codes recognized for reimbursement under the statute are: 90465, 90466, 90567, 90568, 90471, 90472, 90473 and 90474 or their successor codes. In 2011, the coding structure for vaccine administration changed such that four pediatric billing codes specified in section 1902(jj) of the Act (90465, 90466, 90767, and 90468) were replaced by just two billing codes (90460 and 90461). Moreover, the four deleted codes represented vaccine administrations by various routes (for example, intranasal vs. injectable) to children under age 8. However, new code 90460 represents the initial vaccine/toxoid administered through all routes to children under 18 while code 90461 represents additional vaccines/toxoids administered. As a result, States will not be able to identify the rate differential by comparing payments for the codes used in CY 2009 to those in use in CYs 2013 and 2014.

IMMUNIZATION CODES BEFORE AND AFTER 2011

Prior to 2011	Effective 2011
90465, 90466, 90467, 90468	90460, 90461
90471	90471
90472	90472
90473	90473
90474	90474

We propose that the State impute the CY 2009 rate for code 90460 based on the average payment amount for the deleted codes weighted by service volume. That is, each of the four CY 2009 rates for vaccine administration would be multiplied by their respective percentages of service volume and then added to determine one payment amount as demonstrated in the following example:

• 90465 = $10 × 0.50 service volume = $5.00

• 90466 = $10 × 0.10 service volume = $1.00

• 90467 = $8 × 0.30 service volume = $2.40

• 90468 = $8 × 0.10 service volume = 0.80

• Total cost equals $9.20 for the new, single code, 90460.

Code 90461 represents payment for the administration of additional vaccine/toxoid components in a vaccine. Code 90461 is an add-on code that cannot be used without code 90460. Because there were only single payments for vaccines prior to 2011, we believe the rate for code 90461 should be $0. We believe that this is an equitable method of setting the 2009 Medicaid base for code 90460, but welcome comments. For VFC providers, if the rate paid in July 2009 was lower than the regular Medicaid State plan administration fee for non-VFC providers, then the rate for VFC providers should be used as the 2009 base for code 90460. The majority of vaccines administered to Medicaid-eligible children under the age of 18 are administered as part of the Vaccines for Children (VFC) program. Section 1928(c)(2)(ii) of the Act provides that administration fees for vaccines provided under the VFC program cannot exceed the cost of administration as determined by the Secretary for that program. An additional concern for VFC vaccines is that, under the terms of the VFC program, providers can still only bill a flat fee per vaccine given by injection or by intranasal or oral routes, regardless of the number of vaccines/toxoid components, and must use only code 90460. In order to permit providers participating in the VFC program to benefit from the provisions of the Affordable Care Act, this rule proposes that States be required to reimburse VFC providers at the lesser of the 2013 and 2014 Medicare rates or the maximum regional VFC amount in those years. States should qualify for 100% FFP for these increased reimbursements. This policy is consistent with Medicare which limits provider payment to the lesser of the fee schedule amount or provider charges, since VFC provider charges are limited to the regional maximum administration fee. Since the VFC statute prohibits payment for additional vaccines/toxoids, VFC providers would only receive payment for administration fees billed using code 90460. We invite comment on whether these proposed provisions give sufficient effect to the legislative intent to increase provider payments to Medicare levels, or whether we should instead adopt policies that we describe below as alternatives considered in developing this proposed rule.

In proposing a method to determine the CY 2009 rate for code 90460, our goal is to identify a uniform methodology that is not administratively burdensome. We are seeking comments on this proposal and encourage States and other stakeholders to provide additional options for identifying the rate differential.

An additional issue related to the changes made by the Affordable Care Act for vaccine administration is that, in CY 2009, some States did not reimburse providers using the designated vaccine administration billing codes. Rather, some States paid providers on the basis of non standard billing codes developed for the purpose of identifying the type of vaccine being administered. In instances where both the vaccine and administration fee were billed using the vaccine code, States will be required to identify the CY 2009 payment for vaccine administration separate from the vaccine itself.

5. Primary Care Service Payments Made by Managed Care Plans, and Enhanced Federal Match (§ 438.6 and § 438.804)

As amended by the Affordable Care Act, section 1932(f) of the Act requires that the managed care plans pay physicians at the applicable Medicare rates. We propose to implement the managed care requirements through a State-by-State review of managed care contracts and applicable procedures. We will review managed care contracts to ensure that they—

• Provide for payment at the minimum Medicare primary care payment levels;

• Require that eligible physicians receive direct benefit of the payment increase for each of the primary care services specified in this rule. This requirement must be met regardless of whether a physician is salaried, or receives a fee for service or capitated payment. We emphasize that increased payment must correspond directly to the volume and payment amounts associated with the primary care services specified in this rule;

• Require that all information needed to adequately document expenditures eligible for 100 percent FFP is reported

by MCOs, PIHPs, and PAHPs to the States which, in turn, will report these data to CMS; and

• Specify that States must receive from MCOs, PIHPs and PHAPs data on primary care services which qualify for payment under this rule. The managed care reporting requirements would ensure that States have data on increased provider payments necessary to justify any adjustments to the capitation rates paid by the State under the contract.

Additionally, we will review each State's proposed methodology for identifying the discrete amount paid for each of the eligible primary care services that qualifies for 100 percent FFP. Both the managed care contracts and the State's methodology for identifying payment amounts made for each primary care services must be submitted to CMS for review prior to the start of CY 2013.

We acknowledge the diversity of payment arrangements between managed care plans and primary care physicians, and we will not require that managed care plans modify the terms of their payments to eligible primary care physicians beyond the increase in payments for primary care services required by the statute.

In proposing this approach, we are mindful of balancing the need for adequate documentation of the payment with the administrative burden it places on States and managed care plans. We are requesting comment on these provisions and additional suggestions on how to ensure that managed care plans provide the necessary data to the State, as well as how to ensure and monitor that managed care plans appropriately pass on to physicians the portion of the increased capitation rate that is attributable to the primary care rate increase.

States have expressed concern about their ability to align capitated payment made as of July 1, 2009 to payment made for services provided in CYs 2013 and 2014 for the purpose of claiming increased FFP. We recognize the particular challenges inherent in identifying the payment differential eligible for 100 percent FFP for primary care services provided by managed care plans because such payments are not necessarily linked to individual services and physicians. We believe that the most reasonable way to apply this provision for managed care rates is to do the following:

Step I: Identify the proportion of total capitation linked to primary care.

Step II: Identify the fee schedule amount incorporated into the actuarial model for primary care services represented by the proportion of payment for primary care services. Here, we assume the visit rate equals $25.

Step III: Determine the annualized cost built into the actuarial model for primary care. Here we assume 8 visits annually. $25 per visit rate × 8 visits annually = $200

Step IV: Determine the per visit cost discounted for volume. $200/12 = $16.67

In this example, $16.67 equals the imputed amount of the payment made on a fee for services basis for an individual primary care service. The State would compare this amount to the Medicare rate paid in CYs 2013 and 2014 to determine the payment differential eligible for 100 percent Federal matching funds. In proposing this methodology, we realize there may be multiple ways to achieve implementation and specifically request comments on this portion of the proposed rule.

To be clear, we are proposing that States would be required to submit the methodology they intend to use to identify the increment of the capitation payment attributable to increased provider rates to CMS for approval prior to the beginning of CY 2013. Further, we propose that, absent approval of its methodology from CMS, States would not be able to claim the enhanced Federal match for capitation payments to managed care plans.

