This document is scheduled to be published in the
Federal Register on 11/02/2015 and available online at
http://federalregister.gov/a/2015-27697, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2328-FC]

RIN 0938-AQ54

Medicaid Program; Methods for Assuring Access to Covered Medicaid Services

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period provides for a transparent data-driven process for states to document whether Medicaid payments are sufficient to enlist providers to assure beneficiary access to covered care and services consistent with section 1902(a)(30)(A) of the Social Security Act (the Act) and to address issues raised by that process. The final rule with comment period also recognizes electronic publication as an optional means of providing public notice of proposed changes in rates or ratesetting methodologies that the state intends to include in a Medicaid state plan amendment (SPA). We are providing an opportunity for comment on whether future adjustments would be warranted to the provisions setting forth requirements for ongoing state reviews of beneficiary access.

DATES: Effective Date: These regulations are effective on [insert date 60 days after the date of publication in the Federal Register].

Comment Date: To be assured of consideration, comments on §447.203(b)(5) must be received at one of the addresses provided below, no later than 5 p.m. on [insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-2328-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

listed):

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2328-FC,

P.O. Box 8016,

Baltimore, MD 21244-8016.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2328-FC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

FOR FURTHER INFORMATION CONTACT:

Jeremy Silanskis, (410) 786-1592.

SUPPLEMENTARY INFORMATION:

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

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

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

Provisions for Public Comment: We are issuing this final rule with comment period to provide the opportunity for further comment on § 447.203(b)(5) to determine whether further adjustments to the access review requirements would be warranted, including the scope of regular state access reviews in the absence of a triggering circumstance. After consideration of public comments, this final rule with comment period limits the scope of services for which states will be required to review beneficiary access, in order to balance the need for stronger data and processes to ensure beneficiary access with minimizing administrative burden. We believe that additional input would be useful to determine whether modifications of these state access review requirements may be warranted. Therefore, we are providing an opportunity for comment specifically on the access review requirements, including the service categories required for ongoing review, elements of the review, and the timeframe for submission. CMS also requests comment on whether we should allow exemptions based on state program characteristics (for example, high managed care enrollment), the provisions of this rule from which states could be exempted based on these specific program characteristics, and alternatives to ensuring compliance with section 1902(a)(30)(A) of the Act for any exempted services in lieu of the procedures described in this final rule with comment period. For example, the proposed rule included the requirement for states to conduct an access review for all services every 5 years and this final rule with comment period will require that states conduct an access review on five

specific service categories (and other categories when the state or CMS has received a significantly higher than usual volume of beneficiary or provider access complaints for a geographic area) every 3 years. The changes in this final rule with comment period resulted in large part from our consideration of comments received from the public, including requests for additional clarity with respect to some of these matters. While we believe these changes will assist states in implementing the access review and monitoring requirements, we are seeking additional comment on these provisions so that we can determine whether future adjustment of these requirements through additional rulemaking would be warranted. In addition, we are publishing a request for information (RFI) that solicits feedback from stakeholders on whether and which core access measures, thresholds, and appeals processes would provide additional information or approaches that would be useful to us and states in ensuring access to care for Medicaid beneficiaries. We are interested in access measures that would apply regardless of the service delivery approach adopted by the state, and would include access measures applicable for populations enrolled in managed care. Ultimately, our RFI-related goals are to better measure, monitor, and ensure Medicaid access across state program and delivery systems and understand the economic and policy factors that affect access to care. The RFI is published elsewhere in this **Federal Register** along with information on where respondents can send their responses.

I. Background

A. General Information

In the May 6, 2011 **Federal Register** (76 FR 26342), we published the “Medicaid Program; Methods for Assuring Access to Covered Medicaid Services” proposed rule (hereinafter referred to as the “May 6, 2011 proposed rule”) that outlined a standardized, transparent, data-driven process for states to document that provider payment rates are consistent with efficiency, economy, and quality of care and are 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 as required by section 1902(a)(30)(A) of the Social Security Act (the Act). In the May 6, 2011 proposed rule, we recognized that states must have some flexibility in designing appropriate approaches to demonstrate and monitor access to care, which reflects unique and evolving state service delivery models and service rate structures. Within the proposed rule, we discussed how a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act could prove difficult given current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles. For these reasons, we proposed federal guidelines to frame alternative approaches for states to demonstrate consistency with the access requirement using a standardized, transparent process, rather than setting nationwide standards.

In this final rule with comment period, we are providing increased state flexibility within a framework to document measures supporting beneficiary access to services. This final rule with comment period implements methods for states to use in complying with section 1902(a)(30)(A) of the Act by requiring that states review data and trends to evaluate access to care for covered services and conduct public processes to obtain public input on the adequacy of access to covered services in the Medicaid program. This information will be updated and monitored regularly. Should the data reveal short-comings in Medicaid beneficiaries' access to care, states must take corrective actions. The final rule with comment period also recognizes electronic publication as an optional means of providing public notice of proposed changes in rates or ratesetting methodologies that the state intends to include in a Medicaid state plan amendment (SPA). This final rule with comment period will meet the expectations of the May 6, 2011 proposed rule to establish a transparent data-driven process that ensures that rates are consistent with section 1902(a)(30)(A) of the Act.

B. State Ratesetting and Access to Care

The Medicaid statute requires that states provide coverage to certain groups of

individuals, and also requires that such coverage include certain minimum benefits. States may elect to cover other populations and benefits. To give meaning to coverage requirements and options, beneficiaries must have meaningful access to the health care items and services that are within the scope of the covered benefits. This is consistent with the requirements of section 1902(a)(30)(A) of the Act, which provides that states must have methods and procedures to assure that payments to providers are "sufficient to enlist enough providers so that care and services are available under the plan at least to the same extent that such care and services are available to the general population in the geographic area," which we refer to as the "access requirement." Many factors affect whether beneficiaries have access to Medicaid services, including but not limited to: the beneficiaries' health care needs and characteristics; state or local service delivery models; procedures for enrolling and reimbursing qualified providers; the availability of providers in the community; the capacity of Medicaid participating providers; and Medicaid service payment rates to providers. To align with the statutory requirements, states may employ any number of strategies to ensure or improve access to care that are targeted toward one or more of these factors.

We have not previously defined through federal regulation an approach to guide states in meeting the statutory access requirement at section 1902(a)(30)(A) of the Act. In the absence of federal guidance and a clear process for monitoring and ensuring access, at times budget-driven payment changes in state Medicaid programs led to confusion and litigation for states and to possible access problems for beneficiaries. CMS's review of state payment rate methodologies for compliance with this requirement was on a case-by-case basis and was hampered by the lack of consistent information related to beneficiary access. We historically relied on state certifications and available supporting information to conclude that Medicaid payment rates met the statutory standards.

In the May 6, 2011 proposed rule, we proposed to adopt an approach for states to analyze

access to care for Medicaid services through data and information from beneficiaries and providers. The approach specifically focused on: (1) the extent to which enrollee needs are met; (2) the availability of care and providers; and (3) changes in beneficiary utilization. The purpose of the proposed regulation was not to create an access standard or rate thresholds that each state must meet, but to develop a standard process for each state to follow in documenting access to care. The regulation proposed to require that states conduct regular reviews of Medicaid access to care that rely upon: payment data, trends in utilization, provider enrollment, feedback from providers and beneficiaries, and other pertinent information that describes access to Medicaid services. The access data reviews would be used to inform state payment changes as well as our approval decisions when states proposed provider payment reductions. In addition, the proposed rule specified that states must conduct a public process when reducing Medicaid payment rates and monitor changes in access to care after payment reductions are approved by us and go into effect.

Earlier this year, the Supreme Court decided in Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015) that the Medicaid statute does not provide a private right of action to providers to enforce state compliance with section 1902(a)(30)(A) of the Act in federal court. As a result, provider and beneficiary legal challenges are not available to supplement CMS review and enforcement to ensure beneficiary access to covered services. To strengthen CMS review and enforcement capabilities, this final rule with comment period provides for the development of needed information to monitor and measure Medicaid access to care. The final rule with comment period will provide more transparency on access in Medicaid fee-for-service (FFS) systems than ever before and allow us to make informed data-driven decisions and document our decisions when considering proposed rate reductions and other methodology changes that may reduce beneficiaries' abilities to receive needed care. In addition, because the proposed rule was issued several years prior to the Armstrong decision and therefore does not address CMS' or

states' role in light of Armstrong's limits on providers' and beneficiaries' ability to take legal action regarding access, CMS is also issuing a Request for Information to obtain public input into additional approaches to Medicaid's statutory access requirements for CMS to consider.

