

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 438, 441, and 447****[CMS-2370-F]****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:** Final rule.

SUMMARY: This final rule 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. 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 rendered by these provider types paid by Medicaid managed care plans contracted by states to provide the primary care services. It also provides for 100 percent federal financial participation (FFP) for any increase in payment above the amounts that would be due for these services under the provisions of the approved Medicaid state plan, as of July 1, 2009. In other words, there will not be any additional cost to states for payments above the amount required by the 2009 rate methodology. In this final 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 final rule will 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: The provisions of this final rule are effective on January 1, 2013.

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:**I. Executive Summary and Background***A. Executive Summary***1. Purpose**

This final rule implements sections 1902(a)(13), 1902(jj), 1905(dd) and 1932(f) of the Social Security Act directing 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 final rule implements the statutory payment provisions uniformly across all states and 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 rule provides general guidelines for implementing the increased payment for primary care services delivered by managed care plans.

This final rule also provides updates to vaccine rates that have not been updated since the VFC program was established in 1994.

2. Summary of the Major Provisions**a. Payments to Physicians for Primary Care Services**

This final rule will 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 will be applicable in those CYs using the CY 2009 conversion factor (CF). It will also provide for a 100 percent federal matching rate for any increase in payment above the amounts that were due for these services under the provisions of the state plan as of July 1, 2009. In other words, there will not be any additional cost to states for payments above the amount required by the 2009 rate methodology.

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

This final rule updates the 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. The formula used to determine the updated rates used the Medicare Economic Index (MEI) which is a price index used by CMS as part of the updates to 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 final rule is an estimated \$5.600 billion in CY 2013 and \$5.745 billion in CY 2014 (in constant 2012 dollars). In CY 2013, the federal cost for Medicaid and CHIP is approximately \$5.835 billion with \$235 million in state savings. In CY 2014, the federal cost for Medicaid and CHIP is approximately \$6.055 billion with \$310 million in state savings. The associated impact of this final 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 \$975 million in federal costs. Specifically, this reflects federal costs for CYs 2013 and 2014 of \$495 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.

Provision description	Total costs	Total benefits
Increase in Vaccines for Children Program Maximum Administration Fee.	This rule updates the maximum rate that states could pay providers for the administration of vaccines under the VFC program in years after CY 2014. While states have the flexibility to raise their VFC ceilings up to the new regional maximum administration fee, they are not anticipated to do so in 2013 and 2014 because of the implementation of the primary care payment increase. If all states were to increase their reimbursement rates to the updated maximum administration fee, it is estimated that the total economic impact would be \$75 million per year.	The overall benefit of this provision is that it gives states the ability to increase their VFC vaccine administration rates. We expect that this increase will help maintain provider participation in the VFC program.

B. 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 final rule will implement sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Social Security 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 will 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 beneficiaries, to establish a regular source of care and to provide services to a group 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 a state's 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 Medicaid program. Section 1902(a)(13) of the Act is intended to encourage primary care physicians to

participate in Medicaid by increasing payment rates in CYs 2013 and 2014.

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 a range of Medicaid services 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). According to the Medicaid and CHIP Payment and Access Commission (MACPAC), 49 million Medicaid beneficiaries receive services through some form of Medicaid managed care. 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.

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 will apply using the CY 2009 Medicare CF. The directive 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 on a capitated or other basis by Medicaid managed care plans. This regulation will 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 higher FFP for the required increase in physician payment for services provided on a fee for service basis and through managed care arrangements. The FFP rate will be 100 percent for 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, or by application, under section 1932(f). That means that, unless a state has reduced its rates since 2009, it will be fully reimbursed for these increased payments by the federal government.

One goal of this rule is to define the payment provisions further so that states may uniformly identify the rate differential. Specifically, we proposed a payment methodology that took 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 final rule will 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 proposed 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 also proposed 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 solicited comments on how best to implement through regulation the provision that managed care plans pay primary care providers at the Medicare rate for primary care services, consistent with those paid on a FFS basis. Additionally, we solicited comments from states and other stakeholders 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 were 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 proposed to review managed care contracts to ensure that this requirement is imposed on managed care plans by the state. We also proposed 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 were mindful of balancing the need for adequate documentation of the payment with the administrative burden it places on states and managed care plans. We requested 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 final 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 requested 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, people with disabilities or people 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 geographic practice cost indices (GPCIs) for geographic variations in payments, and a global CF, which converts relative value units (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.

This regulation updates the administration fee for the first time since the VFC program began in 1994. We requested comments on the methodology used to calculate the administration fee update as well as the impact of the updated administration fee on uninsured and underinsured VFC-eligible children.

II. Summary of Proposed Provisions and Analysis of and Response to Public Comments

On May 11, 2012, we published a proposed rule (77 FR 27671) in the **Federal Register** entitled "Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration under the Vaccines for Children Program."

We received a total of 171 comments from states, advocacy groups, health care providers, employers, health insurers, health care associations, as well as individual citizens. The comments ranged from general support for the proposed provisions to specific questions or comments regarding the proposed changes.

The following are brief summaries of each proposed provision, summaries of the public comments received, and our responses to those public comments:

General Comments

Comment: Several commenters questioned whether the provisions of this rule apply to services paid under the Children's Health Insurance Program (CHIP). CHIP programs can be structured as expansions of the state's Medicaid program, as separate CHIP programs, or as a combination of a Medicaid expansion program and a separate CHIP program.

Response: The statute applies to fee for service and managed care payments made for services provided to Medicaid beneficiaries. Therefore, this rule applies only to CHIP Medicaid expansion programs since beneficiaries in such programs are Medicaid-eligible. CHIP stand-alone programs are not eligible for 100 percent FFP and physicians providing services to children in those programs are not eligible for higher payment at the Medicare rate by operation of these rules. At state option, states may align their CHIP payment rates for primary care providers with these Medicaid payment provisions.

Comment: Many commenters suggested that the rule be modified to specifically require that states collect and report to CMS data that would help the Congress determine whether or not to extend the provision beyond 2014.

Response: We agree and have revised § 447.400(d) accordingly, as described below.

Comment: Many commenters believe that the budget impact estimates underestimate the time and resources for states to undertake the significant coding and related systems work, conduct the necessary analyses and develop policies, implement the regulation as part of regular operations and maintain compliance with the regulation as proposed in the proposed rule.

Response: We are sensitive to state concerns about the difficulty of implementing some of the provisions of the proposed rule and have modified this final rule to limit the administrative burden on states to the extent possible. We will also provide technical assistance to states as they implement the requirements of this rule to help minimize the administrative burden.

Comment: Several commenters stated that the proposed rule is contrary to current state and federal efforts to incentivize the entire health care delivery system to move away from volume-based reimbursement and would force states to relinquish savings in Medicaid efficiencies that have already been put into place. One commenter disagreed with our determination that each individual service code must be reimbursed at the Medicare payment level and believed that states should be permitted to increase total payments in the aggregate, with flexibility to determine how those payments are distributed. The commenter recommended that, at a minimum, a value-based option for implementing the increase be added to the final rule. Several commenters suggested that the final rule permit states to develop methodologies to calculate the aggregate value of the primary care rate increase across all qualified providers and services and to use non fee for service payment mechanisms to deliver that aggregate increase equitably to eligible providers.

Response: The statute requires that state plans provide for “payment for primary care services * * * at a rate not less than 100 percent of the payment rate that applies to such services and physicians under part B of title XVIII * * *.” Since the Medicare payment rate reimburses services individually, we continue to believe that this language precludes aggregated payments

not specific to the service and physician. However, this does not preclude states from creating incentive payments or penalties based on performance measures. While we believe the Congress intended the payment levels to rise to Medicare payments, there is no prohibition on states having incentives/penalties external to the rates under traditional fee-for-service or managed care delivery systems.

Comment: One commenter asked about the applicability of the rule to services provided under section 1115 demonstration waivers.

Response: This final rule implements the statutory payment provisions uniformly across the states regardless of the authority under which a state’s Medicaid program operates. Specified primary care services delivered by eligible primary care physicians must be reimbursed at the enhanced rate. We intend to continue a dialogue with states with waivers through the implementation process.

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. We proposed that services provided by subspecialists within the primary care categories designated in the statute would also qualify for higher payment. These subspecialists would be recognized in accordance with the American Board of Medical Specialties (ABMS) 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 pediatric medicine. Additionally, we proposed a method for states to use in identifying practitioners who may receive the increased payment.

Under the proposed rule, states were required to establish a system to require physicians to identify to the Medicaid agency their specialty or subspecialty before an increased payment was made. For program integrity purposes, the state would be required to confirm the self-attestation of the physician before paying claims from that provider at the

higher Medicare rate. We proposed that this be done either by verifying that the physician was Board certified in an eligible specialty or subspecialty or through a review of a physician’s practice characteristics.

Specifically, for a physician who attested that he or she was an eligible primary care specialist or subspecialist but who was not Board certified (including those who are Board-eligible, but not certified), we required that a review of the physician’s billing history be performed by the Medicaid agency. We proposed that at least 60 percent of the codes billed by the physician for all of CY 2012 be for the E&M codes and vaccine administration codes specified in this regulation. For a new physician who enrolled during either CY 2013 or CY 2014 and who attested that he or she was within one of the eligible specialties or subspecialties and who was not Board certified we proposed 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.

Comment: Most commenters supported the inclusion of subspecialists. However, some commenters requested that CMS permit payment for subspecialists recognized by Boards outside of the ABMS, pointing out that other Boards are just as relevant. In particular, commenters noted that osteopaths, who are recognized as physicians under Medicaid regulations, are licensed by their own specialty Board and are excluded under the provisions of the proposed rule.

Response: We agree and have revised the rule to include physicians recognized by the American Board of Physician Specialties (ABPS) and the American Osteopathic Association (AOA), as well as the American Board of Medical Specialties. These are the major, nationally recognized physician Boards.

Comment: Many commenters disagreed with the inclusion of subspecialists. The commenters stated that the proposed rule would create disincentives for delivery of primary care services in the most appropriate settings, and posed a “threat” with regard to states’ ability to meet the statutory requirements of section 1902(a)(30) of the Act, which requires that payments under the state plan be consistent with economy, efficiency and quality of care. The commenters stated

that the proposal would add 44 additional specialty designations to the list of physicians eligible to receive higher payments without a “rational” correlation to the subspecialists that do, or that might as a result of the temporary payment increase, deliver primary care. Commenters believed that this provision of the proposed rule would actually work against an expansion in true primary care.

One commenter stated that states will not be able to sustain increased payment after 2014 because the proposed rule would result in payments that are so widely distributed across the delivery system as to make the impact of the increase extremely difficult to evaluate. This, in turn, would hamper states’ ability to demonstrate cost savings necessary to gain approval from their legislatures for continued higher payment.

One commenter noted that CMS said it was particularly swayed by arguments that pediatric subspecialists provide primary care services in deciding to extend higher payment to all subspecialists. The commenter believes that the absence of a justification for including subspecialists does not lead to the conclusion that all subspecialists should be included. Rather, the decision to expand to other subspecialists should be based on an analysis of whether increasing payment rates is likely to improve access to primary care services for Medicaid beneficiaries. Since states are in the best position to make that assessment, the commenter urged CMS to permit states the flexibility to determine which approach best meets the needs of its beneficiaries.

Several commenters were concerned that including subspecialists will add “unwarranted” costs. The commenters encouraged CMS “to adhere more closely to the intent of the law and only qualify true primary care physicians for this increased payment.” Several stated that the regulation exceeds the authority granted in the Affordable Care Act, which they believed limits the categories of providers to physicians with specialty designations of family medicine, general internal medicine, or pediatric medicine.

Response: We continue to believe that the statute supports inclusion of subspecialists related to the three specialty categories designated in the statute and disagree that extending payments to subspecialists will dilute the impact of the regulation on Medicaid beneficiary access to primary care or result in “unwarranted” costs. The American Academy of Pediatrics cited the importance of pediatric subspecialists, particularly

neonatologists, as a source of primary care services. The Web site of the American Academy of Family Physicians notes that primary care services can be delivered outside an office setting and that physicians who are not trained in the primary care specialties of family medicine, general internal medicine or general pediatrics may sometimes provide patient care services that are usually delivered by primary care physicians. This rule only provides for higher payment to subspecialists to the degree that they actually furnish the E&M codes specified in the regulation and, consequently, will not result in costs that are for services that are not properly considered primary care. Therefore, we continue to believe that all subspecialists related to the three specialty categories designated in the statute should be eligible for higher payment to the extent that they provide covered E&M services.

Comment: Other commenters indicated that the proposed rule, while properly recognizing E&M codes provided in emergency departments, unfairly excluded the majority of emergency physicians who are either not Board certified or are certified in emergency medicine. Other commenters urged that obstetricians and gynecologists (OB/GYNs) be included because of the important role they play in providing primary care to women.

Response: The statute provides for higher payment of services furnished by “a physician with a primary specialty designation of family medicine, general internal medicine or pediatric medicine.” Therefore, although we recognize the role that other specialty physicians play in providing primary care services, the authority does not exist to extend the payment to other categories of physicians, including OB/GYNs.

Comment: While some commenters strongly supported the proposed rule requirements that Medicaid agencies verify self-attestations with evidence of Board certification or practice history (60 percent of codes billed in a prior period were to be for E&M codes specified in the proposed rule), others cited both requirements as administratively burdensome and as requiring major and costly modifications to state processes and systems. They indicated that states have different enrollment and claims processing capacity and may not be able to identify all provider subspecialties or reimburse a different rate by subspecialty. Commenters suggested that states be permitted to use their existing enrollment processes, usually

self-attestation alone, to identify which physicians qualify for payment, or to be permitted to use Medicare’s NPI designation, which is also based on self-attestation. One commenter suggested that self-attestation could be verified with a random audit by the Medicaid agency.

Some commenters stated that permitting self-attestation to be verified with evidence of Board certification alone creates an inequity. This is because many traditional primary care providers who are not Board certified and do not reach the 60 percent threshold of E&M codes billed will be excluded from increased payment in favor of subspecialists who provide relatively few primary care services.

One commenter disagreed with our decision to base the 60 percent claims verification threshold on the Medicare primary care incentive program threshold, stating that the Congress could have imposed a similar requirement on Medicaid, but did not. They do not believe it is appropriate to designate any threshold of claims verification. They also suggested permitting non-Board certified physicians to qualify if they completed an approved residency in any of the three designated primary care physician specialties. Other commenters suggested using allowed charges as the threshold to parallel the Medicare primary care payment or services paid, rather than billed, asserting that data on rejected claims is not readily available.