This proposal was developed with input from States. During a January 27, 2011 all-State call specific to the impact of the amended section 1932(f) of the Act on managed care, States reported that the amount and type of data managed care plans report to them varies greatly both across and within States. States expressed the need to be able to identify the rate differential for the purpose of claiming 100 percent FFP and to do so in a manner that is reasonable and documented. We are seeking additional comments on how States might best meet these requirements.

B. Vaccine Administration Under the Vaccines for Children (VFC) Program

1. General Statement

At this time, we are proposing to add 42 CFR part 441 subpart K to codify the requirements of the Vaccines for Children Program. The general requirements of the VFC program will be found at § 441.510, and state that federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

• Eligible for Medicaid.

• Not insured.

• Not insured for the vaccine and who are administered pediatric vaccines by a federally-qualified health center (FQHC) or rural health clinic (RHC).

• An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that—

• Is licensed or authorized to administer pediatric vaccines under the law of the State in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

• Submits to the State an executed provider agreement in the form and manner specified by the Secretary.

• Has not been found, by the Secretary or the State to have violated the provider agreement or other applicable requirements established by the Secretary or the State.

Section 1928 of the Act requires each State to establish a VFC Program (which may be administered by the State Department of Health) and include this program in the State plan (§ 441.505) under which certain specified groups of children are entitled to receive qualified pediatric immunizations without charge for the cost of the vaccine.

In the October 3, 1994 **Federal Register**, we published a notice with comment period entitled, ''Charges for Vaccine Administration Under the Vaccines for Children (VFC) Program'' (59 FR 50235) (hereinafter referred to as the ''October 1994 VFC notice'') that set forth, by State, the interim regional maximum charges for the VFC program. These charges represented the maximum amount that a provider in a State could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC Program. This proposed rule would announce updates to those fees for use on an interim basis. This is the first proposed update of the interim regional maximum administration fees since 1994. We received comments in response to the October 1994 VFC notice and we have reviewed them. We expect to address those comments in a separate document. We will respond to public comments provided in response to this proposed rule. We are interested in receiving comments on this proposed rule and suggestions for potential updates that could be made to the administration fees to ensure that the VFC regional

maximum rates are increased to reflect a more current cost of vaccine administration. As discussed in the October 1994 VFC notice, the interim maximum administration fees apply to all VFC program-registered providers that administer pediatric vaccines to federally vaccine-eligible children. The fees do not apply to children receiving free vaccines under State purchase programs or any other arrangement.

In accordance with section 1928(c)(2)(C)(ii) of the Act, we are proposing § 441.500 to state that physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the State has established a lower administration fee under the Medicaid program. Families of children who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers vaccines would be impacted by this proposed regulation. Providers can bill the families of those children at the State's regional maximum rate for the administration of a vaccine. Therefore, if the proposed updated rates were to become effective, those families could be billed at the published rate for that State. However, section 1928(c)(2)(B)(iii) of the Social Security Act says that ''[t]he provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.'' A recent survey of providers participating in VFC shows that approximately 37 percent of those providers actually charge the State's maximum administration fee to families of children who are uninsured or who do not have insurance that covers vaccines. The remaining 61 percent of providers surveyed either write off the charge or charge a lesser amount. We solicit comments specifically on the impact of the increased fees on uninsured and underinsured VFC-eligible children. However, as discussed in the October 1994 VFC notice, and as proposed in new § 441.515(e), there would be no Federal Medicaid matching funds available for administration since these children are not eligible for Medicaid. Although the cost of the vaccines for the VFC program is funded under Title XIX of the Act, Medicaid will not pay for the administration of vaccines provided to children under the VFC program who are not Medicaid-eligible. A provider may only bill Medicaid for the administration of a vaccine if the child is eligible under Medicaid.

2. Methodology Used To Establish Administration Charges

In 1994, to obtain national average rates for the administration of vaccines, we contracted with the American Academy of Pediatrics (AAP) to purchase data on the normal fee charged by its members for administering the vaccines covered by this program. This was because there was no reliable data available on physicians' actual cost that would provide a valid base for setting these maximum charges on a nationwide scale. The final national average administration charge we obtained from the AAP was $15.09. The national average was then adjusted for regional variations, using indices established for the MPFS.

Before the publication of this proposed rule, we attempted to determine the availability of Medicaid cost data; however, just as in 1994, there is no data readily available on physician's actual costs that would provide a valid basis for recalculating these maximum fees. Therefore, in § 441.515, we are proposing to update the maximum administration fees based on the data and formula established in the October 1994 VFC notice. We continue to believe, given the nature of the program and the requirements applicable to participating providers, that charge data, adjusted for regional variations, is a reasonable proxy for calculating these maximum fees. To adjust the administration charge of $15.09 for inflation, we are proposing to use the Medicare Economic Index (MEI), which is a price index that is used by CMS to update Medicare physician payments. We are proposing to use the MEI because: (1) It reflects input price inflation faced by physicians inclusive of the time period when the national average was established in 1994, and (2) we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices. The MEI was most recently updated at the end of 2011 (76 FR 73275 through 73276, November 28, 2011). Therefore, we have calculated the proposed update based on the MEI up through and including CY 2012. Using that index, we have determined that the updated national average administration charge would be $21.80.

As in the October 1994 VFC notice, we would adjust the national average for regional variations, using indices established for the MPFS. The national average was weighted by the geographic adjustment factors (GAF), which reflects a weighted sum of the three geographic practice cost indexes (GPCIs) (work, practice expense, and malpractice insurance) for a given Medicare PFS locality.

The GAF is a proxy for differences in the cost of operating a medical practice among various geographic areas, and is used as a comparison among Medicare PFS localities (73 FR 69726, 69740 November 19, 2008). Consistent with the methodology in the October 1994 VFC notice, when there was more than one GAF per State, we would select the highest GAF within the State and use that GAF to adjust the average national vaccination administration charge for the entire State to assure that administration charges would fall within our established maximum rates.

The MPFS localities (and corresponding GAFs) are grouped by State and sub-State areas. As discussed in the October 1994 VFC notice, we developed the regional maximum charges for each ''State'' because the geographic area of a State is clearly identifiable by boundary lines recognized nationwide, as opposed to a sub-State area. In this proposed rule, we see no reason to change that interpretation.

We are also proposing to revise the national average for each State to reflect the fully implemented sixth comprehensive update to the MPFS GPCIs and updated GAFs. For more information on the methodology used for the most recent GPCI update, we refer readers to the CY 2012 MPFS final rule with comment period (76 FR 73026 through 73474). Consistent with that rule, the cost share weights for determining the GAF equation are 48.266 percent for physician work, 47.439 percent for practice expense, and 4.295 percent for malpractice insurance.

We derived the proposed interim amounts specified in the chart under section II of this proposed rule as the maximum allowable charges for the administration of qualified pediatric vaccines for each State on the basis of the formula: National charge data × updated GAFs = maximum VFC fee. (See Table 1.)

TABLE 1—EXAMPLE OF THE APPLICATION OF THE FORMULA FOR OHIO

Average national administration charge = $21.80.
Work expense = 0.998; practice expense = 0.927.
Malpractice expense = 1.24.
Using Medicare weights to weigh components of—
Work expense = 48.266 percent.
Practice expense = 47.439 percent.
Malpractice expense = 4.295 percent.
Calculation:
Work expense: 0.998 × 48.266 percent = 0.482.
Practice expense: 0.927 × 47.439 percent = 0.439.
Malpractice expense: 1.24 × 4.295 percent = 0.053.
Total expense = 0.975.
Ohio's updated maximum fee for administration of the vaccine is: $21.80 × 0.975 = $21.25.