While states will continue to have the discretion to set program rates and improve access to care through a variety of strategies, this final rule, and any additional measures we adopt, will increase the information available to CMS, to ensure that rates meet the requirements of section 1902(a)(30)(A) of the Act and that access improvement strategies work to improve care delivery when there are deficiencies. We are also developing internal standard operating procedures to bolster the administrative record that is used to document compliance with the final rule for individual SPAs and ensure that there is consistent national application of these policies.

C. Medicaid Service Delivery Systems and Provider Payment Methodologies

States have broad flexibility under the Act to establish service delivery systems for covered health care items and services, to design the procedures for enrolling providers of such care, and to set the methods for establishing provider payment rates. For instance, many states provide medical assistance primarily through capitated managed care arrangements, while others use FFS payment arrangements (with or without primary care case management). Increasingly, states are developing service delivery models that emphasize medical homes, health homes, or broader integrated care models to provide and coordinate medical services. The delivery system design and accompanying payment methodologies can significantly shape beneficiaries' abilities to access needed care by facilitating the availability of such care. In addition, the delivery system model and payment methodologies can improve access to care by making available care management teams, physician assistants, community care coordinators, telemedicine and telehealth, nurse help lines, health information technology and other methods for providing coordinated care and services and support in a setting and timeframe that meet beneficiary needs.

We have issued a series of State Medicaid Directors (SMD) letters to promote and

provide guidance on pathways to implementing integrated care models which can provide higher quality care at lower cost. We have also worked with states to explore innovative approaches to improving care and lowering cost through the Innovation Accelerator Program, the Medicaid Value-Based Learning Collaborative series, group workshop sessions, and one-to-one technical assistance discussions. All of these efforts seek to drive systemic changes in the Medicaid program that manage program costs consistent with the economy and efficiency provisions of section 1902(a)(30)(A) of the Act while also promoting the quality of care.

As state delivery system models have evolved, so have their provider payment systems. For most services, states develop rates based on the costs 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. Often, rates are updated based on specific trending factors such as the Medicare Economic Index or a Medicaid trend factor that incorporates a state-determined inflation adjustment rate. Rates may include incentive payments that encourage providers to serve Medicaid populations and improve care. For instance, some states have authorized Medicaid providers to receive separate payments for treatment services and for care coordination and care management. Some states have increased provider payments based on achievement of certain specified quality or health outcome measures.

We have worked with states to design payment and service delivery systems to ensure program savings are aligned with better care quality and promote rather than reduce access to services. Although states may experience reductions in service utilization or overall provider payments for high cost services as a result of program innovations that emphasize preventive care and divert individuals into more appropriate treatment modalities, including serving them in the most integrated setting appropriate to the needs of the individual consistent with Olmstead v. L.C. 527 S.Ct. 581 (1999), we do not see those reductions as being at odds with the statutory requirements or provisions described in this final rule with comment period. The provisions of

the final rule with comment period allow states the opportunity to transparently discuss the methods and analyses that they use to demonstrate compliance with section 1902(a)(30)(A) of the Act. The analysis and the follow-up monitoring data should clarify whether and how changes in care and payment data result from delivery and payment systems reform rather than reductions in access to care.

The flexibility in designing service delivery systems and provider payment methodologies, as described above, is consistent with the requirement in section 1902(a)(30)(A) of the Act that state Medicaid plans must provide: such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services. As well, states must assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the same extent that such care and services are available to the general population in the geographic area.

Consistent with the requirement in section 1902(a)(30)(A) of the Act to provide payment for quality care in an effective and efficient manner, states can use their ratesetting policies to seek the best value. Achieving best value has been a key strategy for some states that have attempted to reduce costs in the Medicaid program in these difficult fiscal times. We do not intend to impair states' abilities to pursue that goal, or to impair states’ abilities to explore innovative approaches to providing services and lowering costs for other reasons. In this final rule with comment period, we hope to clarify that, although states must demonstrate that beneficiaries have access to covered services at least comparable to others in the geographic area, this access can be through service delivery networks, using payment methodologies different from other individuals in the geographic area. Comparable access does not necessarily require that beneficiaries obtain services from the same providers, or the same number of

providers, as other individuals in the geographic area.

D. Modifications to State Payment Rates

Payment rates should be neither too low nor too high to ensure access to care for Medicaid beneficiaries and to ensure the economy and efficiency of Medicaid services and spending. Setting total payments too high does not necessarily improve beneficiary access. This is particularly true when higher payments are targeted to select providers and do not necessarily translate into improved access to services. Payment reductions or other adjustments to payment rates can help to manage Medicaid program costs and ensure efficiency of service provision, without necessarily violating requirements to ensure access to care. For example, a state may amend its program to use a selective contract to provide incontinence supplies which results in lower payment rates for those supplies while maintaining statewide access to those supplies. Or a state may reduce payments for hospital readmissions to encourage the hospital to collaborate with a primary care case management provider in the community. A state may also rebalance its long term services and supports spending consistent with Olmstead v. L.C. 527 S. Ct. 581 (1999) to ensure that older adults and individuals with disabilities can receive high quality community-based services.

However, payment reductions or other adjustments can, in some circumstances, compromise beneficiary access to services. Consequently, we affirm in this final rule with comment period that such payment rate changes be made only with consideration of the potential impact on access to care for Medicaid beneficiaries and with effective processes for assuring access. Payment rate changes do not comply with the Medicaid access requirements if they result in a denial of sufficient access to covered care and services. Non-compliant changes could adversely affect beneficiaries' abilities to obtain needed, cost-effective preventive care, create stress on safety-net providers, and counteract state delivery reform efforts that seek to reduce cost and increase quality.

At times, budget-driven payment changes have led to confusion among states and providers about the analysis required to demonstrate compliance with Medicaid access requirements at section 1902(a)(30)(A) of the Act. States attempting to reduce Medicaid costs through payment rate changes have increasingly been faced with litigation challenging payment rate reductions as inconsistent with the statutory access provision. Further, resulting court decisions have not offered consistent approaches to compliance. These decisions have at times left states, providers, and beneficiaries without clear and consistent guidelines and resulted in uncertainty in moving forward in designing service delivery systems and payment methodologies. For instance, several federal Courts of Appeals have addressed access and payment issues, but there has been no consensus concerning the data or standards that would be relevant in determining compliance with the Medicaid statute. More recently, in March 2015, the Supreme Court ruled in Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015) that the Medicaid statute does not provide a private right of action for providers and beneficiaries to challenge payment rates in federal court. The lack of a private right of action underscores the need for stronger non-judicial processes to ensure access, including stronger processes at both the state and federal levels for developing data on beneficiary access and reviewing the effect on beneficiary access of changes to payment methodologies. In issuing this final rule with comment period, we have reviewed options to ensure that states are adhering to the statute in light of the absence of a private right of action for noncompliance in federal court following the Armstrong decision.

In the May 6, 2011 proposed rule, we intended to establish consistent procedures that all states would follow in reviewing and understanding Medicaid access to care on an ongoing basis and monitoring access after reducing or restructuring rates. Specifically, we proposed that states conduct ongoing access reviews for all Medicaid services over 5-year periods that evaluate: the extent to which enrollee needs are met; the availability of care and providers; and changes in

beneficiary utilization of covered services. We proposed that within the reviews, states would need to include information about access gathered through ongoing beneficiary feedback mechanisms and comparisons of Medicaid payments to Medicare, commercials rates, or Medicaid service costs. We proposed that when states reduce or restructure rates in ways that could harm access to care, they consider concerns raised by beneficiaries and stakeholders and develop and monitor indices to ensure sustained access after implementing the rate changes. States would have the discretion to choose the data used to measure and analyze access to care and mechanisms to receive information from beneficiaries and other stakeholders.

This final rule with comment period recognizes the importance of stronger processes and data to ensure access to care while supporting state flexibility to design the appropriate measures to demonstrate and monitor access to care, which reflect the unique and evolving state service delivery models and service rate structures. A uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act could prove challenging at this time, given local variations in service delivery, beneficiary needs, provider practice roles, and limitations on data. At this time, we are issuing this final rule with comment period to establish approaches for states to demonstrate consistency with the access requirement using a consistent, transparent process, rather than setting nationwide standards. These approaches will also strengthen our ability to make sound and data-driven decisions about the adequacy of state payment rates.