One commenter suggested that states be permitted to define eligible physicians based on enrollment criteria for existing state primary care programs. Another commenter suggested that states be given flexibility to rely on methods that already exist within each state’s payment systems, such as requiring eligible providers to bill with a unique modifier.

One commenter also asked that we clarify procedures for the identification of qualifying out-of-state providers, suggesting that the home state’s verification be used.

Response: We agree that there is variation among states for provider enrollment procedures and Medicaid Management Information System (MMIS) capabilities. We acknowledge that many states have existing programs designed to increase the availability of primary care services and that those programs may differ from the provisions of the proposed rule. We also acknowledge that permitting self-attestation to be verified with evidence of Board certification alone creates an inequity in that Board certified physicians who provide few primary

care services will be eligible for higher payment while non-Board certified physicians who provide many primary care services but not enough to meet the 60 percent threshold will be excluded. We continue to believe that there must be uniform, auditable standards for the identification of eligible physicians and that Board certification and claims history are appropriate standards. However, we acknowledge the concerns regarding the significant administrative burden of this requirement. Therefore, this rule removes the requirement that the State Medicaid agency verify the self-attestation of all physicians by confirming Board certification or an appropriate claims history. Instead, this rule requires that physicians self-attest that they are either Board certified in family medicine, general internal medicine, or pediatric medicine or a subspecialty within those specialties or that that sixty percent of all Medicaid services they bill, or provide in a managed care environment, are for the specified E&M and vaccine administration codes. This rule also clarifies that states may defer to the state where the physician's practice is located with respect to a determination of a physician's eligibility for higher payment.

For the threshold itself, we often use Medicare program standards in developing policy for the Medicaid program, and we believe that it is appropriate to apply the 60 percent threshold applicable to the Medicare primary care incentive payment to the Medicaid payment as well.

Comment: One commenter suggested that the proposed § 447.400(a) be amended to add a subsection to define what is meant by self-attestation of a specialty or subspecialty designation.

Response: We believe that the meaning of self-attestation is generally understood in this context as both the states and managed care organizations credential providers. Therefore, we do not agree that an amendment to § 447.400(a) is necessary.

Comment: Commenters questioned whether the process for identifying eligible providers was the same across delivery systems and if states with MCOs, PIHPs or PAHPs could rely on the definition of primary care provider established through the managed care contract. Commenters suggested that the broad definition of primary care provider proposed by the proposed rule would reward providers that do not focus their practice on primary care.

Response: We recognize that the definition of a primary care provider under existing managed care contracts may, in some instances, be more or less

targeted than that proposed under this rule. The contract definition may also exceed the scope of those primary care physicians that qualify for this payment. However, section 1902(a)(13)(C) of the Act, as amended by the Affordable Care Act, specifies that physicians with a specialty designation of family medicine, general internal medicine, and pediatric medicine qualify as primary care providers for the purposes of the increased payment rate. The proposed rule clarified that qualified providers include subspecialists related to the three designated provider practice types. Therefore, we must require that the same approach apply to identifying eligible providers reimbursed under managed care delivery systems.

Comment: A commenter noted that some physicians have more than one identifier and asked if separate information on both identifications would be necessary if the physician receives differing rates based on the identification number used.

Response: This is an operational issue beyond the scope of this rule.

Comment: A commenter suggested that non-contracted providers that deliver primary care services to managed care enrollees that have a permissible out-of-network encounter should not be eligible for payment at the Medicare rate.

Response: We disagree. Section 1932(f) of the Act, as amended by the Affordable Care Act, requires that managed care contracts pay designated providers for the provision of designated services at the Medicare rate. Further, there are no exceptions made in the statute to the minimum payment requirement for services provided out of network. If a Medicaid beneficiary receives eligible services out-of-network from a provider covered by this rule, the reimbursement rate must also align with the requirements stated herein.

Comment: One commenter stated that not all subspecialists providing services through managed care delivery systems have the expertise to function as a primary care provider.

Response: This rule does not create new requirements for primary care providers. Rather, it assures payment of the Medicare rate for services that the subspecialist bills within the E&M and vaccine administration code range specified in the rule.

Comment: One commenter asked if the intent of the managed care payment is to include subspecialties such as otolaryngology, ophthalmology or urology and also stated that the payment should be limited to subspecialists that directly serve primary care needs.

Response: The intent of the managed care payment is to reimburse at the Medicare rate only those primary care subspecialists and related subspecialists designated in this rule and only for the E&M and vaccine administration code range specified in the rule.

Summary of Final Policy: This final rule provides for higher payment in both the fee for service and managed care settings to physicians practicing within the scope of practice of medicine or osteopathy with a specialty designation of family medicine, general internal medicine and pediatric medicine. It also provides for higher payment for subspecialists related to those specialty categories as recognized by the American Board of Medical Specialties, American Osteopathic Association and the American Board of Physician Specialties. Lists of specialists and subspecialists can be found at the respective Board Web sites which are: www.abms.org, www.osteopathic.org and www.abps.org. This rule removes the requirement that the state Medicaid agency verify the self-attestation of all physicians by confirming Board certification or an appropriate claims history. However, in the absence of an industry-wide definition of "primary care physician" we believe it is necessary to impose a uniform standard to identify such providers. Therefore, this rule requires that physicians self-attest that they are either Board certified in family medicine, general internal medicine, or pediatric medicine or a subspecialty related to those specialties or that 60 percent of all Medicaid services they bill, or provide in a managed care environment, are for the specified E&M and vaccine administration codes.

State Medicaid agencies may pay physicians based on their self-attestation alone or in conjunction with any other provider enrollment requirements that currently exist in the state. However, if a state relies on self-attestation it must annually review a statistically valid sample of physicians who have self-attested that they are eligible primary care physicians to ensure that the physician is either Board certified in an eligible specialty or subspecialty or that 60 percent of claims either billed or paid are for eligible E&M codes. In the case of services provided through a managed care delivery system, states will be given flexibility in the manner in which they perform this verification. We expect states to work with the health plans to determine an appropriate verification methodology.

We recognize that data may not be readily available on rejected claims, making services paid a more appropriate

threshold and either claims billed or claims paid can be used in the sample. This rule also clarifies that a state whose beneficiaries receive services from a physician in a neighboring state may accept the determination of eligibility for higher payment made by the physician's home state in making higher payment under this rule.

b. Services 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." The proposed rule specified 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 Federally Qualified Health Center (FQHC) or Rural Health Clinics (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." 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 noted that the Medicaid statute already provides a payment methodology for FQHCs and RHCs that is designed to reimburse those providers at the appropriate rate.

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 usually 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 proposed that primary care services 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 non physician practitioners working under the supervision of physicians have in the delivery of primary care services.

Comment: Most commenters supported the proposal to include practitioners working under the supervision of a physician, however they disagreed with the exclusion of those same practitioners when billing under their own Medicaid number. Numerous commenters urged CMS to include independently practicing certified nurse midwives, nurse practitioners, certified registered nurse anesthetists, clinical nurse specialists and other advanced practice nurses, as well as pharmacists, who often administer vaccines, as eligible practitioners on the grounds that they provide identical services to those provided by primary care physicians.

Some commenters urged CMS to extend increased payment to FQHCs and RHCs, pointing out their important role in the provision of primary care services in underserved areas. Several urged that services provided by other types of clinics and Health Departments be included and asked whether services provided by public health providers in those settings were eligible if billed by an eligible physician using his own National Provider Identifier (NPI). One commenter asked how primary care services reimbursed as part of a nursing facility per diem rate and billed under the nursing facility's Medicaid number would be reimbursed.

Response: The statute provides for higher payments for "primary care services furnished * * * by physicians with a primary specialty designation of family medicine, general internal medicine or pediatric medicine * * *."

Therefore, consistent with the statute, services provided by pharmacists or independently practicing nonphysician practitioners not under the supervision of an eligible physician are excluded. In addition, we continue to believe that eligible services are those reimbursed on a physician fee schedule. Services provided in FQHCs, RHCs and clinics and Health Departments, to the extent that they are reimbursed on an encounter or visit rate, are not eligible for higher payment, nor are services provided in nursing facilities that are reimbursed as part of the per diem rate.

Comment: A commenter noted that managed care contracts may require that FQHC and RHC services be paid at a level not less than that received by other providers under contract for the same scope of services, and that any increase to the FQHC or RHC service rate to account for enhanced payments to primary care providers under this rule should be eligible for 100 percent FFP. One commenter recommended that the final rule clarify that, if a state requires managed care organizations to increase payments to primary care providers in FQHCs, the state should make a corresponding adjustment in the plan's capitation rate in a transparent and timely fashion. An additional comment was made that FQHCs and RHCs should be eligible for higher payment under this rule, thereby reducing the managed care "wrap around" required by the prospective payment system (PPS).

Response: The increased payment for primary care services eligible for 100 percent federal matching funds is implemented as a physician payment under section 1905(a)(5) of the Act. This means that services delivered by physicians under another Medicaid benefit at section 1905(a) of the Act, such as FQHC services, are not subject to the higher payment requirement or eligible for enhanced federal matching funds. Managed care contractual payment arrangements for FQHCs and RHCs are unaffected by and beyond the scope of this rule.

Comment: One state asserted that the proposed rule unfairly treats comparable providers unequally based solely on their practice setting or enrollment status. That same commenter noted that precluding independently enrolled practitioners from receiving the enhanced reimbursement undermines the purpose of section 1902(kk) of the Act to improve data collection and program integrity by requiring "all rendering or referring physicians or other professionals to be enrolled under the state plan or under a waiver as a participating provider." In order to

comply, the state has been requiring independent enrollment of nonphysician practitioners, where possible under state law.

Many commenters expressed concern with the requirement that services be billed under the physician's billing number. They indicated that many states have billing and oversight policies and procedures designed to elicit desirable policy goals or analyses, but which will also make it administratively difficult for nonphysician providers to receive the higher Medicare rate. They also stated that some states require certain nonphysician providers to obtain and bill under their own provider number, even when being supervised by a physician, and that the definition of a physician at § 440.50 does not specify that services must be billed under the physician's number. Another commenter indicated that, in many situations, the billing entity is often a legal entity, not a practitioner. In the case of a group practice, the claim would most likely be billed under the practice number and not the physician's number.

Another commenter stressed that states have varying definitions of "physician supervision" and suggested that CMS defer to state rules on this point. Commenters suggested that CMS permit various kinds of arrangements or agreements between physicians and independently billing nonphysician practitioners so that primary care services such as those provided by nurse practitioners and physician assistants at commercial emergency facilities could receive increased reimbursement.

Response: We acknowledge the variation in billing practices and requirements among states. Therefore, this rule removes the requirement that services be billed under the physician's billing number. We also acknowledge that states have varying requirements with regard to services provided under the supervision of a physician. However, by specifying in the statute that services be furnished by physicians, we believe that the Congress clearly intended that there be direct physician involvement in the services provided. Therefore, while deferring to state requirements, this rule assumes a relationship in which the physician has professional oversight or responsibility for the services provided by the practitioners under his or her supervision. This precludes the types of arrangements in which independent nurse managed clinics or other practitioners enter into arms-length arrangements with physicians for purposes of establishing a relationship

that leads to higher payment of the practitioner services.

Comment: CMS was asked to clarify in the final rule that services provided by all advanced practice clinicians, including nurse midwives, providing services under the supervision of a physician will be eligible for higher payment.

Response: Eligible services provided by all advanced practice clinicians providing services within their state scope of practice under the supervision of an eligible physician will be eligible for higher payment. This includes those not specifically mentioned in the proposed rule, such as nurse midwives.

Comment: CMS was asked to clarify whether services provided by advanced practice clinicians under the supervision of a physician will be billed at 100 percent of the Medicare physician rate, or the practitioner rate, since many states reimburse services provided by supervised nonphysician practitioners at a percentage of the physician fee schedule rate.

Response: The statute provides for 100 percent FFP on the difference between the Medicaid rates paid as of July 1, 2009 and the applicable Medicare rates in CYs 2013 and 2014. Therefore, if the state plan in 2009 reimbursed services provided by nonphysician practitioners under the supervision of a physician at a percentage of the physician fee schedule rate, that same practice must be continued in CYs 2013 and 2014. If a state reimbursed all physician services at a single rate in 2009, it should continue to reimburse in that manner in CYs 2013 and 2014.

Summary of Final Policy: This rule provides for higher payment for services provided by eligible physicians reimbursed pursuant to a physician fee schedule. Higher payment is not available for physicians who are reimbursed through a FQHC, RHC or health department/clinic encounter or visit rate or as part of a nursing facility per diem rate.

This rule provides for higher payment for services provided under the personal supervision of eligible physicians by all advanced practice clinicians. In recognition of state efforts to enroll advanced practice clinicians in the Medicaid program and to require them to use their own Medicaid number, this rule removes the requirement that services be billed under the physician's billing number. However, it requires that the physician have professional oversight or responsibility for the services provided by the practitioners under his or her supervision. This rule also provides that the state reimburse

for services provided by advanced practice clinicians in 2013 and 2014 in the manner in which it reimbursed for those services as of July 1, 2009. If the state reimbursed for services actually rendered by supervised advanced practice clinicians at a percentage of the physician fee schedule rate, it should continue to do so in 2013 and 2014.

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

We proposed 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 will 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.

Specifically, we proposed 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.

Comment: Most commenters were supportive of the range of E&M codes identified for higher payment and of the inclusion of codes not reimbursed by Medicare. Two commenters suggested expanding the list of covered codes to include HCPCS "G" codes and two suggested permitting states to designate additional codes at their discretion. Two commenters suggested extending higher payment to all codes billed by a primary care pediatrician, pediatric subspecialist, or surgical specialist.

Some commenters stated that some of the codes identified by CMS are not viewed by the industry as constituting primary care. These include the following: Hospital Observation Care and Inpatient Consultation codes for inpatient services provided by the non-admitting physician (99217–99220, 99224–99226, 99251–99255, 99231–99233); Consultations (99241–99245, 99251–99255); Emergency Department Services (99281–99288); and Critical Care Services (99291–99292). Commenters stated that some are rendered in settings not known for primary care delivery such as intensive care units and emergency departments. They believe that inclusion of those

codes will encourage inappropriate utilization and result in increased health care costs overall. One commenter suggested limiting increased reimbursement to office-based services.