The maximum updated administration fee would be effective with the publication of a final notice or regulation. We request comments on the methodology used to calculate this administration fee update and will consider revisions to the regional maximum fees in response to public comments. The proposed updated maximum fees are set forth in Table 2.

TABLE 2—REGIONAL MAXIMUM ADMINISTRATION FEE BY STATE

State	Current regional maximum fee	Updated regional maximum fee
Alabama	$14.26	$19.79
Alaska	17.54	27.44
Arizona	15.43	21.33
Arkansas	13.30	19.54
California	17.55	26.03
Colorado	14.74	21.68
Connecticut	16.56	23.41
Delaware	16.55	22.07
District of Columbia	15.13	24.48
Florida	16.06	24.01
Georgia	14.81	21.93
Guam	.....	23.11
Hawaii	15.71	23.11
Idaho	14.34	20.13
Illinois	16.79	23.87
Indiana	14.47	20.32
Iowa	14.58	19.68
Kansas	14.80	20.26
Kentucky	14.17	19.93
Louisiana	15.22	21.30
Maine	14.37	21.58
Maryland	15.49	23.28
Massachusetts	15.78	23.29
Michigan	16.75	23.03
Minnesota	14.69	21.22
Mississippi	13.92	19.79
Missouri	15.07	21.53
Montana	14.13	21.32
Nebraska	13.58	19.82
Nevada	16.13	22.57
New Hampshire	14.51	22.02
New Jersey	16.34	24.23
New Mexico	14.28	20.80
New York	17.85	25.10
North Carolina	13.71	20.45
North Dakota	13.90	20.99
Ohio	14.67	21.25
Oklahoma	13.89	19.58
Oregon	15.19	21.96
Pennsylvania	15.76	23.14
Puerto Rico	12.24	16.80
Rhode Island	14.93	22.69
South Carolina	13.62	20.16
South Dakota	13.56	20.73
Tennessee	13.70	20.00
Texas	14.85	22.06
Utah	14.52	20.72
Vermont	13.86	21.22

TABLE 2—REGIONAL MAXIMUM ADMINISTRATION FEE BY STATE—Continued

State	Current regional maximum fee	Updated regional maximum fee
Virginia	14.71	21.24
Virgin Islands	15.09	21.81
Washington	15.60	23.44
West Virginia	14.49	19.85
Wisconsin	15.02	20.83
Wyoming	14.31	21.72

As noted in the October 1994 VFC notice, these fees are intended as guidance for Universal Purchase States (that is, where the vaccines are purchased by the State for all children in the State). These States may use the maximum charges listed or develop their own maximum fees.

In addition, as stated in the October 1994 VFC notice, State Medicaid agencies would not be obligated to set the Medicaid payment for vaccine administration at the level of the maximum fees set forth in this proposed rule. Therefore, if these proposed maximum fees were to go into effect, the amount that a State pays a provider under the Medicaid program would not increase unless a State were to submit a SPA to CMS that increases the rate. In accordance with sections 1902(a)(30) and 1928(c)(2)(C)(ii) of the Act, States have the flexibility to set their payment rates at a lower level than the State's regional maximum fee. State Medicaid agencies typically take a variety of factors into consideration when setting payment rates, including the need to assure adequate participation by providers.

III. 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. 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.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at approximately 35 percent of salary, which is based on the June 2011 Employer Costs for Employee Compensation report by the Bureau.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs):

A. ICR's Regarding Contract Requirements (§ 438.6)

In § 438.6(c)(3)(v) and (c)(5)(vi), States would be required to implement managed care contracts for payment to a MCO, PIPH or PAHP to comply with the requirements at section 1202 of the HCERA. There is a one-time burden to the State for amending such contracts for the following provisions: (1) To assure that the level of payment is consistent with part 447, subpart G; (2) to assure that the specified physicians (whether directly or through a capitated arrangement) receive an amount at least equal to the amount set for and required under part 447; and (3) to assure that the State receive documentation regarding those payments.

The burden associated with the requirements under § 438.6(c)(3)(v) and (c)(5)(vi) is the time and effort it would take each of the 35 State Medicaid programs with managed care plan payments and the District of Columbia (36 total respondents) to amend an average of three managed care contracts. We estimate it will take three hours to complete this task per contract at an estimated cost of $441.63 per respondent ($49.07/hr × 3 hr × 3 contracts) or $15,898.68 total ($441.63 per respondent × 36 respondents). In deriving this figure, we used a labor rate of $49.07/hr for a State's management, professional and related staff to amend each contract.

B. ICR's Regarding Provider Agreements (§ 441.505(b))

This requirement is exempt from OMB review and approval since we expect to receive fewer than 10 submissions (annually) from providers, if any. The requirement that providers must have provider agreements in place in order to participate in the VFC program has been in effect since the program was implemented in 1994. The provision in this regulation is merely codifying the requirement and no further action is necessary in regard to providers who are currently participating in the VFC program.

C. ICR's Regarding State Plan Amendments for the Vaccines for Children Program (§§ 441.510 and 441.515(d))

This requirement is exempt from the OMB review process as we expect to receive fewer than 10 submissions from States. The requirement that a State submit a State plan was a requirement when the VFC program was first established in 1994, and all States submitted State Plans at that time. A State now only submits a State plan amendment related to the VFC program when it makes a change to the State's administration fee. In 2011, only two States submitted State plans that made changes to the State's administration fee under the VFC program. Even with the publication of the updated fee schedule, we do not anticipate that many States will make changes to their State's administration fee.

D. ICR's Regarding Eligible Services (§ 447.400(a))

In § 447.400(a), States would be required to ensure that physicians identify their specialty to the Medicaid agency before an increased payment is made. Initial identification may be made by self-attestation, but for program integrity purposes the State will be required to verify the physician's claimed specialty status by reviewing the Board certification status of the physician, or reviewing the physician's practice characteristics, before paying for services at the Medicare rate.

The burden associated with the requirements under § 447.400(a) is the time and effort it would take each of the 50 Medicaid Programs and the District of Columbia (51 total respondents) to establish that a physician is qualified, either through Board certification or a supporting history of codes billed, to receive payment under section 1202 of the HCERA. We estimate that it will take 0.5 hours to determine whether a physician may receive payment under section 1202 of the HCERA. We used data from the Medicaid Statistical Information System (MSIS) to identify the number of physicians claiming for the E&M codes specified in this regulation during the fourth quarter of FY 2008 and FY 2009 (the most recent data available). Based on that data, there is an average of 2,245 physicians per State who currently bill, but whose eligibility for increased payment will need to be verified by the Medicaid agency. We increased this number by 10 percent to account for participation by new physicians for a total of 2,470 physicians.

We used the following hourly labor rates and estimated the time to complete each task: 0.5 hours for a State's Medicaid office and support staff working in the medical billing area to retrieve and assess claims for an individual physician; or 0.5 hours for administrative staff to review the Board certification status of a physician. Costs associated with these staff are reported at a cost of $14.12 for each half-hour derived from $28.24/hr each and 2,470 physicians for an estimated cost of $14.12 per response or $34,876.40 (total).

E. ICR's Regarding State Plan Requirements (§ 447.410)

In § 447.410, States would be required to submit a SPA to reflect the fee schedule rate increases for eligible primary care physicians under section 1902(a)(13)(C) of the Act. The purpose of this proposed requirement is to assure that when States make the increased reimbursement to providers, they have State Plan authority to do so and they have notified providers of the change in reimbursement as required by Federal regulations.