This final rule with comment period will not directly require states to adjust payment rates; nor will it require states to adopt policies that are inconsistent with efficiency, economy, and quality of care. Even if access issues are discovered as a result of the analysis that is required under this rule, states may be able to resolve those issues through means other than increasing payment rates. This rule requires that beneficiary access must be considered in setting and adjusting payment methodologies for Medicaid services. If a problem is identified, any number of steps, including payment increases, might be appropriate to address the problem, such

as: redesigning service delivery strategies or improving provider enrollment and retention efforts. This final rule with comment period provides that we will review these access issues in making SPA approval decisions, and describes a more consistent and transparent way for states to collect and analyze the necessary information to support such reviews.

We consider the requirements of this final rule with comment period as a component of a broader strategy to ensure access in the Medicaid program. However, the 2011 proposed rule did not anticipate the Supreme Court decision: Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015), which underscored the primacy of CMS's role in ensuring access. For this reason, CMS may consider additional approaches to promote access to care. We will, for example, examine the feasibility of establishing a core set of access metrics and thresholds that can be universally applied across all states and services, as well as appropriate ways to gather that information. Additionally, we will assess the feasibility of processes that target and resolve access to care issues at an individual level, such as robust complaint resolution or formal hearings processes.

Specifically, as we issue this final rule with comment period, we are concurrently issuing a request for information (RFI) that solicits feedback from stakeholders on whether and which core access measures, thresholds, and appeals processes would provide additional information or approaches that would be useful to us and states in ensuring access to care for Medicaid beneficiaries. We are interested in access measures that would apply regardless of the service delivery approach adopted by the state, and would include access measures applicable for populations enrolled in managed care. Ultimately, our RFI-related goals are to better measure, monitor, and ensure Medicaid access across state program and delivery systems and understand the economic and policy factors that affect access to care. The RFI is published elsewhere in this **Federal Register** along with information on where respondents can send their responses.

In addition to issuing this final rule with comment period and the RFI, we also will

improve our administrative processes associated with documenting the basis for approval and disapprovals when states propose SPAs that reduce rates or restructure payments in ways that may affect access to care. The information that is gathered by states through the processes described in this final rule with comment, as well as through additional state and CMS processes for ensuring Medicaid access to care, will be the basis for our approval decisions and we will build our administrative SPA records with this information.

II. Summary of Proposed Provisions

We proposed to address state processes for setting payment rates by amending existing regulations at §447.203, §447.204, and §447.205. The following is a summary of our proposals.

A. Documentation of Access to Care and Service Payment Rates

We proposed to revise §447.203(b) to require state Medicaid agencies to demonstrate access to care by documenting in an access monitoring review plan their consideration of: enrollee needs; the availability of care and providers; and the utilization of services. The experiences of beneficiaries should be a primary determinant of whether access is sufficient. We solicited comments that would serve to help states narrow the focus of the data review to core elements that would demonstrate sufficient access to care. We received, through public comments, many suggested elements that states could incorporate into access reviews, but there was no consensus among commenters as to measures that could be universally applied across all services. We will continue to study whether a core set of measures and thresholds should be applied to Medicaid access to care and are soliciting more information from stakeholders on this question through the RFI process.

Proposed §447.203(b)(1)(i) through (iii) would have required states to review and make publically available data trends and factors that measure: enrollee needs; availability of care and providers; and utilization of services. Consistent with the statutory requirement, we proposed that states review this data by state designated geographic location.

We proposed revisions to §447.203(b)(1)(iii)(B) to require that the review must include: (1) an estimate of the percentile which Medicaid payment represents of the estimated average customary provider charges; (2) an estimate of the percentile which Medicaid payment represents of one, or more, of the following: Medicare payment rates, the average commercial payment rates, or the applicable Medicaid allowable cost of the services; and (3) an estimate of the composite average percentage increase or decrease resulting from any proposed revision in payment rates.

We proposed in §447.203(b)(1)(iii)(B)(3) that the Medicaid payment rates must include both base and supplemental payments for Medicaid services. Since states often reimburse service providers according to different payment schedules based on governmental status, we proposed at §447.203(b)(1)(iii)(C) that states stratify the access review data by state government owned or operated, non-state government owned or operated and private providers.

In §447.203(b)(1)(iii)(D), we proposed to describe the minimum content that must be in included in the rate review. Specifically, we proposed to require that states describe the measures that were used to conduct the review and their relationship to enrollee needs, the availability of care and providers, service utilization and Medicaid payment rates as compared to other payment structures.

Proposed §447.203(b)(2) described the timeframe for states to conduct the data review and make the information available to the public through accessible public records or Web sites on an on-going basis for all covered services. We proposed that the annual reviews begin no later than 2013, so states would have the discretion to determine a timeframe to review each covered Medicaid service, as long as the state reviewed a subset of services each year and each covered service is reviewed at least once every 5 years. We provided states this 5-year cycle to reduce the burden while accommodating the need for review to assure compliance with section 1902(a)(30)(A) of the Act.

Because of the need to demonstrate service access in the context of a payment rate reduction, we proposed in §447.203(b)(3)(i) that states would need to conduct the review relevant to the affected service prior to submission of a SPA implementing a reduction. If the state had already reviewed access relating to the types of services that are subject to the rate reduction within 12 months prior to the proposed rate reduction, and maintained an ongoing monitoring mechanism for beneficiary complaints, its review relative to the rate reduction could be referenced in the previous review. To ensure sustained access to care, we included provisions at §447.203(b)(3)(ii) that would require states to develop ongoing monitoring procedures through which they periodically review indices to measure sustained access to care. We also proposed at §447.203(b)(4) to require states to have a mechanism for beneficiary input on access to care, such as hotlines, surveys, ombudsman or other equivalent mechanisms. Additionally, we proposed at §447.203(b)(5) a corrective action procedure requiring states to submit a remediation plan should access issues be discovered through the access review or monitoring processes. These requirements were proposed to ensure that states would oversee and address future access concerns.

B. Medicaid Provider Participation and Public Process to Inform Access to Care

In §447.204, we proposed to implement the statutory requirement that Medicaid payment rates must be consistent with efficiency, economy, and quality and are sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that those services are available to the general population. We proposed to revise §447.204(a)(1) through (a)(2) to require that states consider, when proposing to reduce or restructure Medicaid payment rates, the data collected through the proposed requirement at §447.203 and undertake a public process that solicits input on the potential impact of the proposed reduction of Medicaid service payment rates on beneficiary access to care. In §447.204(b), we also proposed to clarify that we may disapprove a proposed rate reduction or restructuring SPA that does not include or

consider the data review and a public process. Disapproving the SPA means that a state would not have authority to implement the proposed rate reduction or restructuring and would continue to pay providers according to the rate methodology described in the state plan.

C. Public Notice of Changes in Statewide Methods and Standards for Setting Payment Rates

We proposed to clarify and modernize changes to the public notice requirement at §447.205. We also solicited comments on whether it is advisable to delete the term "significant" from §447.205(a) and explicitly state that notice is required for any change in rates. Alternatively, we solicited comments on whether to adopt a threshold for significance and what that threshold might be.

Further, we proposed to recognize electronic publication as an optional means of publishing payment notice. To do so, we proposed adding §447.205(d)(iv), which would allow notice to be published on a Web site developed and maintained by the single state Medicaid agency or other responsible state agency that is accessible to the general public on the Internet.

III. Analysis of and Responses to Public Comments

We received at total of 181 comments from states, advocacy groups, providers, provider organizations and individuals on the May 6, 2011 proposed rule. The comments ranged from support for the proposal to specific questions or comments regarding the proposed changes. We received some comments that were outside of the scope of the proposed rule, and therefore, not addressed in this final rule with comment period.

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

A. General Comments

We received many comments that were general in nature and were not specific to any of the provisions of the May 6, 2011 proposed rule. We have summarized and responded to those comments below.

Comment: Several commenters urged CMS to delay implementation of the final rule and work with states to find alternative approaches to measuring access. Commenters also recommended that CMS convene a workgroup with state Medicaid agencies to develop access thresholds. One commenter wrote that CMS and states would be better served to work together to identify reasonable criteria under which state legislatures could make timely and meaningful adjustments to provider rates and states could document the potential impact to access.