However, other commenters commended the inclusion of these same codes. They stated that these settings often are the point of first contact for primary care due to new injuries or lack of timely access to primary care services in the community.

Response: The statute identifies specific services according to HCPCS codes that will receive the increased payment. Accordingly, we are finalizing the list of codes specified in the proposed rule.

Comment: One state indicated that it is still using local codes rather than the E&M codes identified in this rule and asked for confirmation that services billed using those codes will be eligible for higher payment. It was suggested that states be permitted to provide CMS with a crosswalk of those local codes to the E&M codes they represent.

Response: We confirm that higher payment may be made for services billed using local codes. States will need to submit a crosswalk of those codes to the eligible E&M codes as part of the required implementing state plan amendment. However, this flexibility is limited to substitutes for covered E&M codes and does not extend to vaccine administration codes.

Comment: A number of states indicated that they do not reimburse for all of the codes in the specified E&M range and asked that CMS clarify that they are not required to do so for purposes of this rule. Other commenters suggested that states be required to pay for all codes specified in the regulation. Several commenters stated that all of the E&M codes specified in section 1902(jj) of the Act are not necessarily included in managed care contracts and questioned whether reimbursement of all E&M codes was a requirement under this rule.

One commenter stated that the definition of primary care services by CMS is broader than what is currently used by some MCOs and expressed concern that the rate adjustment will inadvertently fail to adjust for the scope in services.

Response: This rule clarifies that states need not pay for codes within the specified range that are not otherwise reimbursable under their Medicaid program and that managed care contracts need not be amended to specifically require coverage of previously non-covered codes. To that end, we do not anticipate an impact on the scope of primary care services

eligible for enhanced federal match under managed care delivery systems that would affect rate setting.

Comment: A commenter asked whether CMS intends for providers to be reimbursed at a higher rate for services provided through managed care irrespective of actual billed charges or if MCOs are required to utilize the Medicaid fee schedule in payment of providers and services designated in the rule.

Response: The statute requires providers to be reimbursed at the Medicare rate for primary care services when furnished by the qualified physicians and does not make exceptions for a situation where a provider may be charging less than the required amount. Therefore, no such exception is carved out for managed care payment. If a MCO reimburses a physician a fee schedule amount then the rate must be at least as much as the Medicare rate used for FFS payment. We intend to continue to work with the states regarding the identification of the 2009 baseline rate for eligible services and the rate differential eligible for 100 percent federal matching.

Comment: A number of states asked if the 2009 base rate for a code not reimbursed by the state in 2009, but currently reimbursed, would be \$0. This includes three codes (subsequent observation care) in the E&M code range which have been added since 2009.

Response: For new codes added to the E&M code range since 2009, we confirm that the 2009 rate would be \$0 and 100 percent FFP will be available for the entire payment. This is also true for other codes within the range not reimbursed by the state in 2009 but subsequently added to the fee schedule as covered codes. However, we do not expect states to make modifications to their code sets in 2013 or 2014 solely for the purpose of maximizing FFP. We will require that the state plan amendment submitted by the state providing for reimbursement under this rule list not only the codes for which higher payment will be available in 2013 and 2014 but that it specifically identify the codes which have been added since 2009 as well.

Comment: One commenter asked if states that reimburse the consultation codes reimbursed by Medicare in 2009 but not covered in 2013 and 2014 still will receive the enhanced federal match for these codes.

Response: States will receive 100 percent FFP for the payment differential for the difference in payment made for codes in effect in 2013 and 2014 and the base year. In general, a state will receive enhanced match for any code that it

reimbursed in the baseline period and in 2013 or 2014, even if the code is not reimbursed by Medicare. As stated earlier, we will develop Medicare-like rates in 2013 and 2014 for CPT codes not reimbursed by Medicare but recognized for reimbursement in the final rule.

Comment: A comment was made regarding the baseline for payment to out-of-state providers, in particular, that states and managed care organizations should be allowed to use statewide or "rest of state" rates to pay those providers for the provision of eligible primary care services.

Response: In setting the requirement for managed care payment the statute does not make an exception to permit out of state providers to be reimbursed at less than the minimum amount. Therefore, managed care contracts must assure such providers receive the Medicare FFS rate.

Comment: We received a number of comments about how states should be able to set the minimum payment in a managed care environment. Some commenters believed that payment should be consistent with the Medicare rate in the aggregate for the capitated group, while another urged us to permit states to implement a rate based on a multiple of the Medicare rate derived from using the state's average Medicaid fee schedule versus the Medicare schedule for the state. Another commenter asked whether we expect MCOs, PIHPs or PAHPs to unbundle payments to be able to track individual services.

Response: We do not specify in this rule how a state must meet the statutory requirement for payment at the Medicare rate under managed care delivery systems. Rather, the methodologies required under new § 438.804(a)(1) will need to identify the 2009 baseline rate and rate differential based on reasonable and documented data and assumptions available to the state. As stated throughout this rule, we will continue a dialogue with the states on these issues during the implementation process.

Summary of Final Policy: This rule requires state Medicaid agencies to reimburse at the applicable 2013 or 2014 Medicare rate for E&M codes 99201 through 99499 to the extent that those codes are covered by the approved Medicaid state plan or included in a managed care contract. The 2009 base rate for codes not covered in 2009 but subsequently added will be \$0. Services billed using local codes will be eligible for higher payment if the state Medicaid agency submits, as part of the required state plan amendment, a crosswalk of

those codes to the specified E&M codes. States will also be required to identify all codes in use and eligible for higher payment as well as those codes added since 2009 for which the base rate will be \$0. States will be given flexibility in developing a methodology to identify the base payment under managed care delivery systems.

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 proposed that states 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 proposed that states would be required to use the MPFS payment amounts applicable to the site of service and geographic location because we believed these are integral to the MPFS payment system. Individual fee schedule amounts for the MPFS are the product of the geographic adjustment, relative value units (RVUs), and conversion factor (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 proposed that states be required to use the MPFS as published by CMS. Medicare primary care incentive payments made under section 1833 of the Act, as amended by section 5501 of the Affordable Care Act, would not be included. Section 5501(a) of the Affordable Care Act amended the statute to provide 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.

Overarching and Fee for Service Comments

Comment: Most commenters strongly urged that states not be required to recognize Medicare place of service and geographic adjusters since Medicaid payment systems do not make these same adjustments. One commenter said that the use of geographic adjustments would perpetuate geographic inequities in payment that have resulted from the

current method of specifying payment locales and for calculating geographic practice cost indices (GPCIs) in the Medicare program. As alternatives, commenters suggested that states be permitted or required to: use only one geographic or place of service schedule or to use weighted average rates; pay at the highest geographic rate in the state and; use a bench-mark statewide Medicare fee schedule or a national fee schedule set by CMS or otherwise determined by the state.

Response: We have considered the comments and the suggestions in light of the clear intent of the statute to enhance Medicaid beneficiary access to care through higher physician payments. In the interests of administrative simplification, the final rule does not require that states make site of service adjustments. Many states have instituted measures designed to reduce inappropriate use by beneficiaries of emergency departments for non-emergent services. We believe that the higher payment for primary care services provided for in this rule will encourage physician participation and will improve beneficiary access to services provided in the community setting. Therefore, this rule provides that states may reimburse all codes at the Medicare office rate as an alternative to making site of service adjustments.

For geographic adjustments, the final rule additionally permits states to either make all appropriate geographic adjustments made by Medicare, or to develop rates based on the mean over all counties for each of the E&M codes specified in this rule. In identifying this alternative, we balanced the desire on the part of states for administrative simplicity against the need to ensure that providers are reimbursed in accordance with the requirements of the statute. There are seventeen states that have multiple Medicare localities and of those seventeen, ten have only two localities. We reviewed various formulas utilizing the mean and median of rates. Our goal was to most closely match the rates that would be generated under the actual Medicare locality fee schedules. By using a single fee schedule based on the mean over all counties, the majority of states will see a reduction of less than two percent. States that will experience a larger impact can elect to use the actual Medicare locality adjusted fee schedule. The required state plan amendment for these changes must describe the methodology the state has chosen.

Comment: A number of commenters asked that CMS clarify that the increased payment to physicians may be made as a lump sum payment rather

than as an add-on to the rate, pointing out that Medicare's primary care payment is paid as a lump sum on a quarterly basis.

Response: The higher payments may be made as either add-ons to existing rates or as lump sum payments. To ensure that physicians receive the benefit of higher payments in a timely manner, lump sum payments should be made no less frequently than quarterly.

Comment: One commenter stated that CMS needs to clarify the specific procedures and guidelines regarding how states and health plans should reprocess claims for supplemental payment to providers if the state chooses to provide increased payments retroactively.

Response: Because MMIS capabilities and payment processes vary by state and between health plans, we are permitting flexibility in the specifics of how these tasks are accomplished.

Comment: A number of commenters suggested that the MPFS be defined as including the primary care incentive payment authorized for the Medicare program by the statute (as amended by section 5501 of the Affordable Care Act) to make up for the fact that pediatricians, in particular, do not receive payments under the Medicare primary care incentive program. These commenters disagreed with CMS's interpretation that the statute precludes the inclusion of these payments.

Response: As noted in the proposed rule, payments under section 5501 of the Affordable Care Act are not made as increases in fee schedule amounts and are not reflected in the MPFS. Therefore, this final rule requires that those payments be excluded when calculating the appropriated 2013 and 2014 Medicare fee schedule rates.

Comment: Many commenters asked that states be given flexibility to implement the program in phases, if necessary, and to make changes to rates retrospectively. They pointed out that the Medicare RVUs for the subsequent calendar year are not published until November, which does not give states enough time to incorporate the Medicare payment rates into fee schedules and contracts by January 1, 2013.

Response: We acknowledge that states will not have information on the final 2013 Medicare RVUs and on final regulatory requirements for the primary care payments until late in 2012. However, we do not have the authority to permit states to implement higher payments "in phases". The statute requires that higher payment be made for services furnished on or after January 1, 2013. However, under

regulations at § 430.20, states have until March 31, 2013 to submit a State Plan Amendment (SPA) that is effective on January 1, 2013. Additionally, it is common practice for states changing reimbursement rates to make retroactive adjustments to claims after a SPA has been approved. This procedure provides additional time for states to make system changes to reflect this final rule and the November 2012 publication of the Medicare 2013 RVUs.

Comment: One commenter stated that the final rule needs to clarify that the billing entity for the primary care provider must receive the higher payment. This comment was made in the context of salaried physicians working for a county provider.

Response: If services delivered by the county employed physician are actually reimbursed under the Medicaid state plan as physician services rather than clinic services, then the physician must receive the increased payment. If, as a condition of employment, the physician agrees to accept a fixed salary amount then we expect an appropriate adjustment to the salary to reflect the increase in payment. We caution governmental providers that services of a physician may be delivered under a variety of Medicaid benefit categories and that services offered by a county run clinic, in general, do not qualify for the enhanced federal match.

Comments Specific to Managed Care

Comment: CMS received many comments on the minimum payment requirement, ranging from concern that primary care providers would not actually receive higher payment to concern that monitoring payment distribution would be unduly burdensome for MCOs, PIHPs and PAHPs. One commenter suggested that CMS consider a MCO, PIHP or PAHP's obligation to have been met if the health plan's contracts with provider groups allowed for the increased payment. Another commenter suggested that states should be required to enact contract amendments that allow full pass through of the rate increase to primary care providers and describe how the MCO, PIHP or PAHP will verify, in the aggregate, the delivery of primary care services at the average enhanced rate.

Response: We recognize that states' managed care contracts with MCOs, PIHPs, and PAHPs vary and that, as a consequence, provider agreements vary as well. We continue to require that qualified providers receive the higher payment but in deference to these varying arrangements, we do not specify how this requirement must be met. We

emphasize that in order for states to gain CMS regional office approval of their managed care contracts they must demonstrate that the higher payment will actually be passed on for services furnished by the primary care physicians designated in statute.

Comment: Some commenters urged CMS to provide flexibility to the states through their contracts with MCOs, PIHPs and PAHPs, to identify an appropriate and reasonable approach to passing through the increased payment when capitated amounts are inclusive of primary and specialty care services. Otherwise, tailoring each physician group increase will be administratively complex, costly, and contrary to the intent of the rule. Another commenter suggested that no administrative/documentation of payment should be required for the following delivery arrangements: (1) Health plan with exclusive contract with a single medical group in a specific geographic area to provide or arrange for professional medical services for the enrollees of the plan; (2) delivery system where Medicaid enrollees are not distinguished from others in terms of access to the same providers and services; and (3) physicians are paid salaries and receive a capitation rate without regard to payment source.

Response: We are sensitive to the issue of administrative burden and are providing flexibility to states with respect to the identification of the required payment in a managed care environment. As specified in § 438.804, the states shall receive approval of two methodologies, contract amendments, and rate certifications to implement this rule, and CMS will focus on the reasonableness and accuracy of the methods proposed by the state.

Comment: One commenter stated that the rule needs to clearly specify that a plan must increase payment to physicians in a managed care environment to meet the minimum payment standard even if a state is not eligible for 100 percent FFP for some portion of the increase (as in the case where a state has reduced payment rates below 2009 levels).

Response: We agree that this payment increase must take place regardless of whether some portion of the increase is not funded with 100 percent FFP.

Comment: A commenter states that the proposed rule fails to ensure that CMS or primary care physicians can determine whether or not the minimum payment requirement has been met. We were urged to require state level transparency in the implementation of the primary care payment increase.

Response: We understand that managed care payment is not necessarily transparent with respect to individual payment for certain services and require MCOs to supply encounter data to states. We expect that encounter data will be sufficient for the states to undertake verification activities. Additionally, MCOs, PIHPs and PAHPs are required by regulation and contract to ensure that eligible primary care providers receive the appropriate rate increase for primary care services rendered.

Comment: A commenter suggested that CMS needs to consider holding harmless health plans if the practice with which the primary care provider is affiliated fails to pass along the increased reimbursement to the affected providers.

Response: MCOs, PIHPs and PAHPs are required by regulation and contract to ensure that eligible primary care providers receive the appropriate rate increase for primary care services rendered. The structure of the health plan's provider network does not mitigate this responsibility.