The burden associated with the one-time requirement under § 447.410 is the time and effort it would take each of the 50 State Medicaid Programs and the District of Columbia (51 total respondents) to modify the Medicaid State plan to reflect payment consistent with the requirements in section 1902(a)(13)(C) of the Act. This will require the preparation and submission of a SPA. We estimate that it will take State staff working 4 hours to complete all of the tasks associated with the preparation of an SPA. The estimated cost is $107.13 ($35.71/hr × 3 hr) per State or $5,463.63 total ($107.13 * 51) for tasks completed by non-management staff working on SPA preparation. We estimate that this task will also require 1 hour for State-employed legal staff at $49.07/hr or $49.07 (per response) for a total of $2,502.57 ($49.07 × 51). The combined total for cost associated with SPA preparation, including non-legal and legal staff employed by the State, is $7,966.20 ($5,463.63 + $2,502.57).

F. ICR's Regarding Additional Requirements (Methodology To Identify Rate Differential) for FFP for Managed Care Payments (§ 438.804(a)(2) and (3))

In § 438.804(a)(3), States would be required to submit the methodology they intend to use to identify the rate differential for managed care payments to CMS for approval 6 months prior to the beginning of CY 2013. Further, we propose that, absent approval from CMS, States would not be able to claim the enhanced Federal match for managed care payments.

The burden associated with the requirements under § 438.804(a)(2) and (3) is the time and effort it would take each of the 35 State Medicaid Programs with managed care plan payments and the District of Columbia (36 total respondents) to develop a methodology for the identification of payment made for primary care services through managed care contracts eligible for 100 percent Federal matching funds. This task will involve a one-time effort on the part of financial, legal and information technology staff. We estimate that it will take 14 hours per respondent at a cost of $637.42 to develop the identification methodology at a total cost of $22,947.12 (36 × $637.42). In deriving these figures, we used the following hourly labor rates and estimated the time to complete this task: $49.07/hr and 2 hours for legal staff to review the methodology for compliance with the statute ($98.14); $48.09/hr and 8 hours for managerial staff to assess the feasibility of implementing the methodology ($384.72); and $38.64/hr and 4 hours for information technology/public administration staff to assess the feasibility of the methodology ($154.56).

TABLE 3—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)
§ 438.6(c)(3)(v) and (c)(5)(vi)	36	108	3	324	15,898.68	15,898.68
§ 447.400(a)	51	2,470	.50	1,235	34,876.40	34,876.40
§ 447.410	51	51	4	204	7,966.20	7,966.20
§ 438.804(a)(2) and (3)	36	36	14	504	22,947.12	22,947.12
Total				2,267	81,688.40	81,688.40

Note 1: All of the proposed collections are new. Therefore, OMB control numbers have not been assigned and the control number column has been omitted from the table.

Note 2: There are no capital or maintenance costs incurred by any of the proposed collections. Therefore, the capitol cost column has been omitted from the table.

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access our Web site at *http://www.cms.hhs.gov/Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and

recordkeeping requirements, 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–2370–P) Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

IV. 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.

V. Regulatory Impact Statement

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980; Pub. L. 96–354) (RFA), 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. We solicit comment on the RIA analysis provided. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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 2012, that threshold is approximately $139 million. This rule does not contain mandates that will impose spending costs on State governments in the aggregate of $139 million. The cost for increasing payment for primary care services in CYs 2013 and 2014 will be borne by the Federal government, which will provide 100 percent matching funds equal to the difference between the Medicaid State plan rate in effect July 1, 2009 and the Medicare rate implemented in CY 2013 and 2014, or the rate using the CY 2009 CF, if higher. Section 1202 of the HCERA requires higher payment to physicians for primary care services but does not impose increased costs on States. For the provisions associated with the charges for vaccine administration under the VFC program, the proposals will have no consequential effect on State, local, or tribal governments or on the private sector.

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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As indicated, this proposed rule will not have a substantial effect on State and local governments.

B. Statement of Need

This proposed rule implements section 1202 of the HCERA requiring payment by State Medicaid agencies of at least the Medicare rates in effect in CYs 2013 and 2014 or, if higher, the rate using the CY 2009 CF for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. Also, this proposed rule implements the statutory payment provisions uniformly across all States, defines, for purposes of enhanced Federal match, eligible primary care physicians, identifies eligible primary care services, and specifies how the increased payment should be calculated. Finally, this proposed rule provides general guidelines for implementing the increased payment for primary care services delivered by managed care plans.

C. Overall Impact

The aggregate economic impact of this proposed rule is an estimated $5.52 billion in CY 2013 and $5.66 billion in CY 2014. In CY 2013, the Federal cost is approximately $5.74 billion with $225 million in State savings. In CY 2014, the Federal cost is approximately $5.96 billion with $300 million in State savings. The State savings are derived from the projected increases in reimbursement rates expected to occur prior to passage of this legislation between years 2009 and 2013 through 2014, which will now be paid for by the Federal government. Absent the legislation, the projected increases in the reimbursement rates would be split between the Federal government and States. This aggregate economic impact estimate includes the requirement that States reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014, which is estimated at $970 million in Federal costs. The Federal costs for funding that increase, in State payments during CYs 2013 and 2014, are estimated at $490 million and $480 million, respectively.

Overall, the estimated economic impacts are a result of this proposed rule providing States the ability to increase payment for primary care services without incurring additional costs. We anticipate higher payment will result in greater participation by primary care physicians, including primary care subspecialists, in Medicaid thereby helping to promote overall access to care. At this time it is not known whether States will be willing or have the ability to sustain this level of payment to providers beyond CY 2014. For managed care plans, this proposed rule would require documentation of the primary care services that are provided in order for States to claim 100 percent FFP. Currently, many States do not receive complete data on individual services provided by managed care plans. We believe, as result of this proposed rule, there will be improved documentation and reporting of primary care services provided by managed care plans. This, in turn, may serve to inform future managed care rate setting.

D. Detailed Economic Analysis

1. Anticipated Effects on Medicaid Recipients

We anticipate this proposed rule will have a positive effect on Medicaid recipients by increasing the availability of services through financial incentives to primary care physicians. The exact number of beneficiaries that will benefit

is not known, however, we believe it will be substantial because this rule directly affects payment for a type of service which is a key component of the Medicaid program. Additionally, we believe primary care physicians will be encouraged to accept more Medicaid beneficiaries into their practices as a result of increased payment.

We believe that this regulation will positively affect the availability of vaccination services as well. Currently, only 5 States reimburse the regional maximum for vaccine administration set by the VFC program. This proposed rule would require States to reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014.

Finally, this rule will positively affect patients who are dually eligible for benefits under the Medicare and Medicaid programs by increasing payment to physicians who serve this population. Specifically, Medicaid will pay higher amounts to providers. We anticipate that increased payment will promote greater access to primary care services for dually eligible beneficiaries.

2. Anticipated Effects on Other Providers

We anticipate this proposed rule would increase physician participation in Medicaid as most States reimburse physicians at well below the Medicare rates. Recently, as States have experienced budgetary constraints, they have sought to address this by reducing payments to providers, including physicians. This proposed rule would ensure that in CYs 2013 and 2014, physicians receive the higher Medicare rate for the specified primary care services.

In addition, this proposed rule would impact States and providers who provide immunizations under the Medicaid program because it will require that such providers be reimbursed at the lesser of the 2013 or 2014 Medicare rate or the Regional Maximum VFC Administration Fee in CYs 2013 and 2014. This rule also raises the maximum rate that States could pay providers for the administration of vaccines under the VFC program in subsequent years. The proposed updated Regional Maximum Administration Fees included in this proposed rule are the maximum amounts that a State could choose to reimburse a provider for the administration of a vaccine under the VFC program after the provisions of the primary care payment increase expire at the end of CY 2014. States have the flexibility to set the rate that they will reimburse providers, and can therefore choose to set it at the State's regional maximum fee or at any other amount below the regional maximum amount. It is not expected that all States will choose to implement the increase.