Response: We have worked with states and federal partners to identify appropriate access measures and a manageable process for state Medicaid agencies to meet the statutory requirements of section 1902(a)(30)(A) of the Act. This included listening sessions with the National Association of Medicaid Directors to hear state concerns regarding Medicaid access to care and how states were working to address access issues. We worked with many states and providers individually to understand state-specific access issues and the types of information that states and providers rely upon to discuss access to care. Finally, we worked with HHS' Assistant Secretary for Planning and Evaluation (ASPE) to investigate if there are national access measures that may be applied across all states and services for compliance with section 1902(a)(30)(A) of the Act. The policies reflected in this final rule with comment period are consistent with these efforts and the public comments we received. This final rule with comment period is being published after extensive consultation, 4 years after we issued the proposed rule. Further delaying this rule could result in confusion as to the application of the access requirements of section 1902(a)(30)(A) of the Act, especially given the Supreme Court's decision in Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015), which specifically stated that providers do not have a private right of action to enforce section 1902(a)(30)(A) of the Act and that CMS is ultimately responsible for enforcing the statutory requirements. This final rule with comment provides a more systematic approach than currently exists in the Medicaid program for states and us to evaluate beneficiary access to services. The

regulatory framework also seeks to ensure that states will have the information necessary to consider and evaluate access issues. We will continue to work closely with states and other partners to appropriately review access to care and address access issues, while remaining cognizant that states need to make program adjustments and operate within budgets. In addition, the RFI will solicit further information on whether and which core access measures, thresholds and appeals processes would provide additional information or approaches that would be useful to us and states in ensuring access to care to Medicaid beneficiaries.

Comment: A number of commenters requested that CMS provide an incentive mechanism to encourage states to address access issues in a timely manner. Commenters specifically suggested that an enhanced administrative matching rate be made available for costs associated with the final rule.

Response: To receive federal financial participation (FFP) for Medicaid services, states must comply with the applicable statutory and regulatory requirements. To the extent that state activities described in this final rule with comment period are for the proper and efficient administration of the Medicaid state plan, the administrative match rate is available to states. We do not have the statutory authority to provide an enhanced administrative match rate for these activities.

Comment: Several commenters requested that CMS clarify what constitutes a payment change. A commenter noted that providers often view years when rates do not increase as payment reductions. Another noted that the preamble of the May 6, 2011 proposed rule refers to “payments” and “rates” interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates. The commenter stated that if the final rule considers all Medicaid revenues received by providers, states may be challenged to make any change to the Medicaid program that might reduce provider revenues. The commenter

also suggested that the final rule clarify that the statute refers to specific service rates under the Medicaid state plan or waiver rather than all Medicaid provider payments.

Response: The statute requires that states have methods and procedures relating to Medicaid payment rates so that such rates are sufficient to enlist enough providers to ensure access to care. The final rule refers to actions to reduce or restructure rates which may result in less access to care. While the final rule applies only to Medicaid fee-for-service rates for state plan covered services, which may not include all Medicaid revenues received by a provider, the rule does contemplate broader payment changes that may affect access, such as reductions to supplemental provider payments. In addition, reviewing additional data will enable CMS to better identify and work with states to address access deficiencies that may arise if rates are not updated for many years, and if necessary to address them through compliance action. At this time, we generally do not review individual Medicaid payment rates as part of the SPA process, but we review the methodologies that states apply to set their provider rates or payments.

This final rule with comment period requires states to review access information on an ongoing basis for primary care services, including physician, federally qualified health centers (FQHC), clinic, dental care, etc.; physician specialist services (for example, cardiology, urology, radiology); behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services (as defined in §440.70), whether or not the payment methodologies change. States may also choose to select additional services to review through the access monitoring review plan. In addition, when changes to payment methodologies are made through the SPA process, the state must be able to support that change with documentation that access to care will not be adversely affected, and must monitor access after the change is made. If, for example, a state removes an annual inflation adjustment and therefore freezes rates from 1 year to the next when an increase in inflation was anticipated, a current access review will be required to support approval of a

SPA, and the state will also need to continue to monitor access. In addition, whether or not the state changes payment methodologies (including for services outside of the ongoing monitoring and review requirements), required ongoing mechanisms to receive beneficiary and provider feedback would indicate to states and CMS access issues that arise for any Medicaid service.

Comment: Several commenters suggested the final rule clarify that all state actions pertaining to provider payment rate setting, including legislatively mandated rate reductions, are subject to the access analysis and public process requirements and that legislatively mandated rate cuts cannot be implemented retroactively.

Response: We agree with the commenters that it is important for states to evaluate access any time the state proposes a change to its Medicaid reimbursement methodologies that will result in a reduction or restructuring of provider rates. This final rule with comment period does not provide for exceptions to this requirement to review access when there is a state legislative requirement. But nothing in this rule changes the longstanding policies that permit a state to submit a SPA with an effective date as early as the first day of the quarter in which a plan is submitted (but only after public notice of the new rates have been issued). This policy permits states flexibility to implement approvable rate changes without delay while it undergoes federal review. Thus, states may continue to implement rate reductions retroactively to the first day of the quarter in which an approvable SPA is submitted to CMS.

Comment: Several commenters requested that we make the following data public for all providers, beneficiaries, and stakeholders to review and comment upon: (1) data analysis and any supporting documentation; (2) SPA submissions and supporting documentation; and (3) all communication between CMS and states pertaining to data analysis and SPAs.

Response: In this rule, we require states to make the data analysis and supporting documentation available both to the public and to CMS. While publication of specific information related to SPA submissions and disposition is not required under this final rule with

comment period, these materials may be available through Freedom of Information Act (FOIA) requests. We recommend that states publish the access monitoring review plans and subsequent data collected through those plans on their Web sites for full transparency. Furthermore, we continue to post approved SPAs on the www.Medicaid.gov Web site and will post state access review plans so that they are publicly available. Issuing all of the communications and documentation associated with the SPA review process as it is ongoing would add burden without adding significant relevant information, and would significantly slow the process for CMS to review and approve state submissions, many of which are time sensitive.

Comment: Many commenters requested that we broaden the proposed regulatory framework to apply to provider payment rates beyond those authorized under the Medicaid state plan. Commenters specifically requested that the regulation apply to rates paid by Medicaid managed care organizations and rates paid under Medicaid waiver programs. Many commenters were concerned that a proposal to address access issues under managed care delivery systems is needed. Some commenters called for specific revisions to managed care regulations to set forth clearer standards for managed care rate reviews. One commenter suggested that CMS should incorporate into the actuarial soundness review, standards for transparency in rate setting for managed care organizations and require states to evaluate the impact of managed care rate cuts on access. Another commenter offered that the rule should be extended to apply to children enrolled in managed care.

Response: As stated in the May 6, 2011 proposed rule, section 1902(a)(30)(A) of the Act specifically applies to payment for care and services available under the state plan, which we interpret to refer to payments to providers and not to capitated payments to managed care entities. While Medicaid access to services under managed care arrangements is an important issue, that issue is addressed through reviews of network sufficiency and managed care quality review processes. As a result, we are not addressing access to care under managed care

arrangements in this rulemaking effort. Similarly, methods to assure access to care, including payment methodologies, are reviewed in the approval process for Medicaid waiver and demonstration programs (and, when appropriate, may be monitored in the evaluation of a demonstration program). As a result, we did not specifically address those programs within the context of this rulemaking process. Separate recent CMS initiatives have addressed the framework for Medicaid managed care and home and community based service programs, including access and quality review methods. In January 16, 2014, we issued the “Home and Community-Based State Plan Services Program, Waivers, and Provider Payment Reassignments” final rule (79 FR 2947–3039), and on June 1, 2015, we published the “Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions related to Third Party Liability” proposed rule (80 FR 31097-31297) which proposed to align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans. The Medicaid managed care proposed rule specifically discusses requirements for network adequacy.

Comment: A commenter requested that the regulation explicitly state that all Medicaid long-term services and supports options must be included in these reviews.

Response: All Medicaid services covered under the state plan are included within the scope of the regulatory requirements of this final rule with comment period. We will require an access analysis to support a request for approval of any rate reduction or restructuring for any service in the state plan. As a baseline, the final rule with comment period will require that states review and publish access studies for primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post- natal obstetric services including labor and delivery; and home health services on an ongoing basis. States may also select additional services to add to this list. In addition, access

studies and continued monitoring will be required for covered services when payment rates have been reduced or restructured, or when the state receives a significant volume of public input raising access to care issues. We are requesting public comment on the service categories selected for inclusion in baseline access analysis. Additional services will need to be reviewed as reductions to payment rates or as access issues become apparent. These additional services must be monitored periodically for a minimum of 3 years following the initial rate reduction.

Comment: One commenter stated that providers can practice cost-shifting by overcharging some patients to make up for low Medicaid rates. The commenter noted that cost-shifting permits equal access even if Medicaid rates are not consistent with economy and efficiency.

Response: The focus of this rule is to provide a reasonable approach for states to document access to care for Medicaid services under the state plan. While we agree with the commenter that the adequacy of payment rates in meeting provider costs are not necessarily the only or the decisive factor in ensuring access to care, in this final rule with comment period, we do not require that states establish access by reviewing the relationship of payment rates to provider costs. Ultimately Medicaid payment rates must sufficient to ensure beneficiary access to care, whether or not providers are shifting costs to other payers.