Comment: One commenter indicated that, to the extent low income health pools (LIHPs) are included in the rule, a specific methodology would be required for PIHPs and MCOs to identify payment amounts. The data source for paid claims data would be from each individual LIHP because the LIHPs are not paid by a particular state's fiscal intermediary.

Response: We will not respond to state-specific comments in this rule, but will continue to work with states to address specific issues that may arise during the implementation process.

Comment: A commenter stated that methodologies used to develop capitation rates to assure the minimum payment need not be grounded in E&M codes, but could be more broadly defined by primary care services as currently defined by the state for managed care. The approach outlined in the proposed rule is problematic for these reasons: most states do not use E&M codes as basis to develop and adjust cap rates; and, due to variations in MCO, PIHP and PAHP payment methods, such as partial capitation, and the relative completeness of data submitted by providers, states do not consistently receive data necessary to affirm that specific E&M services have been delivered at the Medicare FFS rate. The commenter suggested that an alternative approach would be to allow states to define a methodology to estimate: (1) Aggregate volume and baseline payment rate of primary care services expected to be delivered to all

managed care beneficiaries by PCPs; and (2) the differential aggregate payment associated with increasing payment up to average Medicare levels. This methodology, asserts the commenter, would allow for existing assumptions and methodologies states use to develop their capitation rates. States would pass through associated capitation adjustment on a per month basis to their MCOs, PIHPs and PAHPs and use the associated financial transaction information to provide the necessary CMS 64 documentation for federal match.

Another commenter suggested the additional Medicare fee schedule payments be beyond the scope of the risk portion of the MCO, PIHP or PAHP contract. This would allow the amount claimed by the state at 100 percent FFP to be based on calculations made from retrospective review of encounter data.

Response: We will consider these suggestions during our review of states' rate setting documentation and MCO, PIHP and PAHP contracts. As stated throughout this rule, we are not prescribing a particular approach to delivering the enhanced payment to eligible primary care providers but the method must deliver an accurate service payment to eligible providers. However, where MCOs, PIHPs or PAHPs pay their contracted primary care providers on a fee-for-service basis, it is reasonable to expect that they will use the same approach to delivering the enhanced payment (that is, modifying their claims systems to reflect the 2013 and 2014 Medicare rates for eligible E&M codes for eligible providers) as the state will use to pay its fee-for-service providers.

Comment: A commenter stated that MCOs, PIHPs and PAHPs should not be required to make enhanced payments on a retroactive basis and observed that it is administratively complex to analyze service level claims to verify increased payment. Another commenter asked if there would be retroactive reconciliation when additional funding in the capitation rates differs from the actual cost of providing services.

Response: We agree that meeting the minimum payment standard set in statute can be administratively burdensome but emphasize that states must assure that MCOs, PIHPs and PAHPs are reimbursing services provided through managed care at the Medicare rate for the specified primary care services. This will be accomplished through review and approval by the CMS regional offices of states' managed care contracts. We believe the second commenter is asking about the effect on reconciliation when the actual cost of primary care services differs from the

projected cost as expressed through the managed care rate. This question will be addressed on a case by case basis through our review of the managed care contracts and states' methods for identifying the rate differential.

Comment: A commenter stated that CMS should clarify that a mandatory payment rate does not equate to a mandatory payment and that health plans should retain the ability to deny claims for reasons unrelated to payment.

Response: We agree that a provider should be reimbursed the mandatory payment rate only when he or she has delivered services in accordance with the managed care contract and Medicaid requirements.

Comment: Some commenters believe that the proposed rule conflicts with § 438.6(c)(3)(i) which requires that actuarially sound rates be based on utilization and cost data derived from the Medicaid population because the 2009 cost data may not reflect the amount paid to the provider since MCO contracts are risk arrangements.

Response: The rule is not in conflict with the regulation at § 438.6(c)(3)(i) because the state has flexibility within § 438.6(c)(3) to use various sources of data to establish base costs and utilization trends including FFS data, MCO financial data or a combination of both.

Summary of Final Policy: This final rule removes the proposed requirement that states make site of service and geographic adjustments in paying at the applicable 2013 and 2014 Medicare rates. In the interests of administrative simplification, states need not make site of service adjustments but may reimburse all codes at the Medicare office rate, as opposed to the facility rate. With respect to geographic adjustments, states must either make all appropriate geographic adjustments made by Medicare, or may develop a rate based on the mean over all counties for each of the E&M codes specified in this rule. The required state plan amendment for these changes must describe the methodology the state has chosen. These requirements apply to fee for service and managed care delivery systems. Payments may be made as adjustments to rates or, if on a lump sum basis, no less frequently than quarterly. The 2013 and 2014 Medicare "rate" is defined as excluding payments made under section 5501 of the Affordable Care Act. Higher payment must be made for services provided on or after January 1, 2013, but existing state plan amendment procedures provide states with some flexibility in the timing of the payments. Flexibility in regard to timing of payment is

extended to managed care delivery systems.

b. Payment for Services Unique to Medicaid

For services reimbursed by Medicaid but not Medicare, we proposed that payment would be made under a fee schedule developed by CMS and issued prior to the beginning of CYs 2013 and 2014. We proposed 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 solicited comments from states and others on the most appropriate way to set payment rates for services not reimbursed by Medicare.

Comment: Most commenters strongly supported CMS's proposed methodology for developing rates for codes not reimbursed by Medicare. One commenter suggested establishing rates for codes not reimbursed by Medicare using the same standards applied in Deficit Reduction Act of 2005 benchmark state plans (for example, Federal Employee Health Benefit Payment rates, State Employee Health Benefit Coverage).

Response: For purposes of uniformity and to lessen the administrative burden on states, this final rule specifies that we will develop the rates for E&M codes not reimbursed by Medicare.

Comment: A commenter requested that CMS make the fee schedule available to the states at a minimum of five months prior to January 1, 2013.

Response: We will develop this fee schedule and will make it publicly available. We are committed to making this information available as quickly as possible prior to January 1 of CYs 2013 and 2014. We understand that states need this and all other information timely to be able to administer payments appropriately.

Comment: One commenter urged that states be given the choice to use any Medicare conversion factor that has been in effect for at least three months.

Response: The statute requires that states use the 2013 or 2014 Medicare rates or, if greater, the rate that would be applicable if the conversion factor for the year involved were the conversion factor for 2009. There is no flexibility with respect to this requirement.

Summary of Final Policy: We will develop and publish rates for eligible E&M codes not reimbursed by Medicare. In determining the 2013 and 2014 rates, we will use the 2009 conversion factor,

if that factor in conjunction with the 2013 and 2014 RVUs results in rates that are higher than if the 2013 and 2014 conversion factors were used. The rates for Medicaid primary care services not reimbursed by Medicare must be incorporated into managed care contracts for those services covered by the contract.

c. Updates to Medicare Part B Fee Schedule

We recognized 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 proposed that states have 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.

Comment: Most commenters agreed that states should be given this flexibility. One commenter recommended that states be prohibited from changing rates throughout the year because this would cause confusion and undue burden to providers. Another commenter suggested that states should be required to use the fee schedule published in November of the preceding calendar year. One commenter suggested that states be required to update rates every 6 months, while another suggested that states be required to use any rate that had been in effect for at least 3 months. A number of commenters urged that states be required to make all adjustments as the Medicare fee schedule changes, pointing out that changes in the SGR after November could result in States using a lower fee schedule, thereby avoiding higher physician payments.

Response: We are sensitive both to concerns that requiring that states make multiple changes would be an administrative burden and to concerns that changes in the SGR could result in lower payments. We believe that the statutory requirement to use the 2009 Medicare conversion factor if it would result in higher Medicare rates in 2013 and 2014 was intended to offset the potential negative impact of changes in the SGR. Therefore, this final rule permits states flexibility in determining whether to, and how often to, update rates to conform to changes in the MPFS.

Summary of Final Policy: This final rule permits states flexibility in determining whether to, and how often to, update rates to conform to changes in the MPFS. This applies to fee for service and managed care payment.

3. State Plan Requirements (§ 447.410)

We proposed to require that states submit a 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 requirement was 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.

Comment: Commenters agreed that states should be required to amend their state plans. Many commenters asked that CMS develop a SPA template or, if not, specify the contents of the required SPA (for example, assurances required, specificity regarding use of the MPFS, covered codes).

Response: We will provide states with a SPA template. The template will require that states indicate: (1) Whether they will make site of service adjustments or reimburse all codes at the Medicare rate applicable to the office setting; (2) whether they will make all Medicare locality adjustments or develop a statewide rate per code that reflects the mean value over all counties of the Medicare rate; (3) identify the manner in which the state will make higher payment (that is, as a fee schedule or aggregate supplemental payment; and (4) describe the codes which will be paid by the state at the higher rates and the codes that have been added to the fee schedule since 2009. If states do not use HIPAA compliant codes, the SPA must also provide a crosswalk to the covered E&M codes.

Comment: Many commenters asked that CMS clarify that state plan rules at § 447.256(c) apply, meaning that the

SPA may be effective on the first day of the calendar quarter in which it is submitted, giving states until March 31, 2013 to submit a SPA.

Response: Yes, those requirements apply.

Comment: A number of commenters asked that CMS permit states to submit SPAs that will automatically sunset higher payments made pursuant to this rule on December 31, 2014.

Response: We will permit sunset dates. The state and CMS must ensure that, in cases where a sunset date is employed, the rates that the state will revert to after December 31, 2014 are clearly described in the plan and that public notice for the SPA makes it clear that higher payments will end as of that date.

Comment: One commenter asked if states will be permitted to apply existing payment limitations, conditions and policies to the selected procedure codes.

Response: All limitations, conditions and policies that applied to the code prior to January 1, 2013 can be applied to the code after that date.

Comment: One commenter pointed out that CMS often takes 90 days or more to review and approve SPAs and asked whether the state should wait to implement the rate increase until the SPA is approved.

Response: The statute requires that states make higher payments for services provided on or after January 1, 2013. Our policy dictates that FFP is not available for services provided pursuant to an unapproved SPA. Therefore, as is the case with all rate changes, states can either make the higher payments to physicians and wait to submit claims for FFP until the SPA is approved, or can pay physicians at the 2012 Medicaid state plan rates and make supplemental payments once the SPA is approved.

Comment: One commenter believes that public access to the SPA is important to ensuring provide participation and suggested amending the proposed state plan requirement at § 447.410 to indicate that the state must make this information accessible to the public through a Web site or other reasonable means.

Response: Public notice of changes in state plan methodologies in Medicaid is already required at § 447.205. In addition, copies of approved state plan amendments are available through state Medicaid agencies.

Comment: Several commenters recommended that we require states to notify health plans and providers within a specified timeframe after approval of the SPA. One commenter stated that clarification is needed regarding

obligations and responsibilities for MCOs managing the Medicaid program in a state that does not yet have an approved SPA by January 1, 2013.

Response: The SPA will describe methods and procedures relative to fee for service payments. The status of the SPA will not affect a state's ability to negotiate with managed care organizations. Notification to MCOs and providers of changes necessitated by this rule will be handled through normal procedures and processes by the state.

Summary of Final Policy: We will develop a SPA template for use by states in implementing the requirements of this final rule. SPAs should be submitted and will be reviewed in accordance with existing federal requirements at § 447.256 (and by reference § 430.20). States may apply existing payment limitations and policies to services paid pursuant to this rule. Managed care payment policies are not affected by this provision.

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.

Comment: A number of states indicated that they have lowered rates since July 1, 2009. Under the provisions of the proposed rule, they will not be eligible for 100 percent FFP for the difference between the 2009 rate and their current, lower, rates and asked for relief in the final rule. One commenter suggested that such states be permitted to "present the case to CMS for approval of 100 percent funding for the total

increase when it can be shown that the state did not make such a decrease with any expectation or intent that it would be used to restore rates".

Response: The statute provides for 100 percent FFP for the difference between the July 1, 2009 Medicaid state plan rates and the appropriate 2013 and 2014 Medicare rates. States that lowered physician rates after 2009 will receive FFP at the state's regular FMAP rate for the difference between the lowered rates and the Medicaid rates in effect as of July 1, 2009. We have no authority to grant requests for exemptions from this requirement.

Comment: One commenter asked that the final rule clarify that providers have no less than 12 months from the date of SPA approval to file a claim. That commenter also asked that the final rule confirm that the state will receive 100 percent FFP for claims for services rendered during CYs 2013 and 2014 even if they are adjudicated after 2014.

Response: This rule does not change Medicaid timely claims submission and payment requirements. Section 447.45 applies to all claims submitted under this rule, that is, 100 percent FFP will be available for services provided between January 1, 2013 and December 31, 2014 that are processed in accordance with these requirements.

Comment: Two commenters indicated that the rule does not address system changes that states will need to make. One commenter noted that states will not have time to submit Advanced Planning Documents (APDs) for CMS prior approval for enhanced FFP for those changes. The commenters requested that CMS grant retroactive "prior approval" for such APDs.

Response: We do not grant "retroactive prior approvals" of APDs. However, we will work with states to promptly facilitate system changes necessitated by this final rule.

Comment: One commenter suggested that CMS phase down the increased payment to primary care practitioners (PCPs) in the same manner as matching for the expansion populations under the Affordable Care Act. They believe that "a precipitous drop in the PCP payment increase could create access issues".

Response: The statute does not permit such a phase-down.

Comment: One state asked how services eligible for both regular FFP and 100 percent FFP will be reported to CMS.

Response: We will provide states with reporting instructions before the end of the first calendar quarter of 2013. This guidance will be provided for both fee for service and managed care delivery systems.

Comment: One commenter wanted to know if primary care case management (PCCM) fees paid in either the baseline period or in 2013 and 2014 should be included in the calculation of the rate differential.

Response: We clarify that PCCM payment is outside the calculation of the rate differential.

Comment: A number of commenters asked if the 100 percent FFP is based on actual, documented expenditures or based on the actuarial per member per month (PMPM) assumptions built into adjusted capitation rates, including nonclaim components.

Response: States can claim 100 percent FFP based on the CMS approved methodology for identifying the rate differential. Depending on the best data available this may result in an imputed payment differential that is based on actual claims or actuarial assumptions.

Comment: One commenter asked whether state and local taxes associated with the increased fee schedule would be eligible for the enhanced match.