The impact of this proposed rule on the Federal Government is therefore connected to States decisions as to whether to increase the amount that they pay providers for the administration of vaccines after CY 2014. That is, if no States choose to increase the administration fee for providers, there would be no additional costs incurred by the Federal Government.

The same is true for States. There would be no impact of this proposed rule on a State unless the State chooses to increase the amount that it reimburses providers for the administration of vaccines under the VFC program.

Children enrolled in the VFC program who are Medicaid eligible would not incur any additional costs as a result of this proposed rule as there are no out-of-pocket expenses related to the VFC program for Medicaid eligible children.

Families of children who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers vaccines would be impacted by this proposed regulation. The Affordable Care Act does not make any changes to the VFC program and therefore uninsured and underinsured individuals receiving vaccines through the VFC program will continue to pay a single administration fee for any vaccine provided. The provider will also receive a single administration fee for any vaccine provided, regardless of the number of vaccine/toxoid components, and will not receive the Medicare administration rate for those services. Providers can bill the families of those children at the State's regional maximum rate for the administration of a vaccine. As a result, if the proposed updated rates were to become effective, those families could be billed at the published rate for that State. However, section 1928(c)(2)(B)(iii) of the Social Security Act says that ''[t]he provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.''

Therefore, providers could benefit from the proposed regulation as they could charge and receive the State's regional maximum rate for their patients who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers immunizations. A provider would not receive an increased administration fee for Medicaid-eligible children unless a State chose to increase the amount that it pays providers under the Medicaid program.

3. Anticipated Effects on the Medicaid Program Expenditures

Table 4 provides estimates of the anticipated Medicaid program expenditures associated with increasing payment for primary care services. CMS' Office of the Actuary (OACT) developed estimates for the impact of this section of the Affordable Care Act, which were initially published in April 2010, (*https://www.cms.gov/ActuarialStudies/downloads/PPACA_2010-04-22.pdf*). Initially, projections of Medicaid spending on primary care physician services by FFS Medicaid and Medicaid managed care plans were created. For this, OACT developed assumptions of (1) what share of Medicaid physician spending was for primary care and (2) what share of managed care spending was for physician services, relying on several studies on physician service utilization and expenditures. OACT then projected spending for 2013 and 2014 based on the projections of Medicaid physician spending in the President's Fiscal Year 2010 Budget Mid-Session Review. To determine the impact of using Medicare physician payment rates for Medicaid payments, OACT compared the ratio of Medicaid rates to Medicare rates, based on a study of Medicare and Medicaid physician payment rates across all States. Finally, OACT projected growth in Medicaid physician payments and the rates prescribed by section 1202 of the HCERA, based on Medicare payment rates; these estimates were revised to incorporate the actual CY 2011 CF, (75 FR 73169). OACT assumed that physician services covered by Medicaid would increase over 2013 and 2014 as a result of higher payments and expected increases in physician participation in Medicaid. Additionally, these changes were estimated to result in a slight decrease to projected State spending as future projected Medicaid payment rate increases would be covered by increased Federal matching funds in 2013 and 2014. The studies and data sources used for developing these estimates included: S. Zuckerman, ''Trends in Medicaid Physician Fees, 2003–2008,'' *Health Affairs,* 28 April 2009; the American Medical Association; the Medical Group Management Association; and the Bureau of Labor Statistics.

TABLE 4—FEDERAL AND STATE MEDICAID IMPACTS FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS DURING CALENDAR YEARS 2013 THROUGH 2014

[Millions of 2012 dollars]

	CY 2013	CY 2014
Federal Share*	$5,740	$5,960
State Share	−225	−300
Total	5,515	5,660

*Federal cost estimates reflect the additional $490 million and $480 million in CYs 2013 and 2014, respectively, as a result of States reimbursing specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum.

The Medicare payment rates used in this estimate were the actual 2009 MPFS and the current statute projections of the CYs 2013 and 2014 MPFS.

In addition, it should be noted that these estimates are based on the current statute which includes a significant projected reduction to payment rates in the CY 2013 MPFS under the Sustainable Growth Rate (SGR) formula. Every year since 2003, the Congress has passed legislation overriding projected cuts that otherwise would have resulted from the SGR formula. Furthermore, it is possible that the Congress may enact legislation that averts the currently projected reduction in MPFS rates for 2013 which would affect the CYs 2013, and 2014 rates that are being used to estimate the payment impacts in this rule. Consequently, if the Congress enacts legislation resulting in increased payment rates to replace the payment rate reduction called for under the SGR formula in CYs 2013, and 2014, and in turn the CYs 2013 or 2014 rates exceed the rates calculated using the CY 2009 CF, then this would result in higher costs for the CYs 2013 and 2014 Medicaid physician payments presented in this rule. Additionally, other changes to the CF in these years may also affect the costs of this section. Therefore, currently it is not possible to accurately estimate the impact of these potential future changes, since definitive action, if any, by the Congress regarding the MPFS CF is unknown.

4. Anticipated Effects on States

The Federal government would provide 100 percent matching funds for the difference between the Medicaid State plan rate in effect July 1, 2009 and the Medicare rate in CYs 2013 and 2014 or the rate using the CY 2009 Medicare CF, if higher. Therefore, we believe this proposed rule would result in a positive effect on States, since it reduces their expenditures for primary care services. State savings are estimated at $225 million and $300 million in CYs 2013 and 2014, respectively. However, for Medicaid State plan rates below the 2009 level, States would be required to reimburse the non-Federal share of that portion, so as to return to the 2009 level of payment. We are unable to accurately quantify the impact of this effect on States, since there is not a precise relationship between any of the Medicaid State plan rates and the Medicare rates.

5. Anticipated Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. 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 and having revenues of less than $7.0 million to $34.5 million in any 1 year. (For details, see the Small Business Administration's Table of Size Standards at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*.) For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. Individuals and States are not included in the definition of a small entity.

We anticipate that this regulation would primarily impact individual physicians and State Medicaid agencies. This proposed rule requires States to increase payment for primary care services without incurring additional State cost. As previously noted, we anticipate that this higher payment would impact physicians by encouraging greater participation by primary care physicians, including primary care subspecialists, in Medicaid, thereby helping to promote overall access to care. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule would not have a significant impact on small rural hospitals because it only affects physicians. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that none of the provisions in this proposed rule would have a significant impact on the operations of a substantial number of small rural hospitals.

E. Alternatives Considered

This section provides an overview of the issues addressed in the proposed rule and the regulatory alternatives considered. In identifying the issues and developing alternatives, we consulted with States and other interested stakeholders such as primary care specialists and policy makers. We solicit comment on the assumptions and analyses presented in the Alternatives Considered section.

1. Eligible Providers

The statute specifies that increased payment may be made for primary care services furnished by a physician with a primary specialty designation of family medicine, general internal medicine or pediatric medicine. Because States have varying methods of identifying a physician's specialty this poses a challenge to the uniform implementation of the increased payment. Currently, there are no Federal requirements surrounding how States must enroll Medicaid providers. In this rule, we propose to use Board certification and a supporting history of codes billed in the absence of Board certification as a means of identifying eligible primary care physicians but seek comment on the time period from which claimed codes would be drawn. We considered permitting physicians to qualify for payment based solely on self attestation in the absence of Board certification but were concerned that without an objective measure, such as a supporting history of codes billed, certain physicians could be unfairly advantaged or disadvantaged in receiving the increased payment. We also believe that an objective measure is more supportive of program integrity.