Comment: A commenter suggested that CMS exempt the effects of care coordination initiatives from access documentation requirements. Other commenters more specifically suggested that CMS should exempt from access documentation requirements services to which beneficiary access is limited by coordination of care activities of home and community based providers, especially when these activities may result in loss of access to care in medically underserved or rural areas.

Response: Care coordination is an important aspect of a well-designed health care system and this regulation does not intend to discourage states from implementing care

coordination programs or other efforts that seek to lower cost and improve the quality of care. Such activities should enhance access to care by arranging for individuals to receive appropriate care when needed. Therefore, we do not agree that exemptions to the requirements of this final rule with comment period should be applied to states that offer care coordination.

Comment: Commenters requested specific exceptions to the procedures described in the final rule based on state Medicaid program features. As examples, commenters requested exceptions for states with a majority of individuals enrolled in managed Medicaid and relatively few enrolled in FFS systems, states with all payer payment systems, states that pay Medicare rates, and for services where Medicaid is the only or primary payer of care. The commenters stated that requiring states with these program features to follow the procedures described in the rule would be inefficient.

Response: This final rule with comment period applies to all covered services under the state plan for which payment is made on a FFS basis. However we are soliciting comments through the final rule with comment period on whether we should consider further rulemaking or guidance, as appropriate, to allow for such exemptions to the scope of required access reviews required under §447.203(b)(5), including whether to permit streamlined approaches to measuring access to care based on specific circumstances within states. For instance, we are particularly interested in whether states with higher percentages of beneficiaries enrolled with managed care organizations should be exempt from conducting the ongoing access data reviews and/or the rate reduction monitoring procedures and what threshold for such exemptions would be appropriate. We understand that many states carve out certain services from managed care capitation rates and continue to pay for those services through FFS. We also understand that many of the individuals who remain in state FFS systems may have complex care needs. We note that states already have significant flexibility within the final provisions of the rule to choose measures within their access monitoring review plans that are tailored to state delivery systems. This

could allow, for instance, a state with high levels of managed care enrollment to focus on specific care needs of the populations that remain in FFS after a managed care transition.

Comment: A number of commenters offered that the rule inhibits a state's ability to make adjustments to payment rates that may be necessary to deal with state economic and fiscal crisis. Commenters also noted that CMS should acknowledge that states cannot dismiss local budgetary issues or casually increase revenue to address perceived access to care issues. Other commenters stated that the rule will infringe on states' abilities to make budget decisions. Some commenters raised concerns that the timing of a state legislative session makes it difficult for states to comply with the due dates of the access monitoring review plans.

Response: The final rule with comment period does not prohibit states from implementing (through a SPA) payment rate reductions, as long as beneficiaries will maintain sufficient access to care. In the May 6, 2011 proposed rule, we acknowledged the reality that state budgets often play a role in Medicaid rate-setting. This final rule with comment period requires that states have a process in place to review and monitor access to care to determine the impact various program changes have on beneficiary access. The rule does not prescribe specific state actions to address access to care issues. The rule instead requires procedures that will inform states and CMS of access concerns before SPA approval and on an ongoing basis. This information should be useful to state legislators as they make budgetary decisions and is not intended to hamper the legislative process.

Comment: A commenter requested that we clarify how CMS would handle access issues that arise due to events that are not within the state's control, such as through competitive bidding programs for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Response: There may be any number of issues that contribute to inadequate service access within state Medicaid programs. Though some causes of access issues may be out of a

state's control, the statutory requirements still apply and a state must implement appropriate remediation measures in an effort to address access issues. The strategies for remediation are not limited to increases in payments and states may employ any number of approaches to assuring better access to Medicaid state plan services. To competitively bid for medical devices and supplies, states are currently required to waive "freedom of choice" through the exception provided under section 1915(a)(1)(B) of the Act and federal regulation at 42 CFR 431.54(d). Section 1915(a)(1)(B)(i) and the regulation at §431.54(d) expressly require that adequate services or devices must be available to recipients under a competitive bidding program. States should consider this requirement in structuring their competitive bidding programs and drafting requests for bids. If a state's competitive bidding program does not meet this standard, than it is not in compliance with §431.54(d) and section 1915(a)(1)(B) of the Act.

Comment: One commenter requested that CMS clarify whether states would need to have CMS approval for a change to payment rates or methodologies prior to implementing a change. The commenter noted that a SPA should be necessary any time a state proposes to implement changes in law, policy, or practice that may result in reduction of payment, regardless of whether it requires modification of existing plan language. Similarly, commenters urged that state Medicaid programs cannot implement provider payment reductions until they have complied with the proposed regulatory process for assuring access to care and CMS has approved the state's SPA to reduce provider payments.

Response: Without exception, our policy, as set forth in §447.201(b), is that states must receive approval through the SPA process to modify Medicaid payment methodologies. CMS approval ensures that the changes in service payment methodologies comply with all applicable regulatory and statutory requirements and are eligible for FFP. SPAs may be effective no earlier than the first day of the quarter in which a state submits an amendment. While there is no specific regulatory or statutory requirement that a state wait until SPA approval to implement a

reduction in payment rates, the state must reimburse providers at approved state plan rates, and thus would need to make corrective payments if the amendment is disapproved.

Comment: Many commenters offered that CMS should require higher standards for services with known access issues. Many providers and provider groups highlighted access challenges unique to the services that they provide. These providers noted access challenges specific to many services, including, but not limited to: primary care services; mental health services; maternity services; long term care and supports; family planning and contraception; pharmacy; specialty care; dental care; hospital services; End Stage Renal Disease (ESRD) services; physical therapy; transplants for essential body organs; and community and ambulatory care. Similarly, commenters wrote that state access reviews should be segmented to identify the needs of children and individuals with particular health care needs that may go unmet.

Response: We agree that there are unique qualities in service categories, delivery systems, and populations that require independent analysis and that certain categories of service are known to be more prone to access to care issues in the Medicaid program. This is one of the challenges that CMS and states face in selecting access data and measures that are appropriate and also addressing concerns on the part of states regarding administrative burden. Based on the public comments we received, the final rule with comment period requires that ongoing access reviews focus on the following categories of services: primary care services; physician specialist services (for example, cardiology, urology, radiology); behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services. We believe these services are both in high demand and commonly utilized by Medicaid beneficiaries (see: The Kaiser Commission on Medicaid and the Uninsured. Medicaid Moving Forward. Julia Paradise. March 2015). States may also select additional services to add to this list. This final rule with comment period also requires that all services that are subject to reduced rates or restructured rates and that could

impact access will also need to be reviewed and monitored as part of a state's access monitoring review plan.

We will work with states to identify, based on feedback from beneficiaries and providers and other available information and data, additional services that may require more regular review based on data analysis or known concerns. We are soliciting comments in this final rule with comment period on whether additional categories of service should be added to the list of required ongoing reviews included in the rule.

Comment: Commenters suggested that as part of the final rule, CMS should recognize that some states are entirely or in part Health Professional Shortage Areas (HPSA) or Medically Underserved Areas (MUA) which makes increasing access a more difficult challenge, particularly in a 12-month frame.

Response: We appreciate that some states or geographic areas within states are in HPSAs or MUAs, which present challenges in improving access to care. We are restating that this final rule with comment period does not require specific improvements or timeframes for improvement in access to care when Medicaid access is consistent with the statute and the availability of care for the general population in a geographic area. We recognize that some areas within states may face particular challenges in meeting the health needs of the individuals residing in those areas, and states should describe the challenges within their access reviews and discuss how they affect the Medicaid program in particular.

Comment: Some commenters stated that the proposed rule did not provide an appropriate balance between economy and efficiency and access by allowing states to invoke cost as a constraint only when they can address access issues in some way other than an increase in payment rates. Other commenters noted that emphasizing access to care over economy and efficiency is at odds with many state innovation strategies that aim to lower cost and improve care.

Response: The rule does not limit a state's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that states take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. Under the Act, rates are neither economic nor efficient if they do not also ensure that individuals have appropriate access to covered services. We interpret section 1902(a)(30)(A) of the Act as a balanced approach to Medicaid rate-setting and we encourage states to utilize appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect states to document that Medicaid rates are economic and efficient when the state submits changes to payment methodologies through a SPA. We will continue to document as part of our SPA review process why the methodology is in line with statutory requirements. We will continue to work with state leaders and stakeholders and will consider issuing policy guidance on standards for economy and efficiency through future rulemaking efforts. We are actively working with states toward innovative delivery system designs that promote economy and efficiency through person centered coordinated care and value-based purchasing. We do not view the requirements described in this final rule with comment period or the access provisions under section 1902(a)(30)(A) of the Act in conflict with these efforts.