Response: Enhanced federal matching funds are available only for the difference in payment between the Medicaid state plan rate in effect July 1, 2009 and the applicable Medicare rates in CYs 2013 and 2014. If the nonfederal share of the rate in effect during the baseline period was funded by state and local taxes then that portion of the payment would continue to be matched at the state's regular FFP. This applies to FFS and managed care reimbursement.

Comment: We received a request for clarification as to whether an increase in managed care premiums for the following non-claim related components would be eligible for 100 percent FFP: the Federal Health Insurer Fee, premium related taxes imposed by states, underwriting gain and administrative expenses.

Response: We are clarifying that non-claim related costs are excluded for purposes of 100 percent FFP. The statute narrowly defines the scope of the enhanced match to the differential between the Medicare rate and 2009 baseline rate for the direct provision of specified primary care services delivered by eligible primary care providers.

Summary of Final Policy: States will receive 100 percent FFP for the difference between the July 1, 2009 Medicaid state plan rates and the appropriate CY 2013 and 2014 Medicare rates. States that lowered physician rates after 2009 will receive FFP at the state's regular FFP rate for the difference between the lowered rates and the

Medicaid rate in effect as of July 1, 2009. Medicaid timely claims submission and payment requirements at § 447.45 apply to all claims submitted under this rule, that is 100 percent FFP will be available for services provided between January 1, 2013 and December 31, 2014 that are processed in accordance with these requirements. No phase-down of higher payments or FFP is permitted. Enhanced federal match is available for the payment differential in managed care.

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 covers the cost-sharing amounts. 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 percent of the allowed amount, or \$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.

Comment: Most commenters were supportive of these provisions of the rule. A number of commenters indicated that payment of crossover claims poses a significant administrative challenge because not all states' enrollment and adjudication processes mirror Medicare's and they may have limited ability to capture all details needed on crossover claims to limit payment by subspecialty. One commenter suggested that CMS require 100 percent of such claims to be paid by Medicare. Another commenter noted that the proposed rule does not require states to pay cost sharing amounts.

Response: The Medicaid requirements applicable to claims for services for beneficiaries who are dually eligible for Medicaid and Medicare are not changed by this rule. States must comply with all requirements for payment of claims for services provided to Medicaid beneficiaries who are also eligible for Medicare.

Comment: One commenter recommended that states that enter into Duals Special Needs Plans (DSNPs) be required to amend contracts to ensure that providers receive the enhanced rate. Currently, these contracts provide for \$0 cost sharing as they are associated with the Medicaid rate.

Response: DSNPs are Medicare managed care plans and are not subject to the requirements of this rule. However, states are responsible for ensuring that payments for Medicaid enrollees of DSNPs reflect the appropriate payment increase.

Comment: One commenter recommended that CMS permit states to develop a methodology to identify what the difference in the capitation rate would be for crossover claims and to claim enhanced FFP for the difference, similar to the process proposed for managed care at § 438.804.

Response: We agree that a state must have the ability to identify the 2009 baseline rate for primary care services and the managed care rate differential eligible for 100 percent FFP. We will permit a state up to 3 months after January 1 of CY 2013 to submit the methodologies for our review and approval as specified in § 438. We expect this methodology to account for managed care payment for services delivered to all beneficiaries covered by Medicaid, including beneficiaries in CHIP Medicaid expansion programs and those beneficiaries also eligible for Medicare.

Summary of Final Policy: This rule does not in any way negate the need for states to comply with all Medicaid requirements applicable to payment for services provided to Medicaid beneficiaries who are also dually eligible for Medicare. In managed care environments, states will be granted flexibility in determining the portion of the capitated payment that is related to such beneficiaries. However, the methodology must be approved by CMS.

b. Identifying the July 1, 2009 Payment Rate

For the purpose of identifying the differential between the Medicaid rate and the Medicare rate, we proposed 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.

Comment: The majority of commenters requested that incentive payments, bonus payments and performance-based supplemental payments be excluded from the definition of the base payment.

Response: Incentive payments, bonus payments and performance-based supplemental payments are only paid to those certain physicians who meet specified goals or criteria. They are not part of the statewide fee schedule rates and we agree that they should be excluded from the determination of the 2009 base rate.

Comment: Many commenters urged CMS to exclude other supplemental payments made on a lump sum basis from the definition of the base rate, pointing out the administrative burden of linking those payments to individual codes and eligible physicians. In practice, this would consist of the supplemental payments up to the average commercial rate made to physicians associated with academic medical centers. They stated that CMS excluded the Medicare primary care bonus payment, which is made as an aggregate payment, from the definition of the MPFS, and suggested that Medicaid supplemental payments made as lump sum payments be excluded from the 2009 base following the same logic.

Response: We do not agree that volume-based payments such as those made up to the average commercial rate should be excluded from the determination of the 2009 base rate. The CMS-approved methodologies for determining those supplemental payments are calculated on a code-specific basis even when payments are aggregated and paid on a lump-sum basis. Since the code-specific calculation is performed before the SPA methodology is approved, states do have the data necessary to determine the rate for each code inclusive of the supplemental payment. In addition, the methodologies that have been approved for those payments provide that the base Medicaid payment in addition to the supplemental payment up to the ACR are equal to or significantly greater than Medicare rates. Were the supplemental

payments to be ignored, physicians in those settings would receive disproportionately high compensation with no additional impact on access. We do not believe that is in keeping with the intent of the statute.

Comment: One commenter urged that CMS clarify how health plans should report to the state the supplemental and increased payment for individually billed codes made under the approved state plan in effect July 1, 2009. Otherwise, the state will not know what incentive payments were made to the impacted providers.

Response: We understand that the commenter is asking how health plans should report “catch up” payments to providers for the increase in primary care payments to the Medicare rate as specified under this final rule. States should specify in encounter data reporting requirements how health plans should reflect those payments.

Summary of Final Policy: This final rule defines the 2009 Medicaid base payment as excluding incentive, bonus and performance-based supplemental payments. Other volume-based payments, particularly those associated with academic medical centers, must be included in determining the 2009 base rate. This policy applies to fee for service and managed care payment.

c. Federal Funding for Increased Payments for Vaccine Administration

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 the proposed rule, we clarified 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.

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. This is consistent with section 1928(c)(2)(C)(ii) which permits the

provider to impose an administration fee based on the cost of administering a qualified pediatric vaccine, and does not authorize different fees based on the type of vaccine. To permit providers participating in the VFC program to benefit from the provisions of the Affordable Care Act, we proposed 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 would qualify for 100 percent FFP for these increased reimbursements.

In the proposed rule, we provided a formula for states to impute the 2009 rates due to the coding change that took effect on January 1, 2011. In addition, we stated that qualifying providers who provide vaccines to children enrolled in Medicaid who receive vaccines through the VFC program cannot be paid for additional vaccine/toxoid components of a combination vaccine.

Comment: A number of commenters disagreed with CMS’ proposal not to reimburse providers for additional vaccine/toxoid components of combination vaccines using code 90461. One commenter stated that this provision falls short of the statutory standard to the extent that it allows states to pay less than is required by the 2011 component-based code methodology currently used by Medicare. Another commenter said that CMS should pay for the additional vaccine/toxoid components in combination vaccines because each vaccine/toxoid component protects against a different disease. Two commenters also expressed concern that proceeding with the proposed policy could result in a disincentive for providers to comply with optimal medical practice and result in more shots for children.

Response: We agree with commenters in part. We agree that additional payment can be made for additional vaccine/toxoid components in combination vaccines using code 90461. But we disagree that this methodology is appropriate for vaccines furnished through the VFC program. While preparing the proposed rule, we considered a number of alternative approaches for enhanced payment for vaccine administration within the VFC program. This included paying an increased amount for administration of additional vaccine/toxoid components in combination vaccines using code 90461. That approach was not selected in part because we believe that it was not the intent of the Affordable Care Act to supersede the VFC provision, which does not give CMS the authority to make multiple payments for a single vaccine

administration. Therefore, we believe that the requirement that under VFC there cannot be multiple payments for a single vaccine applies to the Affordable Care Act. As such, we are not changing the policy in the final rule from what was published in the proposed rule, and providers will be reimbursed at the lesser of the 2013 and 2014 Medicare rates or the maximum regional VFC amounts in those years. In making this determination, we also considered that the payments at issue are not for the vaccine ingredients, but only for vaccine administration. We received no information that indicated that administration of multiple antigen vaccines was more costly than administration of single antigen vaccines.

We are concerned by the comments that this policy could result in additional shots for children if providers were to use single component vaccines where a combination vaccine exists. Under the VFC statute at section 1928(c)(2)(B)(i) of the Act, VFC providers are required to comply with the Advisory Committee for Immunization Practices (ACIP) schedule regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines. It is important that vaccines are administered following the ACIP recommendations and that combination vaccines are used if recommended. If necessary, we will work with states to ensure that children receive appropriate vaccines and receive as few shots as are necessary following the ACIP schedule. As a practical matter, CDC orders and provides few single antigen vaccines through the VFC program when combined antigen drugs are available. In addition, section 1903(i)(15) of the Act provides that no payment shall be made “with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary) * * *.” So we believe states will have some incentive to monitor and oversee the appropriate use of combined antigen vaccines.

Comment: CMS received a comment asking if a state could have the flexibility to pay at the greater of the 2013 and 2014 Medicare rates or the maximum regional VFC rates instead of the lesser of those two rates. CMS also received a number of comments expressing confusion as to whether this policy applies to qualified providers or to all VFC providers.

Response: We adopted the lesser of the Medicare rates or the maximum

regional VFC amounts because the VFC statute prohibits payment above the regional maximum ceiling and because it is consistent with Medicare policy which limits provider payment to the lesser of the fee schedule amount or provider charges. Therefore states do not have the flexibility to pay at the greater of the two amounts instead of the lesser of the two. This policy is consistent with the larger intent of this provision of the Affordable Care Act to increase payments to primary care providers within the framework of the Medicare program.

This policy applies only to qualified physicians. If a non-qualified physician provides a vaccine to a VFC-eligible child enrolled in Medicaid, the physician will be reimbursed for the administration fee at the rate in the corresponding state plan.

Comment: Three states submitted comments expressing concern that the proposal not to recognize additional vaccine/toxoid components under the VFC program will create an administrative burden for States because providers would be paid at different rates.

Response: Although the proposed policy will result in variable rates for providers, we do not believe there will be an administrative burden for states specific to the increased payments. It is correct that the policy to not recognize additional vaccine/toxoid components only applies to the VFC program. However, because only vaccines given to those under age 19 are eligible for payment for additional antigens, and all Medicaid enrollees under age 19 qualify for VFC, there will not be an administrative burden as there will not be any variation in payment rates. We expect that there will be few situations where a state would have to establish different payments to providers for administration fees for children enrolled in Medicaid, or where a payment would be made for code 90461.

Comment: CMS received one comment that addressed the formula for imputing the 2009 rate for code 90460 that was established because of the new codes that went into effect in 2011. Specifically, the commenter recommended that CMS revise the formula to instead use the payment rate for deleted code 90465 for the new code 90460 and the payment rate for deleted code 90466 for new code 90461. The commenter suggested eliminating the reference to deleted codes 90467 and 90468 because there is no crosswalk to these codes.

Response: We agree that code 90465 should be used to determine the 2009 rate, and that codes 90467 and 90468

should not be used. However, code 90465 was only for children younger than 8 years of age and the new code 90460 is for children through age 18. Therefore, states need to use claims volume for code 90465 and code 90471 to impute the payment amount in the base period for the current code 90460. Code 90471 is also included because prior to January 1, 2011, code 90471 was used for children above age 8. This change is demonstrated in the following example:

- 90465 = \$10 × 0.70 service volume = \$7.00
- 90471 = \$10 × 0.30 service volume = \$3.00
- Total cost equals \$10.00 for the new, single code, 90460.

Comment: Several commenters expressed concern that their state does not currently use the immunization administration code and instead uses the product code so that the state has vaccine-specific data.

Response: This issue was discussed in the proposed rule. States that do not currently use the immunization administration code, or did not use it in 2009, will need to identify the CY 2009 payment for vaccine administration separate from the vaccine itself. We understand that using the product code provides vaccine specific data, however, since we will only issue additional payment based on the immunization administration code, all states will need to submit data using the correct codes. We will provide future assistance to states on ways to modify the immunization administration codes so that they can be used properly but still capture vaccine-specific information.

Summary of Final Policy: This final rule defines the policy for additional payments for qualifying providers under the VFC program and how to establish the 2009 Medicaid rate for vaccine administration. Because the immunization administration codes changed in 2011, states will need to determine the payment amount from other codes based on service volume. The service volume of code 90465 and of the pediatric claims for code 90471 will need to be imputed to determine the new payment amount for code 90460.

In addition, VFC providers will be reimbursed at the lesser of the 2013 and 2014 Medicare rates or the maximum regional VFC amount in those years.

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

We proposed 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 PAHPs 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.

We solicited 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 \times 8 visits annually = \$200.

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

In this example, \$16.67 equals the imputed amount of the monthly payment made on a fee for services basis for an individual primary care service. The state will 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.

Specifically, we proposed 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.

We solicited additional comments on how states might best meet these requirements.

Comment: A number of commenters expressed concern about the short timeframe for implementing new managed care contracts, developing revised rate certifications, and identifying the rate differential eligible for 100 percent FFP, given the obstacles of obtaining historic claim and encounter data.

Response: We are cognizant of the amount of planning and activity that must occur at the state, federal, health plan, and provider levels to implement the increase in primary care provider payments in CY 2013. Therefore, we will extend the deadline for CMS approval of all necessary documentation into CY 2013 in accordance with the following guidelines. States must submit the methodologies for identifying the 2009 baseline rate and the rate differential eligible for 100 percent federal match to CMS no later than the end of the first quarter of CY 2013. These requirements are specified in § 438.804 as modified from the proposed rule. Implementation of the increased payments for eligible primary care services to designated primary care providers is contingent upon CMS approval of the aforementioned methodologies, any necessary contract amendments, and certification of rates that take this rule into account. We will approve all required documents in a timely manner. In the interim, the state and contracting MCOs, PIHPs, and

PAHPs have the option of issuing payment for primary care services in accordance with existing contracts for CY 2012 or under contracts executed under standard contracting schedules for CY 2013 that do not account for the increased payments. Once the state receives CMS approval of the methodology for calculating the primary care rate differential, certified rates, and contract amendments, the state will adjust their rates previously paid to the MCOs, PIHPs and PAHPs to reflect the enhanced payment. All eligible claims that were claimed and paid in CY 2013 prior to CMS approval will be re-adjudicated and the MCO, PIHP or PAHP will direct the full amount of the enhanced payment to the eligible provider. The MCO, PIHP or PAHP must remit the enhanced payment to eligible primary care providers without any effort from the provider. We will review managed care contracts for this assurance.