This proposed rule clarifies that subspecialists related to the specialty designations identified in the statute would be eligible for payment. We considered extending eligibility for increased payment to only those physicians with a primary care specialty designation of family medicine, general internal medicine or pediatric medicine and not to subspecialists within those categories. However, through our engagement with the provider community we learned that pediatric subspecialists routinely deliver primary

care services. Therefore, we propose to make all subspecialists within the primary care specialties designated in the statute eligible for the enhanced payment. Due to the limited data available, including the lack of discrete data on physician specialty or subspecialty, we are unable to accurately estimate the impacts representing the exclusion of subspecialties relative to this proposed regulation. The analysis is further complicated by the observation that some types of subspecialists may provide a significant amount of primary care services, while other types of subspecialists may provide very little primary care services, thereby limiting any sound assumptions presented including the entailed impact modeling.

2. Payment Made Under the Physician Benefit as a Physician Service

This rule clarifies physician services to mean any service delivered under the physicians' services benefit at 1905(a)(5)(A) of the Act. First, we considered whether the statute limited increased payment to services provided only by physicians. In the Medicaid program, a significant proportion of primary care services are actually rendered by advance practice nurses, and other types of independently practicing non-physicians. We recognize the importance of these non-physician practitioners in the provision of primary care services in many States. However, section 1902(a)(13)(c) of the Act limits eligibility for higher payment to services provided by physicians. Next we considered whether the statute limited increased payment to services provided directly by physicians. Medicaid regulations at 42 CFR 440.50 define ''physician services'' as services provided by or under the personal supervision of a physician. Therefore, we concluded that, in light of the important role of these practitioners in delivering primary care to Medicaid beneficiaries and the regulatory definition of a ''physician service,'' those services delivered under the personal supervision of a specified primary care physician could qualify for the increased payment. This means that specified primary care services rendered by non physicians such as advanced practice nurses and other mid-level professionals qualify for payment when billed under the Medicaid enrollment number of any designated primary care specialist or subspecialist.

Due to the limited data available, we are unable to accurately estimate the impacts representing the inclusion of services provided by practitioners under the supervision of a physician. All such services are billed under the supervising physician's billing number and are reported as physician services to CMS making it impossible to determine the impact of this proposal.

We also considered whether services provided by physicians in settings such as FQHCs, RHCs, or clinics would be eligible for increased payment. In Medicaid ''physician services'' is a distinct benefit from other benefits such as the FQHC, RHC or clinic benefits. We believe that the statute limits payment to physicians who, if Medicare providers, would be reimbursed using the MPFS. The MPFS is not used to reimburse physicians in settings such as FQHCs and RHCs and we believe that enhanced payment should not be extended to physicians under other Medicaid benefit categories. Furthermore, the Medicaid statute already requires that FQHCs and RHCs be reimbursed at cost.

We estimate that the inclusion of services provided by physicians in settings such as FQHCs, RHCs, or clinics for increased payment would result in an aggregate Federal cost of approximately $820 million for CYs 2013 and 2014. The limitations of this impact estimate to more accurately reflect clinic participation include, (1) determining whether the services provided in the various clinic types are in fact performed by a qualifying physician, and (2) determining the direct link between Medicaid clinic payment rates, as they vary substantially across codes and states, and Medicaid physician rates.

3. Eligible E&M Services

The statute requires enhanced payment for E&M services/codes. The proposed rule specifies the E&M Codes eligible for the increased payment. They include all primary care E&M codes, including some codes not recognized for payment by Medicare. Because the statute requires payment at the Medicare rate, we considered not extending the requirement for increased payment to codes not reimbursed by Medicare. However, many of those codes represent services provided to children. While Medicare covers relatively few children, payments for services provided to children constitute a larger proportion of Medicaid expenditures. We therefore include these additional codes because they represent core primary care services that are important to the Medicaid program.

We estimate that approximately 6 to 7 percent of all expenditures on services eligible for the increased payment rates are for services not covered by Medicare. Furthermore, we believe that a corresponding amount of the Federal costs associated with this proposed regulation would be related to these services, reflecting an impact range of $670 million to $780 million over the two CYs 2013 and 2014.

The eligible codes are listed in the regulatory text. We propose to set rates for codes not covered by Medicare based on a calculation of the CF and RVUs that are published by CMS. We establish RVUs based on recommendations from the AMA RUC and clinical review by Medicare. We considered setting rates for these codes by looking at rates paid by Medicare for comparable services. However, each code is designed to represent a distinct service and we could not find codes that we were comfortable substituting on a one for one basis for purposes of rate setting. We seek comment on the proposed rate setting methodology for codes not reimbursed by Medicare.

4. Eligible Vaccine Administration Services

The statute specifies payment at the CY 2013 and 2014 Medicare rate for certain vaccine administration billing codes or their successor codes. A State may receive 100 percent FMAP for the difference between the Medicaid rate as of July 1, 2009 and the Medicare rates in CYs 2013 and 2014 or the rate using the CY 2009 CF, if higher. In 2011, the coding structure for vaccine administration changed such that two codes replaced four of the specified codes. Moreover, the four deleted codes represented vaccine administrations by various routes (e.g., intranasal vs. injectable) to children under 8. However, new code 90460 represents the initial vaccine/toxoid administered through all routes to children under 18 while code 90461 represents payment for additional vaccines/toxoids administered. This rule proposes a method for imputing a vaccine administration rate in 2009 for code 90460. The proposed 2009 would equal the average payment amount weighted by volume of the four codes used in 2009. The 2009 value for code 90461 would be $0, since there was no payment for additional vaccines/toxoids prior to 2011. We seek comment from States and other stakeholders on this proposed methodology.

In 2009, approximately 20 States used a bundled rate to reimburse vaccines and vaccine administration, complicating the identification of the rate differential. This rule clarifies that, for any bundled rate payments such as this, States must correctly identify the rate differential for the included primary care service only (in this case,

vaccine administration). We added this provision in the interest of promoting program payment integrity but defer to the States to develop a methodology.

In this rule, we propose that providers administering vaccines under the VFC program be reimbursed the lesser of the Medicare rates in 2013 or 2014 or the Regional Maximum Administration Fee per vaccine, with no payment for additional vaccine/toxoid components. We considered proposing that States be required to pay VFC physicians for vaccine administration associated with the VFC program the amounts required by sections 1902(a)(13)(c) and 1932(f) of the Act, notwithstanding limitations on provider billing for vaccine administration under the VFC program. Free vaccine is made available through the VFC program to ''program registered providers'' who have entered into a VFC provider agreement. Under section 1928(c)(2)(C)(ii) of the Act, one of the requirements of that agreement is that program registered providers limit administration fees to an amount that ''does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration).''

This rule would not have changed the statutory requirement in section 1928(c)(2)(C) of the Act that a qualified physician administering a vaccine obtained from the VFC program is limited under the VFC provider agreement to charging an amount for vaccine administration that is no more than the VFC maximum allowable charge. However, we considered proposing that States comply with the requirements of sections 1902(a)(13)(c) and 1932(f) of the Act and pay the designated Medicare amount despite the fact that this amount might have been higher than the amount that was billed by the provider. To meet this requirement we considered proposing that States re-price vaccine administration billing codes, resulting in payment equal to the applicable Medicare-based rate.