Comment: A commenter noted that by using only access metrics, it would be very unlikely that state access reviews would ever show that emergency room rates violate the statute because hospitals, in practice, usually do not opt out of serving Medicaid patients. The commenter further stated that rates to Medicaid hospitals could sustain equal access to emergency room services, but could simultaneously be entirely inconsistent with efficiency, economy, and quality of care.

Response: This final rule with comment period focuses specifically on documenting compliance with the access to care requirements of section 1902(a)(30)(A) of the Act. This rule includes a multi-faceted approach to reviewing access data, soliciting feedback from

beneficiaries, providers and other stakeholders, and public processes to raise issues specific to state rate actions that may impact access to care. We do not disagree that providers that have a requirement or mission to provide care could still receive Medicaid payment that falls short of their full cost of providing the care furnished. This is an issue that is relevant to the state's rate-setting process, but not necessarily an access issue. These issues could be raised by hospitals in the rate-setting procedures required under section 1902(a)(13)(A) of the Act, but we agree that there could be additional opportunities for public input. We are including in the final rule with comment period, requirements that states develop mechanisms for ongoing provider feedback, which should allow hospitals and other providers who seek higher rates to raise concerns to states.

Comment: A commenter stated that the proposed rule does not provide sufficient discretion to consider market considerations and expressed concern that the proposed rule should require states to implement a process to evaluate access regardless of whether a state is seeking changes to rates. Further, the commenter expressed concern regarding the establishment of a price floor for Medicaid services.

Response: The statute requires Medicaid payment rates to be sufficient to ensure access to care and services for beneficiaries, and this final rule with comment provides considerable flexibility to consider relevant factors including market rates. The requirement to assure access to services is not limited in scope to when a state is proposing a change to its payment rate methodology, but rather, applies to current rates as well. If a state has not changed its Medicaid payment methodology for many years, we believe it is just as important to assess those rates to determine if the rates are still sufficient to ensure access as it is to evaluate the effect of proposed changes to rate methodologies. The provisions of the final rule with comment period allow for state flexibility to take into account market conditions in carrying out their access monitoring review plans. We have considered state concerns with the burden associated with the rule and

have focused the ongoing access reviews on: primary care services; physician specialist services (for example, cardiology, urology, radiology); behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services. Access to these services should be indicators that beneficiaries have ongoing access to primary sources of care. States may also select additional services to add to this list. Ongoing access concerns with other services can be addressed through public input processes also required under this final rule with comment period. We note that the final rule with comment period does not require a payment floor for any Medicaid service.

Comment: One commenter recommended that CMS clearly explain in the rule that the statute includes strong policy against over-utilization of medical services, and it is both appropriate and desirable that states adopt rate policies that will discourage unnecessary utilization of services and embody incentives for more efficient use of health care resources. Commenters wrote that measuring utilization of covered services to determine appropriate access is in conflict with and ignores many states' efforts to ensure appropriate utilization. To remedy this conflict, commenters suggested that CMS clarify the law requires states to enroll enough providers to ensure access rather than ensure that people are actively seeking treatment. These commenters also objected to measuring enrollee needs and the comparison of Medicaid rates to other payer systems.

Response: We agree that state oversight efforts and rate setting policies should discourage over-utilization. We support state efforts to identify utilization associated with inappropriate care through processes that can include prior authorization, claims review, and care management initiatives. Regulations at 42 CFR part 456 specifically discuss the requirements concerning control of the utilization of Medicaid services in certain settings, or for certain services. The regulatory framework presented in this final rule with comment period describes

several data points that may be indicators of access within a given state; however, we recognize that no one measure offers a precise indication of sufficient or insufficient access to care. If a state experiences a severe decline in service utilization without a plausible explanation, there may be an access concern worthy of investigation. The same is true of beneficiary needs. If a state experiences a spike in beneficiaries who experience difficulty receiving a particular service in a geographic region, this could indicate access issues and should be investigated. Because the statutory provisions at section 1902(a)(30)(A) of the Act refer to payment rates and comparisons to the general population, it is necessary for states to compare Medicaid payment rates to the rates of Medicare or private payers. We expect that states will evaluate access in consideration of outcome-based care as new approaches to payment and deliver systems take form. The final rule with comment period allows states broad flexibility to consider the impact of new types of payments and care delivery in the access monitoring review plans.

Comment: One commenter requested that CMS specifically examine out-of-state Medicaid payments, particularly in states with historically high-volume, out-of-state use of services.

Response: We have not set out specific requirements for out-of-state providers in this final rule with comment period. To the extent that individuals in the state obtain access to a particular type of service through out-of-state providers, including through telemedicine or telehealth, or to the extent that individuals in a geographic area generally obtain services through out-of-state providers, the state will need to consider such providers in reviewing access to care.

Comment: One commenter stated that the regulatory effort should be expanded to address section 1902(a)(30)(A) of the Act's quality of care requirements.

Response: We currently have several initiatives in place to improve upon quality within Medicaid delivery systems and strengthen quality measures. We are actively engaged with states and other stakeholders in developing quality guidelines, for example the Child and Adult Core

Health Care Quality Measurement Sets developed in conjunction with the National Quality Forum. While the focus of this final regulation is limited in scope to access to care, we will continue our work to promote quality improvement within state Medicaid programs and may, in the future, develop regulatory or subregulatory guidance on quality standards. We also recognize that access and quality can be related and beneficiaries may provide beneficial input to states on this relationship through the processes states develop in accordance with this rule.

Comment: Several commenters stated that the requirements of the notice of proposed rule-making create a stricter standard than what is required under the statute. Some commenters offered that the requirement will be difficult to meet and would effectively preclude a state from making program changes.

Response: Prior to the issuance of this final rule with comment period, several states implemented a number of the regulatory provisions we proposed in the May 6, 2011 proposed rule. These states recognized the need to review and monitor data and to work with stakeholders to address potential access issues in light of cuts to Medicaid payment rates. Based on the work of these states, we consider the requirements of the final rule with comment period to be reasonable and achievable. As discussed in the May 6, 2011 proposed rule and in this final rule with comment period, the requirements of the rule do not limit state flexibility in program operation. Nor do the regulatory requirements go beyond the scope of what is necessary to reasonably document beneficiary access to care. Instead, the rule provides states with procedures to document compliance with the statutory requirement to ensure access to care. These procedures permit states considerable flexibility in the analysis of data reflecting access, and in the measures that a state must take to respond to access concerns.

Comment: One commenter stated that Medicare and Social Security have not experienced the same challenges facing Medicaid, likely because their beneficiaries have considerable political clout. The commenter stated that policymakers must factor in this reality

when reviewing the proposed rule comments and provide special consideration to comments from those who advocate on behalf Medicaid beneficiaries.

Response: The public comment period is a unique opportunity for the public to contribute to the regulatory process. All comments are considered in the development of final regulations. Input from beneficiaries and their advocates is essential because that input most directly reflects the success or failure to obtain beneficiary access to care. And the importance of that input is not limited to the rulemaking process. This is why this final rule with comment period requires that states maintain ongoing systems to collect and analyze beneficiary comments and complaints concerning access to care. The importance of beneficiary needs and ongoing feedback are highlighted in the framework described in the proposed and final rules.

B. Documentation of access to care and service payment rates (§447.203)

Comment: Many commenters agreed that it is important for states to conduct access reviews to examine access and related data in different geographic regions throughout the state.

Response: We appreciate support for the proposed data analysis requirements. We have adopted without change many of the proposed requirements in this final rule with comment period.

Comment: Many commenters suggested that we modify the access review procedures to require baseline access analysis prior to taking action to approve provider rate reductions, ongoing monitoring to detect problems, and corrective action when problems are detected. Some commenters offered that CMS should suspend the rate reduction until corrective measures are taken.

Response: Consistent with the commenters' suggestion, this final rule with comment period requires that states conduct baseline reviews of the core services defined in this regulation and monitor access data to ensure compliance with section 1902(a)(30)(A) of the Act. States are also required to review and submit access data when states submit rate proposals that may have a

negative impact on access to care and continue monitoring for 3 years afterwards through the process outlined in the access monitoring review plan. In addition, we have revised the ongoing access monitoring review plan activities to require a review of primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services. We have made this change in consideration of state burden and to focus ongoing access monitoring on highly needed and utilized services. States may also select additional services to add to this list. While the suspension of a rate reduction may be an appropriate corrective action, we are not requiring a specific approach to addressing access issues within the final rule with comment period and we will work with states on appropriate remedies.