Comment: A commenter asked whether certification (of the rate) is needed if the methodology is to be submitted separate from the rate certification.

Response: We anticipate that states will first receive CMS approval of the baseline and payment differential methodologies, and then receive concurrent approval of managed care contracts. Section 438.804(a)(1) requires that the states submit the methodologies for determining the 2009 baseline rate and the payment differential for CMS review no later than the end of the first quarter of CY 2013. Submission of the above-mentioned methodologies does not negate the requirements of § 438.6(c). Again, we emphasize that contracts approved after January 1 must be effective for services provided on and after January 1 of CYs 2013 and 2014. We have awarded a technical assistance contract to a firm with actuarial expertise and experience with rate setting activities across the states to develop a framework for states in developing the methodologies required under this rule. Written guidance and informational calls will be made available before CY 2013.

Comment: A commenter urged that health plans should be provided with 90 days notice prior to the implementation of reimbursement changes.

Response: Although we agree that states should notify health plans in a timely manner of changes in reimbursement, adding a federal notification requirement for the state to the health plan is beyond the scope of this rule and exceeds the normal and customary role of the federal

government in the relationship between the state and the health plan.

Comment: One commenter suggested that CMS should clarify that the managed care payment will be based on FFS or base utilization data used for rate setting. A commenter also noted that developing a reasonable estimate of the increased amount paid for primary care services was difficult due to lack of encounter data as of July 1, 2009. Other commenters requested guidance on how to develop the baseline 2009 rate for primary care services when populations may not have been enrolled in MCOs, PIHPs or PAHPs in 2009. Other commenters requested clarification as to whether the four-step process provided in the proposed rule for identifying the rate differential is a preferred approach.

Response: We acknowledge the variance that exists among the states in terms of the types of encounter, claim and pricing information available from MCOs, PIHPs and PAHPs for rate setting purposes, and the complexity entailed in defining the baseline service rate for populations that may not have been in managed care delivery systems in 2009. We expect that, where feasible, the state will use the same methodology for fee-for-service payments through MCOs that is provided for direct fee-for-service payments from the state. In cases where this is not possible, however, we do not prescribe a uniform approach to identifying the 2009 baseline but we have revised § 438.804(a) to add the new § 438.804(a)(1)(i) to require states to submit the methodology for the 2009 baseline rate in conjunction with the methodology used to identify the rate differential as specified in § 438.804(a)(1)(ii). The four-step process outlined in the proposed rule is one suggested approach for states that would find it produces an accurate result based on reasonable and documented data and assumptions available. As stated throughout the rule, we will continue a dialogue with states on valid and reasonable approaches to defining the 2009 baseline rate and identifying the rate differential required under § 438.804(a)(1)(i) and (ii). We reserve the right to request and inspect the supporting data used by the state and actuaries to develop the methodologies required under § 438.804(a)(1)(i) and (ii).

Comment: A commenter urged that CMS should not increase payments only to MCOs that had been paying for the Medicaid primary care services at less than the Medicare rates as this would result in rewarding low paying plans.

Response: The statute applies equally across all eligible providers for all of the services specified in this rule. This may

result in increased payment to MCOs, PIHPs and PAHPs that previously had reimbursed providers less than the Medicare rate. However, we expect that physicians—not the MCOs, PIHPs or PAHPs—will receive direct benefit of the higher payment.

Comment: Several commenters requested general guidance if the enhanced payment to primary care providers should be disseminated on a retroactive or prospective basis and other commenters urged CMS to provide overall flexibility in this process. For example, the American Academy of Actuaries asked CMS to consider a number of approaches, including (1) an add-on payment to the PMPM based on a retrospective review of eligible primary care utilization; (2) full risk capitation; (3) prospective capitation with some type of risk sharing that incorporates retrospective reconciliation to the documented expenditures; and (4) non risk payment with retrospective reconciliation. Another commenter recommended that CMS impose a threshold for enhanced reimbursement that is based on encounter data submitted to the states' MMIS.

Response: We appreciate the amount of feedback and thoughtful suggestions received from our request for comment on how the enhanced payment is made to eligible primary care physicians. Because claims and payment processes vary by state and between health plans, we are permitting flexibility in the specifics of how these tasks are accomplished. Should a state obtain approval of the required methodologies, the MCO, PIHP or PAHP contract amendments, and rate certifications after January 1 of 2013 and 2014, the state will need to clarify to CMS how it will implement payment retroactively to the beginning of the year. We expect to address retroactive claims processing as part of CMS's ongoing dialogue with the states.

Comment: One commenter asked whether a state's adherence to the documentation requirements specified in § 438.6(c)(4) were sufficient to meet the documentation requirements provided under the new § 438.6(c)(5)(vi)(B). Additionally, another commenter queried whether the documentation requirement in § 438.6(c)(5)(vi)(B) sufficiently described CMS's oversight role to ensure that payments are made in accordance with this final rule.

Response: The documentation requirement in the new § 438.6(c)(5)(vi)(B) is more expansive, therefore, a state may not assume that it has met the new requirements by satisfying those of the existing managed

care regulation. In deference to the wide variation in states' current oversight and reporting mechanisms for health plans, we will permit states to specify the documentation needed from health plans to substantiate that the enhanced primary care rate was delivered to eligible primary care providers. The health plans must make such documentation available to the state for verification of payments made as well as make such documentation available for audit or reconciliation processes. However, in response to the comment about our oversight role, we have modified the language in § 438.6(c)(5)(vi)(B) to require health plans to provide sufficient documentation so that the state and CMS can ensure that complaint payments have been made in accordance with this rule.

Comment: One commenter noted that there is no explicit reference in the proposed rule to the data certification requirements at § 438.604.

Response: We believe that a specific reference to the data certification requirements at § 438.604 is not warranted because those requirements are not being modified by this rule. Further, we believe that the documentation required under this section falls under the scope of § 438.604.

Comment: We received a number of comments expressing concern about the projected overall impact of this payment on the future of doing business under managed care delivery systems. One commenter stated that in CYs 2013 and 2014 MCOs, PIHPs and PAHPs may find contracting with specialists more difficult when these providers receive less than the Medicare rate. Conversely, providers were concerned that MCOs, PIHPs and PAHPs would reduce payment for primary care services after the 2-year period and believed that states should be mindful of this.

Response: We expect this rule to have positive effects on payment rates for primary care physicians serving Medicaid patients that will justify the operational changes required to implement the increased rates.

Comment: A commenter stated that CMS oversight and enforcement of actuarial soundness policies should ensure that rate adjustment increase to plans do not result in an inappropriate decrease in other factors used in rate setting methodology. Plans must provide access to all information used to make adjustment for this provision.

Response: We will exercise oversight and enforcement of appropriate policies through our review and approval of

managed care contracts and certification of the actuarially sound rate.

Comment: One commenter stressed that health plans must be given the right to appeal new health plan capitation rates to an unbiased third party if they believe they do not meet actuarial soundness requirement.

Response: The ability to negotiate capitation rates remains between states and health plans and this rule does not affect any established process, or create a new process, for a health plan to appeal revised capitation rates devised for purposes of implementing this rule.

Summary of Final Policy: We recognize the implementation challenges for identifying the 2009 baseline rate and the payment differential eligible for 100 percent federal financial participation, as well as appropriate methods for delivering the payment to eligible providers contracted with MCOs, PIHPs and PAHPs. To that end, we have extended deadlines for states to submit the abovementioned methodologies as required by § 438.804(a)(1) into CY 2013 and necessary contract amendments and rates may be approved by CMS within that CY. The regulations clearly provide that the state has the flexibility in determining the 2009 baseline rate and the rate differential to comply with this rule, but the approach taken must be based on reasonable and documented data sources available to the state to accurately define these amounts to the fullest extent possible. We will review and approve the methodologies and refer to these methodologies to approve MCO, PIHP and PAHP contract amendments and rates necessary to implement this rule. This rule does not require a specific method for the MCOs, PIHPs or PAHPs to make the enhanced payment for primary care services to eligible providers, but the approach taken must ensure that the eligible primary care provider receives the full benefit of the enhanced payment. In deference to the wide variation in states' current oversight and reporting mechanisms for health plans, we will permit states to specify the documentation needed from health plans to substantiate that the enhanced primary care rate was delivered to eligible primary care providers. The health plans must make such documentation available to the state for verification of payments made as well as make such documentation available for audit or reconciliation processes. As stated throughout this rule, we will continue a dialogue with the states on implementation challenges that may arise.

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

1. General Statement

On May 11, 2012, we issued a proposed rule (77 FR 27671) in the **Federal Register** titled “Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration under the Vaccines for Children Program”. In that proposed rule, we specified that we would add 42 CFR part 441 subpart K, § 441.500 through § 441.515, to codify the requirements of the Vaccines for Children Program. However, on May 7, 2011, we issued a final rule (77 FR 26828) in the **Federal Register** titled “Medicaid Program; Community First Choice Option”, which codified subpart K, § 441.500 through § 441.590. Therefore, we are adding the provisions to codify the requirements of the Vaccines for Children Program as subpart L, § 441.600 through § 441.615.

This final rule adds 42 CFR part 441 subpart L to codify the requirements of the Vaccines for Children Program. CMS is finalizing the general requirements of the VFC program in this final rule at § 441.610. 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 (§ 441.605) 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 final rule updates those fees.

In accordance with section 1928(c)(2)(C)(ii) of the Act, § 441.615(e), we proposed 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.

Section 441.615(e) provides that there will be no federal Medicaid matching funds available for administration of vaccines to children not enrolled in the Medicaid program. A provider may only bill Medicaid for the administration of a vaccine if the child is enrolled in Medicaid.

Of the 171 comments received in response to the proposed rule, 21 of them addressed the updated administration fee schedule in the VFC program.

Comment: One comment questioned the codification of the VFC program and stated that this represented major changes in the VFC program.

Response: The intent of this section of the final rule is not to create new requirements for states or to change any rules of the VFC program, but instead to codify existing rules and update the administration fee rates. All states currently have established pediatric vaccine distribution programs in place that meet the requirements of section 1928 of the Act, and therefore, states are not required to change their existing state plan to reflect the codification of the VFC program. Submission of a new SPA is only necessary if the state chooses to change the amount that it pays Medicaid providers for the administration fee.

Comment: Two commenters discussed the impact of the updated fee

schedule on the uninsured and underinsured. The first commenter recommended that uninsured children be exempt from paying administration fees and the second recommended that VFC providers continue to have flexibility to provide VFC vaccines at no administrative cost or at reduced cost to uninsured children.

Response: While we acknowledge the commenter’s concern, under section 1928 of the Act, we do not have the authority to exempt uninsured children from administration fees. Providers continue to have the flexibility to determine the administration fee they will collect from families of uninsured and underinsured children, as long as the administration fee does not exceed the state’s regional maximum administration fee. However, section 1928(c)(2)(C)(iii) of the Act provides that providers cannot deny administration of VFC vaccines to a vaccine-eligible child due to the inability to pay the administration fee.

Comment: Several comments expressed support of the updated regional maximum administration fee schedule. None of the comments were critical of the updated fee schedule or the methodology used to update the fee schedule, or provided alternative suggestions.

Response: Based on the support of the methodology used to update the fee schedule and the acknowledgement that an updated fee schedule is needed, we are finalizing the updated fee schedule as proposed.

Comment: One commenter suggested that we link the regional maximum administration fee to the Medicare Economic Index, and publish the fee schedule annually.

Response: The purpose of this final rule is to update the fee schedule, which has not been updated since 1994.

Comment: Two commenters suggested that CMS consider establishing a minimum payment rate for providers.

Response: The establishment of a minimum payment level for VFC providers goes beyond the scope of what was included in the proposed rule.

Comment: Multiple commenters questioned whether states will continue to have the authority to set their payment rates under the Medicaid program at a rate that is lower than the State’s regional maximum administration fee.

Response: Updating the fee schedule will not impact states’ ability to establish payment rates under the VFC program. States continue to have the flexibility to establish their payment rate for the VFC program at any level that does not exceed the newly updated

regional maximum administration fee. If a state wishes to change its payment rate, it needs to submit a SPA to CMS. Much of the confusion related to state flexibility to establish payment rates is due to the requirements in the primary care payment increase section of this rule which requires that qualifying providers are paid at the lesser of the

Medicare rate or the updated state regional maximum administration fee in 2013 and 2014. While states do maintain the flexibility to set the reimbursement rate for the VFC program, qualifying primary care providers who administer vaccines to children enrolled in Medicaid under the VFC program are required to be paid at

the lesser of the Medicare rate or the updated State regional maximum administration fee for vaccine administration for those 2 years.

Summary of Final Policy: We are finalizing the updated regional maximum VFC ceilings as proposed, as shown in Table 1.

TABLE 1—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
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

III. Provisions of the Final Regulations

This final rule incorporates many of the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- Section 438.6(c)(5)(vi)(B) has been modified to clarify our oversight role by requiring health plans to provide sufficient documentation so that both the state and CMS can ensure that complaint payments have been made in accordance with this rule.

- Section 438.804(a)(1) has been changed from a description of the 2009 baseline rate to a general statement of the two methodologies the states are required to submit to CMS for review and approval to implement the payment increase to primary care providers.

- Section 438.804(a)(1)(i) replaces the description of the 2009 baseline payment as provided in § 438.804(a)(1) in the proposed rule to clarify that the states must submit a valid and reasonable methodology for identifying the provider payments that would have been made by the MCO, PHIP or PAHP for specified primary care services furnished as of July 1, 2009. This change is in recognition of the varying sources of data available to the states and the challenges associated with determining the rate for primary care services in 2009 for populations that have transitioned from fee-for-service to managed care delivery systems after 2009. We will need to review and approve the methodology for determining the 2009 baseline rate for specified primary care services to ensure that the data sources used are reasonable, reliable, and accurate to the fullest extent possible.