We considered this alternative to fully reflect the requirement in section 1202 of the HCERA that Medicaid payment for primary care services be not less than the MPFS payment rate. While Medicare provider payment is limited to the lesser of provider charges or the fee schedule amount, we considered that allowing provider payment to exceed provider charges in this instance could be allowable in order to achieve the objectives of sections 1902(a)(13)(c) and 1932(f) of the Act. We also considered proposing that VFC providers account for the payment in excess of the billed amount as a Medicaid receipt for vaccine administration and that they ensure that it was not considered as an increase in the billed amount, or as a credit toward either the beneficiary account or toward payment for other services.

The primary benefit of this alternative is higher reimbursement for vaccine administration fees associated with the VFC program. Although the VFC ceilings have not been modified since 1994, the majority of States have paid for vaccine administrations at rates well below the ceilings. For example, California's maximum rate was $17.55, but the State paid $9.00. Approximately five States reimbursed vaccine administration fees within close proximity to the ceiling. Medicare's 2011 reimbursement rate for the first vaccine was $23.10 and for subsequent vaccines was $11.55. Therefore, we believe that requiring VFC administrations be reimbursed at the Medicare rate will help to ensure adequate compensation for VFC providers. However, we were concerned about the potential Federal budget impact of this proposal, with initial estimates indicating a potential cost impact of approximately $970 million over CYs 2013 and 2014, and the administrative burden it would place on States to reprice claims for these services.

We also considered whether the requirements of the VFC statute preclude application of sections 1902(a)(13)(c) and 1932(f) of the Act to vaccine administration under the VFC program. However, this would mean that participating providers would be limited to the State-specific VFC rates in the Medicaid State plan as well as to payment per vaccine administered.

Another alternative was to require payment at the DHHS VFC regional maximum fee schedule amount but to also require reimbursement for each vaccine/toxoid administered. This would comply with VFC requirements that providers charge no more than the regional maximum amount, but would permit providers to benefit from the coding change that requires payment per vaccine/toxoid administered.

We recognize the complexity of the issues surrounding the interplay of the VFC statutory requirements and the requirements of the Affordable Care Act and specifically request comment on these proposals.

5. Method of Payment

Section 1902(a)(13)(C) of the Act requires payment in CYs 2013 and 2014 of the current Medicare rate, unless the rate set using the CY 2009 CF was higher. Historically, Medicare has issued multiple updates to its MPFS within a single year.

Based on input from States, and to assure the feasibility of implementation, we propose to permit States the option to either adopt the MPFS in effect at the beginning of CYs 2013 and 2014 or the rate using the CY 2009 CF, if higher or a methodology to update rates to reflect changes made my Medicare during the year. If the State chooses to reflect changes made by Medicare, the methodology for those updates must be specified. States would be required to use the MPFS applicable to the place of service and geographic location. We considered requiring States to make changes throughout the year, as Medicare changed its MPFS. However, our proposal to permit States to use a single version of the MPFS reflects extensive comment received from States concerned about balancing the need for administrative ease with meeting the requirements to make this payment.

We also propose that payment not be made inclusive of Medicare's incentive payment as authorized under section 5501(a) of the Affordable Care Act. We considered defining the Medicare ''rate'' as being inclusive of the incentive payments. However, the Medicare incentive payments are supplements made to specific providers based on total Medicare allowed charges and do not represent increases to the MPFS rates for specific CPT codes. Moreover, even if the same providers qualified for both the Medicare incentive payment and this Medicaid payment, it would be administratively difficult for State Medicaid agencies to determine the Medicare ''rate'' for purposes of the increased Medicaid payment since States do not have access to Medicare payment data.

For the purpose of identifying the differential between the Medicaid rate and the Medicare rate, this proposed rule would define the Medicaid ''rate'' under the approved Medicaid State plan as the final rate paid to a provider inclusive of all supplemental or enhanced payments made to that provider. For example, many States reimburse physicians affiliated with academic medical centers the Medicaid State plan rate plus a supplemental amount that together equal the average amount paid by commercial third party payers. Therefore, in calculating the rate differential, these States would determine the CY 2009 Medicaid rate inclusive of this type of supplemental payment. We considered not defining ''rate'' but, recognizing the wide variety of ways in which States characterize their payments, we chose to make this

clarification to promote uniform and fair implementation of this payment.

6. VFC Administration Fee Increase

We considered a number of options when determining to update the average national administration charge portion of the formula used to calculate the VFC administration fee. These options included using the Medicare Economic Index (MEI), Consumer Price Index (CPI) or the Gross Domestic Product Deflator. We have determined the best option is to utilize the MEI, which is a price index used by CMS to update Medicare physician payments. The MEI reflects input price inflation experienced by physicians inclusive of the time period when the national average was established in 1994. Therefore, we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices.

The overall economic impact, as a result of this proposed rule announcing updates to the regional maximum charges for the VFC program for use on an interim basis, is estimated at $75 million per year. The Federal cost of this total is approximately $45 million per year. These estimates assume that every State would increase its reimbursement rate to the new VFC maximum fee.

F. Accounting Statement and Table

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb//circulars_a004_a-4/*), in Table 5 we have prepared an accounting statement illustrating the classification of the Federal and State expenditures associated with this proposed rule.

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS DURING CALENDAR YEARS 2013 THROUGH 2014

[Millions of 2012 dollars]

Category	Transfers		
Annualized monetized transfers	Discount rate		Period covered
	7%	3%	
Primary Estimate	$5,846	$5,848	CYs 2013–2014
From/To	Federal Government to Medicaid Providers.		
Primary Estimate	−$261	−$262	CYs 2013–2014
From/To	State Governments to Medicaid Providers.		

List of Subjects

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

1. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 438.6 is amended by adding new paragraphs (c)(3)(v) and (c)(5)(vi) to read as follows:

§ 438.6 Contract requirements.

* * * * *

(c) * * *

(3) * * *

(v) For rates covering CYs 2013 and 2014, complying with minimum payment for physician services under paragraph (c)(5)(vi) of this section, and part 447, subpart G, of this chapter.

* * * * *

(5) * * *

(vi) For CYs 2013 and 2014, and payments to an MCO, PIHP or PAHP for primary care services furnished to enrollees under part 447, subpart G, of this chapter, the contract must require that the MCO, PIHP or PAHP meet the following requirements:

(A) Make payments to those specified physicians (whether directly or through a capitated arrangement) at least equal to the amounts set forth and required under part 447, subpart G, of this chapter.

(B) Provide sufficient documentation to the State, as determined by the State, regarding the amount provider payments increase as a result of meeting the requirement of paragraph (c)(5)(vi)(A) of this section.

* * * * *

3. Section 438.804 is added to read as follows:

§ 438.804 Primary care provider payment increases.

(a) For MCO, PIHP or PAHP contracts that cover calendar years 2013 and 2014, FFP is available at an enhanced rate of 100 percent for the portion of the expenditures for capitation payments made under those contracts to comply with the contractual requirement under § 438.6(c)(5)(vi) only if the following requirements are met:

(1) The State makes a reasonable estimate of the increased amounts paid for specified primary care services provided by eligible primary care physicians resulting from the contractual requirement under § 438.6(c)(5)(vi), based on information received from the managed care provider for services furnished as of July 1, 2009.

(2) The State develops a methodology for identifying the differential in payment between the provider payments that would have been made by the managed care provider on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi).

(3) The State must submit the methodology in paragraph (a)(2) of this section to CMS for approval before the beginning of CY 2013.

(b) [Reserved]

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

4. The authority citation of part 441 is revised to read as follows:

Authority: Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

5. Subpart K is added to read as follows:

Subpart K—Vaccines for Children Program

Sec.

Subpart K—Vaccines for Children Program

§ 441.500 Basis and purpose.