Comment: A commenter requested that CMS provide a list of the covered services and benefits that fall under the 5-year access review cycles described in the May 6, 2011 proposed rule to ensure that all services are included.

Response: We proposed that states review all services covered in the Medicaid state plan over 5-year cycles. Medicaid allows states the option to cover certain services and the list of services that individual states would have been required to review would vary. The scope of services proposed for review are described in regulation at 42 CFR Part 440. Based on public comments, we have revised the access review requirements in this final rule with comment period to be more targeted so as to only require measurement of a discrete set of services, which provides additional data on access while reducing administrative burden on states. States must conduct access monitoring reviews every 3 years for the following categories of service: primary care services; physician specialist services (for example, cardiology, urology, radiology); behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services. States may also need to add additional services to the access monitoring review plan

based on access to care concerns that arise out of the information received by states through the public input processes described in this final rule with comment period. We note that states may have additional alternative processes to identify access to care issues for services in addition to those required under the final rule. This rule is not intended to preclude states from continuing to use those processes and does not intend to limit additional state access to care review activities for Medicaid services that are already effective.

Comment: We received several comments that requested additional guidance on how states should review access to consider geography. Commenters recommended that CMS define the relevant "geographic area" that states should use for access comparisons, while others specifically suggested that CMS should require states to assess Medicaid beneficiary access in designated rural geographic locations of a state. One commenter suggested that we require states to review trends and factors as they vary by state geography and to emphasize the importance of geographic variation through specific changes to the regulatory text.

Response: To clarify, states must assure that access is available to Medicaid beneficiaries to the extent that care is available to the general population in a geographic area. The actual definition of geographic area may vary by state and the extent and need to which states review and monitor access based on geographic area may depend on the data and other information that states are required to review as part of the framework of this final rule with comment period. For instance, states may receive information that access to care is an issue in one specific region within the state and focus monitoring and remediation strategies on that region. Other states may have more statewide access concerns that require a county-by-county analysis and strategy to address access on a statewide basis. At this time, we are not defining state geographic areas or the specific geographic considerations that states must include in access reviews. CMS will rely on states and the processes described in this final rule with comment period, including the public

processes that allow stakeholders to comment on the access monitoring review plans, to determine appropriate geographic considerations.

Comment: Commenters requested that we clarify the difference between a “comparable population” to Medicaid and statutory designation of “the general population in a geographic area.” A few commenters wrote that the regulations need to acknowledge that the law requires Medicaid to be compared to the general population. Some commenters stated that the appropriate comparison is between Medicaid and those in the general population regardless of insurance status, while others stated that the comparison to the general population is unrealistic and should be removed from consideration.

Response: The regulation adopts the statutory standard of “the general population” and we have applied this in this final rule with comment period. States are allowed to analyze access issues within broad parameters in a manner that appropriately reflects the local health care delivery system of each state, as outlined in this final rule with comment period. A state’s rate of insured and uninsured may not be directly related to the ability of an individual on Medicaid to access a covered Medicaid benefit since the ability to access care is different from having the means to pay for care. While the final rule with comment period does not specify how states should make such comparisons to the general population, we note that a state’s analysis should be robust and consider both demands for care and whether individuals have an ability to pay for such care if individuals without coverage are included in the analysis.

Comment: Several commenters noted that courts have determined that the term “general population” only means people who have private insurance and not the uninsured and requiring Medicaid to compare its coverage to private plans without accounting for the access of the uninsured is an artificial standard.

Response: The final rule does not define standards for measuring medical services available to the general population in a geographic area. States are instead allowed to analyze

access issues within broad parameters in a manner that appropriately reflects the local health care delivery system of each state, as outlined in this final rule with comment period.

Comment: Several commenters requested clarification as to how the agency will evaluate the data from access reviews. The commenters also sought clarification as to how CMS would apply or evaluate the data when deciding to approve or disapprove a SPA.

Response: Under this final rule with comment period, states will follow specific procedures to review and monitor access to care and to solicit feedback from stakeholders through ongoing public processes. We also require a public review timeframe for the access monitoring review plan which will allow interested parties to review and comment on states' access monitoring review plans for a period no less than 30 days before the monitoring plan is finalized and submitted to CMS. We will review this information in total when reviewing SPAs but have not, at this time, required any specific thresholds that would determine an amendment to be approved or disapproved. We will document as part of our SPA review process that states are following the process described in this final rule with comment period, that access to care is consistent with the statutory requirements, and the reasons for our determination. We continue to consider whether core measures and access thresholds would help states and CMS assure access to care in the Medicaid program and we are accordingly issuing a RFI, as well as this final rule with comment period, to gather additional information on this topic.

Comment: Commenters requested that we clarify scenarios when restructuring rate methodologies would result in access issues and trigger the requirements of this rule.

Response: There may be any number of payment methodology changes that could harm access to care and we cannot set forth an exhaustive list. One common type of restructuring is a change in the targeting of supplemental payments. States may alter payments in ways that are budget neutral as a whole for the amendment action, but would reduce payments for some providers. For instance, some states make up for low base payment rates through lump sum

supplemental provider payments. The supplemental payments are often targeted to certain providers and may be dependent upon the availability of local governments to fund the nonfederal share of payments. A change in supplemental payments that reduces the total amounts that providers receive or shifts funds from one provider to another could result in access to care issues and is one example of a potential payment restructuring that could negatively impact access to care. Where there is uncertainty, we will work with states to help identify other situations where the processes described in this final rule with comment period should apply.

Comment: Several commenters requested that CMS mandate that states make the annual data reviews publically available. Commenters further requested that CMS require states to disclose the reports with a sufficient amount of time to review the data and provide comments prior to the state's submission of a SPA.

Response: We are finalizing the provision to require that states make access data reviews available to the public and to CMS for review. In addition, prior to submitting a SPA that reduces or restructures Medicaid payment rates or otherwise have a negative impact on access to care, states are required to conduct a public process that solicits feedback from stakeholders in consideration of the access reviews conducted by the states. Access monitoring review plans will be published and made available to the public for review and comment for a period of no less than 30 days, prior to being finalized and furnished to CMS for review.

Comment: We received many comments that requested more detail on how a state can sufficiently demonstrate access to care, including thresholds for sufficient access. Some commenters raised concerns that without mandatory thresholds states would never know CMS' expectations for meeting the requirements of the statute. Other commenters recommended that we provide states with the flexibility to determine the elements most appropriate for review of access to care that are meaningful for their specific populations and programs.

Response: Currently, there are no national standards to demonstrate access for each Medicaid covered service that would take into account differences in state geographic locations. Since the issuance of the May 6, 2011 proposed rule, we have worked with many states to review state data sources and develop monitoring plans to demonstrate compliance with the statute. That experience and the public comments received through this rulemaking process have further suggested that particular measures may be specific to individual services and systems and that states should have some flexibility and discretion in determining the measures and thresholds, to allow states to take into account varying circumstances. We requested comments on specific thresholds that states could use to measure access within their Medicaid programs. While we received some comments with suggestions of thresholds, we did not receive suggestions for metrics that could be applied across all states without additional consideration or compelling evidence that the standards offered in comments would necessarily ensure consistency with section 1902(a)(30)(A) of the Act. We will continue to study whether a core set of measures or thresholds should be applied to the Medicaid program and are soliciting more information from stakeholders through the RFI process described earlier.

Therefore, while we continue to study this issue, in this final rule with comment period we are adopting the proposed multi-faceted approach to reviewing access to care that includes data analysis and feedback from beneficiaries, providers and stakeholders rather than national thresholds. The analysis of this information must also weigh relevant state-specific circumstances. As a result, we are requiring states to have a public review timeframe for the access monitoring review plan which will allow interested parties to review and comment on the state's monitoring plans for a period of no less than 30 days before the monitoring plan is finalized and submitted to CMS.

Comment: Commenters requested that the ongoing access reviews include the agency's summary of the views of beneficiaries and of providers of the covered service obtained through the input of medical care advisory committee under §431.12(e).

Response: We agree that feedback from beneficiaries and providers on access to care is important and should be considered by states in evaluating access and as they make decisions about Medicaid rates. This final rule with comment period requires that states have a mechanism for ongoing beneficiary input and that states log the volume and nature of responses to beneficiary input. In addition, we have added a requirement that states establish and maintain a similar provider feedback mechanism. Both feedback mechanisms are incorporated into state access monitoring review plans within the final rule with comment period. CMS will rely on information from the beneficiary and provider feedback mechanisms to understand real-time access to care concerns and may require states add services to their access monitoring review plans based on this information. Depending on the nature of the concerns, states may need to take actions to address more immediate needs though, as the concerns may vary, CMS is not specifying actions or timeframes that states must take at this time.