- Section 438.804(a)(1)(ii) replaces the description of the methodology to identify the rate differential between the amount paid as of July 1, 2009 for specified primary care services and the rate required under this rule. This requirement was designated as § 438.804(a)(2) under the proposed rule. The reference to “managed care provider” was removed and replaced with “MCO, PIHP or PAHP” for consistency with 42 CFR part 438.

- Section 438.804(a)(3) has been revised and redesignated as § 438.804(a)(2) to indicate that the methodology for identifying the 2009 baseline rate and the differential in payment between the provider payments that would have been made by the MCO, PIHP or PAHP on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi) must be submitted to CMS for approval by the end of the first

quarter of CY 2013. This is in recognition of the amount of planning and activity that must occur at the state, federal, health plan and provider levels to implement the increase in primary care provider payments in CY 2013.

- A new § 438.804(a)(3) has been added to clarify that the methodologies required under the section will be used by CMS in reviewing necessary MCO, PIHP and PAHP contract amendments and rates to implement the enhanced payment to primary care providers under this rule.

- Section 447.400(a) has been revised to permit recognition of physician specialties and subspecialties by the American Board of Physician Specialties (ABPS) and the American Osteopathic Association (AOA) as well as the American Board of Medical Specialties, which was the only Board referenced in the proposed rule. This change recognizes the fact that these three Boards are the three nationally recognized physician certification Boards.

- Section 447.400(a)(2) has been revised to require physicians to self-attest that they are appropriately Board certified or that 60 percent of their Medicaid claims are for eligible E&M codes. This lessens the burden on State Medicaid agencies which, under the provisions of the proposed rule, were required to use these measures to verify the eligibility for higher payment of all physicians who self-attested to eligibility.

- A new § 447.400(b) has been added, specifying that, at the end of CY 2013 and CY 2014, the Medicaid agency must review a statistically valid sample of physicians who received higher payments to verify they met the requirements for such payment. Section 447.400(3) has been deleted because Medicaid agencies need no longer verify the self-attested eligibility of the physician.

- A new § 447.400(d) has been added to require that states collect and report to CMS data on the impact of the higher rates on physician participation. That data will assist Congress in determining determine whether or not to extend the provisions of this rule beyond the end of CY 2014.

- Section 447.405(a)(1) has been revised to require Medicaid agencies to pay eligible providers in CYs 2013 and 2014 at the Medicare part B fee schedule rate that is applicable either to the specific site of service or to the office setting. States must also either make all Medicare locality adjustments or may pay a statewide rate per E&M code based on the mean Medicare rate across counties. The final rule makes these

changes in recognition of the administrative burden to states associated with the need to make all site of service and geographic adjustments.

- Section 447.410 has been revised to add a new requirement that Medicaid agencies identify in the required state plan the eligible codes that will be paid at the Medicare rate in CYs 2013 and 2014 that were not paid under the state plan as of July 1, 2009. This is to assist in ensuring that eligible codes are not added solely for purposes of receiving 100 percent FFP. This section also requires that the state plan specify the methodology the state will use to identify the 2013 and 2014 Medicare rates.

- Section 447.415(b) has been revised to specify that, in calculating the 2009 Medicaid base rate, incentive, bonus and performance-based payments may be excluded. This is because these payments are not part of statewide fee schedule rates, but are paid only to physicians who meet specific goals or criteria. However, volume based payments, such as those made up to the average commercial rate, must be included since those payments, even when paid as aggregate payments, are based on code-specific calculations.

- Section 447.410(d) has been revised to clarify that bundled payments exclude encounter and per diem rates. This clarifies that physician services provided at sites such as clinics or nursing homes which are reimbursed as part of the encounter or NF per diem and not under a physician fee schedule are not eligible for higher payment.

IV. 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 Bureau's June 2011 Employer Costs for Employee Compensation report.

In our May 11, 2012, proposed rule, we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). PRA-related comments were received as indicated below.

A. ICRs Regarding Contract Requirements (§ 438.6)

In § 438.6(c)(3)(v) and (c)(5)(vi), states are required to modify managed care contracts and accompanying capitation rates through which MCOs, PIHPs or PAHPs will comply with the requirements of the Affordable Care Act. 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 42 CFR 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 receives sufficient documentation regarding those adjusted payments.

The one-time 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 37 state Medicaid programs with MCOs, PIHPs or PAHPs and the District of Columbia (38 total respondents) to amend an average of three managed care contracts. The associated requirements and burden estimates have been approved by OMB under OCN 0938–0920. Section 438.6(c)(3)(v) and (c)(5)(vi) would not impose any new or revised reporting or recordkeeping requirements and, therefore, does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The burden estimates approved under OCN 0938–0920 take into account the number of modifications required to managed care contracts by the states on an annual basis due to changes in federal law and the operations of a state's Medicaid program. As the amount of activity that would require contract modifications may vary across the states, the approved burden estimates accommodate that variation. Therefore, the one-time contract modification required by this rule fits within the existing estimates.

B. ICRs Regarding Primary Care Provider Payment Increases (§ 438.804(a)(1) and (2))

In § 438.804(a)(1) and (2), states are required to submit the methodologies they intend to use to develop a baseline for primary care service payments in 2009 as well as the differential between that baseline and the CY 2013 and 2014 rate to CMS for review and approval no later than the end of the first quarter of CY 2013. Further, we indicate that we will use those approved methodologies to review and approve managed care contracts and rates that are compliant with this provision.

The burden associated with the requirements under § 438.804(a)(1) and (2) is the time and effort it would take each of the 37 state Medicaid programs and the District of Columbia (38 total respondents with managed care delivery systems) to develop both methodologies, as well as managed care capitation rates which reflect the increased payments to implement this section. We received comments maintaining that the proposed rule had significantly underestimated the costs of implementing this provision in a managed care delivery system. In response, we are revising the burden estimates that were set out in the proposed rule. The task of developing both methodologies will involve a one-time effort on the part of financial, legal and management staff, as well as significant contractual actuarial resources. Most of the 38 states use contracted actuarial firms to develop managed care capitation methodologies and rates. Since the development of the 2009 baseline and CYs 2013–2014 rate differentials require actuarial analysis, we have estimated those contractual costs. Once the methodologies are developed by each respondent's contracted actuary, each respondent will need to review and approve them prior to submission to CMS.

We estimate that it will take approximately 100 hours of contractual actuarial services per respondent at a cost of \$5,398 to complete the data and actuarial analysis to develop these methodologies at a total cost of \$205,124 (38 × \$5,398). It will also take 10 hours per respondent at a cost of \$482.86 to review and validate these methodologies in order to submit them to CMS at a total cost of \$18,348.68 (38 × \$482.86). In deriving these figures, we used the following hourly labor rates and estimated the time to complete this task: \$53.98/hr and 100 hours for contracted actuarial staff; \$49.07/hr and 2 hours for legal staff to review the methodology for compliance with the

statute (\$98.14); and \$48.09/hr and 8 hours for managerial staff to review and submit these methodologies to CMS (\$384.72). The total one-time burden amounts to \$223,473 (\$205,124 + \$18,349).

C. ICRs Regarding General Requirements—Provider Agreements (§ 441.605(b))

This requirement is exempt from the PRA 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.

D. ICRs Regarding Administrative Fee Requirements (§ 441.615(d))

This requirement is exempt from the PRA since we expect to receive fewer than 10 submissions (annually) 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 administration fee.

E. ICRs Regarding Primary Care Services Furnished by Physicians With a Specified Specialty or Subspecialty (§ 447.400(a), (b), and (d))

In § 447.400(a), physicians are required to self-attest that they are Board certified in an eligible specialty or subspecialty or that 60 percent of the claims that they submit are for eligible E&M codes. In § 447.400(b), at the end of CY 2013 and CY 2014, the state must review a statistically valid sample of physicians who received higher payments to verify that they meet the one requirement to which they attested.

The burden associated with the requirements under § 447.400(a) and (b) is the time and effort it will take each of the 50 Medicaid Programs and the District of Columbia (51 total respondents) to establish a protocol for physician self-attestation and to conduct

and review a statistically valid sample of “eligible” physicians once in each of CYs 2013 and 2014. In the proposed rule we estimated that it would take 0.5 hours to determine whether a physician may receive payment under the Affordable Care Act. In this final rule, we assess the burden based on MSIS data from the fourth quarters of FY 2008 and 2009 which showed an average of 2,245 physicians per state who currently bill, but whose eligibility for increased payment would 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. The reported burden, which relies on a review of each physician qualifications, represents CMS’s best estimate of the cost to sample data on physicians who self-attested. We relied on the data reported above in the absence of information about how each state plans to implement its sampling methodology.

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 \$34,876.40 per state (\$14.12/hr × 2,470 responses/state) or \$1,778,696.40 total (\$34,876.40 × 51 states).

While proposed in the proposed rule, this final rule removes the provision that would have required states to verify the self-attestations of all physicians by confirming Board certification or an appropriate claims history. In this final rule, states must annually sample (in a statistically valid manner) the physicians who receive higher payment

to ensure that they are either Board certified or that 60 percent of the codes they bill to Medicaid are those codes identified in this rule. We are not able to estimate this burden with greater precision due to lack of data about the varying methods states will use to fulfill this requirement (see discussion under preamble section 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*). Therefore, we are not modifying our estimate of the impact of this section of the rule.

In § 447.400(d) the state is required to submit to CMS the information relating to participation by physicians as well as the E&M codes. The form and timeframe for such submission has yet to be determined by CMS.

F. ICRs Regarding State Plan Requirements (§ 447.410)

In § 447.410, states will 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. They will also be required to submit a SPA that reflects the payment increase for vaccine administration. The purpose of this 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. In accordance with § 447.205, public notification prior to the effective date of a SPA must be made whenever a state proposes a change to its methods and standards for setting payment rates for services. Consequently, the notification burden is included in the following estimate.

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 review, preparation, approval, and submission of a CMS-provided SPA template. We estimate that it will take state staff working 48 hours to complete all of the tasks associated with the review, preparation, approval, and submission of the SPA template. The estimated cost is \$1,606.95 per state (\$35.71/hr × 45 hr) or \$81,954.45 total (\$1606.95 × 51) for tasks completed by non-management staff working on SPA preparation. We estimate that this task will also require 3 hour for state-employed legal staff at \$49.07/hr or \$147.21 (per response) for a total of \$7,507.71 (\$147.21 × 51). The combined total for cost associated with SPA preparation, including non legal and legal staff employed by the state, is \$89,462.16 (\$81,954.45 + \$7,507.71).

The ongoing burden for states is the determination of the updated fee for service rate in CY 2014. We estimate that it will take state staff working 20 hours to set the new rate in accordance with the approved state plan amendment for this payment. The estimated cost is \$607.07 (\$35.71/hr × 17 hr) per state or \$30,960.57 total (\$607.07 × 51) for tasks completed by non-management staff working on SPA preparation. We estimate that this task will also require 3 hours for state-employed legal staff at \$49.07/hr or \$147.21 (per response) for a total of \$7,507.71 (\$147.21 × 51). The combined total for cost associated with SPA preparation, including non legal and legal staff employed by the state, is \$38,468.28 (\$30,960.57 + \$7,507.71).

G. Summary of Annual Requirements and Burden Estimates

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS AND ASSOCIATED BURDEN ESTIMATES ¹

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting (\$)	Total cost (\$) (rounded)
§ 438.804(a)(1) and (2).	0938–1170	38	38 (total)	110	4,180	223,472.68	223,473
§ 447.400(a) and (b)	0938–1170	51	2,470 (per state) or 125,970 (total).	.50	1,235 (per state) or 62,985 (total).	34,876.40 (per state) or 1,778,696.4 (total).	1,778,696
§ 447.410 (SPA amendments).	0938–1148	51	51 (total)	48	2,448	89,462.16	89,462
§ 447.410 (amending FFS rate).	0938–1148	51	51 (total)	20	1,020	38,468.28	38,468
Total	70,633	2,130,099.52	2,130,100

¹ There are no capital or maintenance costs incurred by any of the collections. Therefore, the capitol cost column has been omitted from the table.

H. Submission of PRA-Related Comments

We have submitted a copy of this final 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 submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, (CMS-2370-F) Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final 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 solicited 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. The Affordable Care Act 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 final rule will not have a substantial effect on state and local governments.

B. Statement of Need

This final rule will implement provisions of the Affordable Care Act that require 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 final rule will implement 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 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 final rule is an estimated \$5.600 billion in CY 2013 and \$5.745 billion in CY 2014 (measured in constant 2012 dollars). In CY 2013, the federal cost is approximately \$5.835 billion with \$235 million in state savings. In CY 2014, the federal cost is approximately \$6.055 billion with \$310 million in state savings. The state savings are derived from the projected increases in reimbursement rates expected to occur between 2009 and 2013 through 2014, in the absence of the Affordable Care Act, 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 \$975 million in federal costs. The federal costs for funding that increase, in State payments during CYs 2013 and 2014, are estimated at \$495 million and \$480 million, respectively. This also includes the impact on Medicaid-expansion CHIP expenditures; total CHIP expenditures are estimated to increase by \$145 million in CY 2013 and again in CY 2014, reflecting an increase in federal CHIP expenditures of \$155 million and a decrease in state CHIP expenditures of \$10 million in each year.

Overall, there is a net increase of \$165 million in the impact estimates of the final rule versus the proposed rule. This includes a \$290 million increase in the estimates due to the inclusion of the costs associated with the primary care payment increase for enrollees in the Medicaid-expansion CHIP plans. Furthermore, this impact is partially offset by a decrease of \$130 million as a result of the additional flexibility provided to states to determine the scope of the geographic adjustment to the MPFS. Lastly, there is a \$5 million increase in the cost estimate for vaccine administration related to VFC provided in the final rule versus the proposed rule.

Differences in the estimates provided in the final rule, versus those in the proposed rule, are mainly attributable to the inclusion of the Medicaid-expansion CHIP expenditures, as well as changes to the policy that allow states to either use the Medicare physician payment locality factors to determine the rates or

to develop a methodology to calculate mean or median Medicare rates to use statewide. The impacts presented in the proposed rule assume that states would pay primary care physician service rates that included the different Medicare locality factors.

Overall, the estimated economic impacts are a result of this final rule providing states the ability to increase payment for primary care services without incurring additional costs (with the exception of states that did or would have reduced primary care physician service reimbursement rates in their Medicaid programs between 2009 and 2014). 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.