This subpart implements sections 1902(a)(62) and 1928 of the Act by requiring States to provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children.

§ 441.505 General requirements.

(a) Federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

(1) Eligible for Medicaid.

(2) Not insured.

(3) Not insured with respect to the vaccine and who are administered pediatric vaccines by a federally qualified health center (FQHC) or rural health clinic.

(4) An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

(b) Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that meets the following requirements:

(1) Is licensed or authorized to administer pediatric vaccines under the law of the State in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

(2) Submits to the State an executed provider agreement in the form and manner specified by the Secretary.

(3) Has not been found, by the Secretary or the State to have violated the provider agreement or other applicable requirements established by the Secretary or the State.

§ 441.510 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of this subpart.

§ 441.515 Administration fee requirements.

(a) Under the VFC Program, a provider who administers a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine.

(1) A provider can impose a fee for the administration of a qualified pediatric vaccine as long as the fee does not exceed the costs of the administration (as determined by the Secretary based on actual regional costs for the administration).

(2) A provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

(b) The Secretary must publish each State's regional maximum charge for the VFC program, which represents the maximum amount that a provider in a State could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC program.

(c) An interim formula has been established for the calculation of a State's regional maximum administration fee. That formula is as follows: National charge data x updated geographic adjustment factors (GAFs) = maximum VFC fee.

(d) The Medicaid Agency must submit a State plan amendment that identifies the amount that the State will pay providers for the administration of a qualified pediatric vaccine to a Medicaid-eligible child under the VFC program. The amount identified by the State cannot exceed the State's regional maximum administration fee.

(e) Physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the State has established a lower administration fee under the Medicaid program. However, there would be no Federal Medicaid matching funds available for the administration since these children are not eligible for Medicaid.

PART 447—PAYMENTS FOR SERVICES

6. The authority citation for part 447 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

7. Subpart G is added to read as follows:

Subpart G—Payments for Primary Care Services Furnished by Physicians

Sec.

Subpart G—Payments for Primary Care Services Furnished by Physicians

§ 447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

(a) States pay for services furnished by a physician as defined in § 440.50 of this chapter, or under the personal supervision of a physician who self-attests to a specialty designation of family medicine, general internal medicine or pediatric medicine or a subspecialty recognized by the American Board of Medical Specialties and is verified by the Medicaid agency as meeting one of the following requirements:

(1) Is Board certified with such a specialty or subspecialty.

(2) Has furnished evaluation and management services and vaccine administration services under codes described in paragraph (b) of this section that equal at least 60 percent of the Medicaid codes billed during the most recently completed CY.

(3) For physicians who do not have 12 months of paid Medicaid claims history, data on codes billed must be reviewed from the date of enrollment through the end of the enrollment CY.

(b) Primary care services designated in the Healthcare Common Procedure Coding System (HCPCS) are as follows:

(1) Evaluation and Management (E&M) codes 99201 through 99499.

(2) Current Procedural Terminology (CPT) vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474, or their successor codes.

§ 447.405 Amount of required minimum payments.

(a) For CYs 2013 and 2014, a State must pay for physician services described in § 447.400 based on the lesser of:

(1) The Medicare Part B fee schedule rate that is applicable to the site of service and geographic location of the service of, if there is no applicable rate the rate specified in a fee schedule established and announced by CMS (that is, the product of multiplying the

Medicare CF in effect at the beginning of CYs 2013 or 2014 (or the CY 2009 CF, if higher) and the CY 2013 and 2014 relative value units (RVUs).

(2) The provider's actual billed charge for the service.

(b) For vaccines provided under the Vaccines for Children Program in CYs 2013 and 2014, a State must pay the lesser of:

(1) The Regional Maximum Administration Fee; or,

(2) The Medicare fee schedule rate in CY 2013 or 2014 (or, if higher, the rate using the 2009 conversion factor and the 2013 and 2014 RVUs) for code 90460.

§ 447.410 State plan requirements.

The State must amend its plan to reflect the increase in fee schedule payments in CYs 2013 and 2014 unless, for each of the billing codes eligible for payment, the State currently reimburses at least as much as the higher of the CY 2013 and CY 2014 Medicare rate or the rate that would be derived using the CY 2009 conversion factor and the CY 2013 and 2014 Medicare relative value units (RVUs).

§ 447.415 Availability of Federal financial participation (FFP)

(a) For primary care services furnished by physicians specified in § 447.400, FFP will be available at the rate of 100 percent for the amount by which the payment required to comply with § 447.405 exceeds the Medicaid payment that would have been made under the approved State plan in effect on July 1, 2009.

(b) For purposes of calculating the payment that would have been made under the approved State plan in effect on July 1, 2009, the State must consider all supplemental and increased payments made for the individually billed codes, including any incentive payments and other supplemental payment in effect at that time.

(c) For vaccine administration, the State must impute the payment that would have been made under the approved Medicaid State plan in effect on July 1, 2009 by calculating the average payment for codes 90465, 90466, 90467 and 90468 weighted by volume.

(d) For any payment made under a bundled rate methodology, including bundled rates for vaccines and vaccine administration, the amount directly attributable to the applicable primary care service must be isolated for purposes of determining the availability of the 100 percent FFP rate.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.)

Dated: April 17, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 18, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–11421 Filed 5–9–12; 11:15 a.m.]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[WO–300–L13100000.FJ0000]

RIN 1004–AE26

Oil and Gas; Well Stimulation, Including Hydraulic Fracturing, on Federal and Indian Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) is proposing a rule to regulate hydraulic fracturing on public land and Indian land. The rule would provide disclosure to the public of chemicals used in hydraulic fracturing on public land and Indian land, strengthen regulations related to well-bore integrity, and address issues related to flowback water. This rule is necessary to provide useful information to the public and to assure that hydraulic fracturing is conducted in a way that adequately protects the environment.

DATES: Send your comments on this proposed rule to the BLM on or before July 10, 2012. The BLM need not consider, or include in the administrative record for the final rule, comments that the BLM receives after the close of the comment period or comments delivered to an address other than those listed below (see **ADDRESSES**). If you wish to comment on the information collection requirements in this proposed rule, please note that the Office of Management and Budget (OMB) is required to make a decision concerning the collection of information contained in this proposed rule between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it by June 11, 2012.

ADDRESSES: *Mail:* U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134 LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004–AE26. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions at this Web site.

Comments on the information collection requirement: *Fax:* Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Desk Officer for the Department of the Interior, fax 202–395–5806. *Electronic mail: oira_docket@omb.eop.gov*. Please indicate ''Attention: OMB Control Number 1004–XXXX,'' regardless of the method used to submit comments on the information collection burdens. If you submit comments on the information collection burdens, please provide the BLM with a copy of your comments, at one of the addresses shown above.

FOR FURTHER INFORMATION CONTACT: Steven Wells, Division Chief, Fluid Minerals Division, 202–912–7143 for information regarding the substance of the rule or information about the BLM's Fluid Minerals Program. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Executive Summary

''Hydraulic fracturing,'' a process used to stimulate production from oil and gas wells, has been a growing practice in recent years. Public awareness of fracturing has grown as new horizontal drilling technology has allowed increased access to shale oil and gas resources across the country, sometimes in areas that have not previously experienced significant oil and gas development. The extension of the practice has caused public concern about whether fracturing can allow or cause the contamination of underground water sources, whether the chemicals used in fracturing should be disclosed to the public, and whether there is adequate management of well integrity and the ''flowback'' fluids that return to the surface during and after fracturing operations.

The Bureau of Land Management (BLM) oversees approximately 700 million subsurface acres of Federal