D. Detailed Economic Analysis

1. Anticipated Effects on Medicaid Recipients

We anticipate this final rule will have a positive effect on Medicaid beneficiaries 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 provision of the regulation will positively affect the availability of vaccination services as well. Currently, approximately 5 states reimburse the regional maximum for vaccine administration set by the VFC program. This final rule will 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 people 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 final rule will 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 final rule will ensure that in CYs 2013 and 2014, physicians receive the higher Medicare rate for the specified primary care services.

In addition, this final rule will 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 updated Regional Maximum Administration Fees included in this final 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 final 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 will be no additional costs incurred by the federal government.

The same is true for states. There will be no impact of this final 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. It is estimated that if all states were to reimburse providers at the maximum administration fee, the total cost to states and the federal government would be \$75 million. Of this, the federal share is estimated to be \$45 million.

Children enrolled in the VFC program who are Medicaid eligible will not incur any additional costs as a result of this

final 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 will be impacted by this regulation. 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 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 will benefit from the regulation as they can 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 will 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 3 provides estimates of the anticipated Medicaid program expenditures associated with increasing payment for primary care services. CMS's 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 2013 Budget. (The original estimates that appeared in the April 2010 estimates were based off of 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 the Affordable Care Act, based on Medicare payment rates; these estimates were revised to incorporate the actual CY 2011 CF (75 FR 73169). OACT assumed that the volume of physician services covered by Medicaid would increase by 5 percent in managed care plans and by 10 percent in fee-for-service programs 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 in 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.

As a result of the changes to the policy that allows states to either use the Medicare physician payment locality factors to determine the rates or to develop a methodology to calculate the mean over all counties for each E&M code to use statewide, the estimates have been revised since the proposed rule. The estimates in the proposed rule reflect the expected impacts of the rule assuming that states would pay primary

care physician service rates that included the different Medicare locality factors. As states now have the option to develop a methodology using a mean over all counties based on the different locality payment rates within a state, the estimates have changed to reflect the different options states might use.

OACT has reviewed several possible methods states might consider using to determine the mean rates. The states' decisions to use the rate based on the Medicare locality rate or the mean rate measured over all counties may result in impacts ranging from \$11.185 billion over CY 2013 and CY 2014 to \$11.495 billion over the two years. It is assumed for the purposes of this rule that the expected cost would be equal to the median of this range, as no assumptions have been made for which states (with multiple Medicare physician payment localities) would choose each methodology.

TABLE 3—FEDERAL AND STATE MEDICAID AND CHIP IMPACTS FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS DURING CALENDAR YEARS 2013 THROUGH 2014 (MILLIONS OF 2012 DOLLARS)

	CY 2013	CY 2014
Federal Share*	\$5,835	\$6,055
State Share	– 235	– 310
Total	5,600	5,745

(* Federal cost estimates reflect the additional \$495 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.

Other changes made in the final rule increase the uncertainty regarding these estimates. In the final rule, states are no longer required to verify the self-attestation of all physicians that they are eligible for the higher payment rates. As a result, the review of a sample of the self-attesting physicians may find some physicians who are ineligible. To the extent that more physicians may self-attest as being eligible than would have been determined eligible by the state, there may be additional costs; the potential additional costs have not been quantified here.

It is important to note that, consistent with the proposed rule, these estimates do not include any impact related to the impact of the expansion of Medicaid eligibility beginning in 2014 as provided

by the Affordable Care Act. It is expected that the costs related to this rule would be even greater in 2014 than those listed in Table 3, as Medicaid enrollment increases with the new eligibility standards, as well as with efforts to simplify Medicaid enrollment and outreach efforts to enroll people in Medicaid, CHIP, and the Health Insurance Exchanges. As these new enrollees utilize primary care physician services that would be eligible for higher reimbursement rates, there would be additional costs related to this rule. These costs would dependent upon several factors, including: The number of new enrollees in 2014; the amount of primary care physician services the new enrollees utilize; the extent to which new enrollees participate in managed care Medicaid plans or in fee-for-service Medicaid; and the number of new enrollees in each state, as the impacts vary widely across the states. Furthermore, the cost would be highly dependent on which states elect to expand Medicaid eligibility in 2014, which is not known at this time. We further emphasize the uncertainties

associated with this estimate, especially regarding the participation of states in the Medicaid eligibility expansion.

4. Anticipated Effects on States

The federal government will 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 final rule will result in a positive effect on states, since it reduces their expenditures for primary care services. State savings are estimated at \$235 million and \$310 million in CYs 2013 and 2014, respectively. However, for Medicaid state plan rates below the 2009 level, states will 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/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 will primarily impact individual physicians and state Medicaid agencies. This final rule requires states to increase payment for primary care services without incurring additional state cost. As previously noted, we anticipate that this higher payment will 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 final

rule will 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 will 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 final rule will 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 final 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 solicited comment on the assumptions and analyses presented in the Alternatives Considered section. Detailed analysis on the alternatives considered to the provisions in the final rule is provided in the responses to comments in section II.

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. In the proposed rule, we included related subspecialists and used Board certification or subspecialty recognition by the American Board of Medical Specialties (ABMS) and a supporting history of codes billed in the absence of Board certification as a means of identifying eligible primary care physicians. We considered permitting physicians to qualify for payment based solely on self-attestation. The final rule CMS continues to recognize subspecialists related to the primary care specialists specified in the statute as eligible for this payment. We accept Board certification by the ABMS, American Osteopathic Association and ABPS. We permit payment based on self-attestation alone but, to promote program integrity, we are requiring that

states, at the end of each of CYs 2013 and 2014, review a statistically valid sample of providers who received higher payment to verify that they either were appropriately Board certified or that 60 percent of their claims during that period were for the identified E&M codes. Comments on this aspect of the final rule and our responses may be found in section II.A.1.a.

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

This rule clarifies physician services to mean any service delivered under the physician 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 nonphysicians. We recognize the importance of these nonphysician 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 § 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 meant that specified primary care services rendered by nonphysicians such as advanced practice nurses and other nonphysician professionals qualified 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.

In the final rule, higher payment is still limited to the qualified physicians and advanced practice professionals practicing under their personal supervision. However, services no

longer need to be billed under the physician's billing number, as long as the physician has professional responsibility for the services provided. The comments we received on this topic and CMS responses are found in section II.A.1.b.

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 estimated 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 \$755 million for CYs 2013 and 2014. In the final rule, we continue to believe that only those services reimbursed pursuant to a physician fee schedule and through the Medicaid state plan as a physician service are eligible for higher payment. In section II.A.1.b. we provide more detail about comments and our responses.

3. Eligible E&M Services

The statute requires enhanced payment for E&M services/codes. The proposed rule specified 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 included these additional codes because they represent core primary care services that are important to the Medicaid program.

We estimated 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 believed that a corresponding amount of the federal costs associated with this final regulation would be related to these services, reflecting an impact range of \$655 million to \$765 million over CY 2013 and 2014. As a result, the final rule specifies that all E&M codes identified in the proposed rule are eligible for higher payment. Rates for codes not reimbursed by Medicare will be developed by us based on a calculation of the CF and RVUs that are published by us. Comments and alternatives

considered regarding this section of the rule are presented in section II.A.2.b.

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 FFP 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 (for example, intranasal vs. injectable) to children under 8. However, new code 90460 represents the initial vaccine/toxoid administered through all routes to children through age 18 while code 90461 represents payment for additional vaccines/toxoids administered. This rule finalizes a method for imputing a vaccine administration rate in 2009 for code 90460. The 2009 rate would equal the average payment amount weighted by volume of codes 90465 and 90471. The 2009 value for code 90461 would be \$0, since there was no payment for additional vaccines/toxoids prior to 2011. We received one comment on this proposed methodology, which led to a revision of the formula.

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. Also, providers administering vaccines under the VFC program will be reimbursed the lesser of the Medicare rates in 2013 or 2014 or the Regional Maximum Administration Fee per vaccine. This final rule does not change 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. A more detailed analysis of the alternatives considered for increased payments for vaccine administration under the VFC program is discussed in

the response to comments in section II.A.4.c.

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. This rule continues to permit states 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 by Medicare during the year. It permits states to either make site of service adjustments or pay at the Medicare office rate. It requires states to either make all Medicare locality adjustments or to pay a statewide median rate over all counties. A discussion of the alternatives considered and comments received can be found in sections II.A.2.a. and c.

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 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 economic impact associated with updates to the regional maximum charges for the VFC program 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 will increase its reimbursement rate to the new VFC maximum fee.

7. Implementation of Payment Provision in Managed Care Delivery System

Section 1932(f) of the Act requires the application of the provisions of section 1902(a)(13) of the Act to managed care organization contracts and payments. The complexity of such an application was reviewed in several different areas—the varied scope of primary care providers that operate within managed care plans; identifying both the 2009

baseline payments for affected primary care services to managed care organizations as well as the amount of managed care capitation payments that would be eligible for 100 percent federal match; and the documentation that states must collect from managed care plans to verify that the Medicare rate is paid to eligible providers in CY 2013 and 2014.

The final rule require states to submit to us two methodologies, one for determining the 2009 baseline and the other for identifying that proportion of managed care capitation rates that represents the difference between the

2009 baseline rates and the applicable CY 2013 and 2014 Medicare rates. Both methodologies must be valid and reasonable and must acknowledge and accommodate each state's current rate-setting framework.

Finally, we considered specifying the documentation that states must collect from managed care plans to ensure that primary care providers are the beneficiaries of these increased payment rates. However, in deference to the wide variation in states' current oversight and reporting mechanisms for MCOs, PIHPs, and PAHPs, the final rule requires states to specify the documentation needed

from health plans to substantiate that primary care payment increases were made to eligible providers by the managed care plan.

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 4 we have prepared an accounting statement illustrating the classification of the federal and state Medicaid and CHIP impacts for the payment increases to primary care providers and VFC, as a result of the provisions in the final rule.

TABLE 4—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR FEDERAL AND STATE MEDICAID AND CHIP IMPACTS FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS AND VFC DURING CALENDAR YEARS 2013 THROUGH 2014

[Millions of 2012 dollars]

Category	Transfers			
	Discount rate			Period covered
Annualized monetized transfers	0%	7%	3%	CYs 2013–2014.
Primary Estimate	\$5,945	\$5,941	\$5,943	
From/To	Federal Government to Medicaid Providers			
Category	Transfers			
	Discount rate			Period covered
Annualized monetized transfers	0%	7%	3%	CYs 2013–2014.
Primary Estimate	–\$273	–\$271	–\$272	
From/To	State Governments to Medicaid Providers			

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

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 amends 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 documentation to the state, sufficient to enable the state and CMS to ensure that provider payments increase as required by 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 must submit to CMS the following methodologies for review and approval.

(i) The state develops a reasonable methodology, based on rational and documented data and assumptions, for identifying the provider payments that would have been made by MCO, PIHP or PAHP for specified primary care services furnished as of July 1, 2009. This methodology can take into consideration the availability of data, and the costs and burden of administering the method, but should produce a reliable and accurate result to the fullest extent possible.

(ii) The state develops a reasonable methodology, based on rational and documented data and assumptions, for identifying the differential in payment between the provider payments that would have been made by the MCO, PIHP or PAHP on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi). This methodology can take into consideration the availability of data, and the costs and burden of administering the method, but should produce a reliable and accurate result to the fullest extent possible.

(2) The state must submit the methodologies in paragraphs (a)(1)(i) and (ii) of this section to CMS for review no later than the end of the first quarter of CY 2013.

(3) CMS will use the approved methodologies required under this section in the review and approval of MCO, PIHP or PAHP contracts and rates consistent with § 438.6(a).

(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 L is added to read as follows:

Subpart L—Vaccines for Children Program

Sec.

- 441.600 Basis and purpose.
- 441.605 General requirements.
- 441.610 State plan requirements.
- 441.615 Administration fee requirements.

Subpart L—Vaccines for Children Program

§ 441.600 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.

§ 441.605 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.

§ 441.610 State plan requirements.

A state plan must provide that the Medicaid agency meets the requirements of this part.

§ 441.615 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 × updated geographic adjustment factors (GAFs) = maximum VFC fee.

(d) The State 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.

- 447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.
- 447.405 Amount of required minimum payments.
- 447.410 State plan requirements.
- 447.415 Availability of Federal financial participation (FFP).

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 (ABMS), the American Board of Physician Specialties (ABPS) or the American Osteopathic Association (AOA). A physician self-attests that he/she:

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

(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 he or she has billed during the most recently completed CY or, for newly eligible physicians, the prior month.

(b) At the end of CY 2013 and 2014 the Medicaid agency must review a statistically valid sample of physicians who received higher payments to verify that they meet the requirements of paragraph (a)(1) or (2) of this section.

(c) 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.

(d)(1) The state must submit to CMS, in such form and at such time as CMS specifies, information relating to participation by physicians described in paragraph (a) of this section and the utilization of E&M codes described in paragraph (c) of this section (whether furnished by or under the supervision of a physician described in paragraph (a)) of this section for the following period—

(i) As of July 1, 2009, and

(ii) CY 2013

(2) As soon as practicable after receipt, CMS will post this information on www.Medicaid.gov.

§ 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:

(1) The Medicare Part B fee schedule rate that is applicable to the specific site

of service or, at the state's option, the office setting and is also adjusted for either the specific geographic location of the service or reflects the mean over all counties of the rate for each E&M code. 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 state 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). The amendment must:

(a) Identify all eligible codes that the state will reimburse at the Medicare rate in CYs 2013 and 2014.

(b) Identify all codes that were not reimbursed under the Medicaid program as of July 1, 2009.

(c) Specify either that the state will make all adjustments applicable to the specific site of service or, at the state's option, the office setting and will also either adjust for the specific geographic location of the service or pay rates that reflect the mean over all counties of the rate for each E&M code. The state must specify the formula that the state will use to determine the mean rate for each E&M code.

§ 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 exclude incentive, bonus, and performance-based payments but must include supplemental payments for which the approved methodology is linked to volume and payment for specific codes.

(c) For vaccine administration, the state must impute the payment that would have been made for code 90460 under the approved Medicaid state plan. The imputed rate for July 1, 2009, for code 90460 equals the payment rates for codes 90465 and 90471 weighted by service 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. Bundled rates, for purposes of this provision, do not include encounter and per diem rates.

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

Dated: September 12, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 2, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012-26507 Filed 11-1-12; 4:15 pm]

BILLING CODE 4120-01-P