States are expected to solicit feedback during the development of the access monitoring review plan and corrective action plans and could also use the existing Medical Care Advisory Committees for input into the process.

Comment: Several commenters suggested that CMS should develop a template for access monitoring review plans that includes the Medicaid payment rate comparisons, stakeholder feedback, and provider feedback.

Response: Each state Medicaid program is unique, and as such, this final rule with comment period allows states the flexibility to design and implement access measures specific to the characteristics of their state. At this time, we are not issuing a template or specific format for

states to conduct their access monitoring review plans. However, CMS will identify model plans for states to consider as they develop their own plans.

Comment: Several comments suggested that the scope of access reviews should be limited to mandatory services. Other comments urged that access reviews only be required where there is considerable empirical evidence of an access problem such as: primary care; and physician specialist services; and dental services for children. Additional commenters suggested state access reviews should focus on access to specialists, especially pediatric subspecialists.

Response: After careful consideration of all the comments received, we are revising this final rule with comment period to eliminate the requirement that states review all covered services within a 5-year period, and instead will require that states review a discrete set of services provided by various provider types and site of service that are related to particular types of beneficiary needs every 3 years. These are: primary care services; physician specialist services (for example, cardiology, urology, radiology); behavioral health services (including both mental health and substance abuse disorder treatment services); pre- and post-natal obstetric services including labor and delivery; and home health services. These categories represent frequently used services in Medicaid and can serve as indicators that beneficiaries are receiving access to care. States may at their discretion add additional services to their access review monitoring plans. In addition, we have included a requirement for states to review additional service categories as determined necessary based on the public input processes described in this rule. We note that states may have alternative processes to identify access to care issues for services in addition to those required under the final rule. This rule is not intended to preclude states from continuing to use those processes and does not intend to limit additional state access to care review activities for Medicaid services that are already effective.

Comment: One commenter suggested that FQHC reimbursement rates be given a separate category in the access review process as they receive an advantageous Medicaid

reimbursement rate which could skew the lower rates for many Medicaid family planning services.

Response: The final rule requires states to identify payment rate comparisons for service by provide type and site of service. This should address the commenters concerns. We recognize the important role FQHCs play in delivering health care services to Medicaid beneficiaries. We expect that states would include them, as appropriate, in the ongoing access to care reviews for the types of services that they provide. The statute requires that states pay an all-inclusive prospective payment system (PPS) rate to FQHC providers or an alternative payment methodology that results in payment at least at the PPS rate. The PPS rate recognizes costs associated with all of the Medicaid services that FQHCs provide and is not specific to particular service. So, while services furnished by FQHCs may increase beneficiary access to certain categories of care, payments made to FQHCs are not going to be relevant to the payments made to other types of providers.

Comment: Several commenters suggested that state-level reviews of beneficiary access to specialty pharmacies are critically important for assisting states in determining whether Medicaid beneficiaries' access to specialty pharmacy services under the state plan is at least equivalent to that available to the general population is the geographic area. Commenters also noted that access issues may already exist in most states due to the combination of low dispensing fee rates and insufficient reimbursement for specialty products.

Response: As discussed, this final rule with comment period will require states to review a certain subset of services every 3 years, including primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; and home health services. While we have not included specialty pharmacies, we have included the requirement for states to review access for additional services based on a significantly higher than usual level

of beneficiary or provider access complaints. States may also select additional services to add to reviews at their discretion.

Comment: Another commenter expressed concern that states will attempt to satisfy pharmacy access requirements simply by demonstrating or offering the availability of mail order pharmacy, which may not be adequate for certain Medicaid beneficiaries.

Response: Access requirements are not met by the "availability" of provider types if the Medicaid population cannot obtain needed services from those provider types. To the extent that mail order pharmacies are not adequate or appropriate for some Medicaid beneficiaries, availability of mail order pharmacies would not constitute access to pharmacy services.

Comment: Several commenters requested that CMS clarify the anticipated approach for reviewing access when a state adds a new service or benefit.

Response: This final rule with comment period clarifies that states must conduct a baseline access review for new services within 3 years of the effective date of the SPAs that authorizes the service for FFP if the service falls under a certain subset of service categories defined in this regulation. All other new services will fall under the rate reduction or payment restructuring protocol outlined in this final rule with comment period whereby SPAs reducing or restructuring payment rates for the services are submitted with an analysis of access to care and are monitored periodically for a minimum period of 3 years.

Comment: Some commenters suggested that CMS allow independent third parties to conduct the access reviews, stating that access reviews should be objective and conducted by an organization/academic institution that is impartial.

Response: Ultimately, states are responsible for ensuring compliance with statutory and regulatory requirements. States have flexibility in determining the available resources to meet the regulatory requirement described in this final rule with comment period. While we are not requiring use of an independent third party to conduct access reviews, the option is certainly

available to states. Additionally, we will consider alternative approaches to addressing Medicaid access issues that beneficiaries face through a hearing or complaint driven process. We intend to solicit feedback on the feasibility and implementation options for such an approach through an RFI process.

1. Access review data requirements

Comment: Several commenters suggested that CMS should require states to disclose payment and other claims data states use to conduct their access reviews.

Response: Section 447.203(b)(1) will require states to review and make publically available data trends and factors that measure access, as represented by beneficiary needs, availability of care and providers, utilization of services, and service payment information. These publically available measures will support the SPA submission.

Comment: Comments suggested provider and service specific metrics, threshold, and considerations should be incorporated into the final rule. For instance, one commenter suggested that CMS require an impact analysis of rate cuts on the ability of high Medicaid volume providers to meet staffing requirements and quality and safety standards. Other commenters recommended that the numbers of providers willing to care for Medicaid patients be compared to some measure of patient need to provide an indication of whether access is adequate. Commenters lamented that the rule did not specifically address circumstances related to care in hospitals, family planning centers, long term services and supports and many additional benefit categories.

Response: While we are not adopting any specific metrics at this time, we are continuing to evaluate the feasibility of establishing a set of core metrics and thresholds and are soliciting input from stakeholders on these approaches through the RFI. We considered these comments in developing this final rule with comment period, and hope that the information provided through the public comment process informs state access monitoring review plans. We included

examples of a number of metrics that states should consider within the regulatory text. These measures represent the type and scope of information that states should review through the access monitoring review process. As we review state access monitoring review plans, our expectation will be that the plans are robust and are carefully designed to indicate access to care issues as they develop. We also anticipate that stakeholders will provide feedback on state access monitoring review plans, including on proposed, baselines, metrics and thresholds, and that states will review the feedback and make appropriate changes to their monitoring plans.

Comment: Some commenters suggested that the proposed regulations should be revised to allow for some metrics that establish a prima facie assurance that care and services for Medicaid enrollees are available at least to the extent that they are available to the general population in the geographic area. For instance, if at least 80 percent or more of the service providers for a particular service such as hospitals, physicians, labs, etc. in a geographic area are enrolled in the Medicaid program, the commenter offered that would reasonably mean access is available.

Response: As we discussed in the preamble of the May 6, 2011 proposed rule, CMS is not currently proposing national standards to be applied across all service categories or uniformly for all states. We also think it is important to note that enrollment alone in the Medicaid program does not mean sufficient access is available. There are other factors that must be considered. However, we are continuing to study whether a core set of measures or thresholds should be applied to Medicaid, and, if so, what those specific measures would be, and are soliciting input through the RFI process.

Comment: Several commenters suggested that specific information for specific populations be required data elements within the access reviews. In particular, one commenter suggested children and young adults with ESRD should have specific consideration in access reviews since they have complex care needs. Other commenters suggested that states should

examine the needs of adolescents ages 12 to 21 as a distinct subgroup in the pediatric population due to their significant unmet health needs. Others requested that CMS articulate that child and adolescent mental health services are a high priority for monitoring access in recognition of the severe shortages of child and adolescent mental health professionals.

Response: We do not dispute the importance of these types of services and we understand the commenters' concerns. To the extent that states understand that there are specific access issues for certain populations, it would be prudent to develop remediation plans that focus on improving access for those populations. States will be required to review, at a minimum, primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery, home health services, and other service categories when the state or CMS has received a significantly higher than usual volume of beneficiary or provider access complaints for a geographic area. States may also select additional services to add to this list. We are requesting comments on the selected categories of services outlined above.

Comment: One commenter suggested that CMS should require that Medicaid payment analyses determine the degree to which Medicaid payments are sufficient by, at a minimum, following the same set of analyses that MedPAC undertakes when assessing the adequacy of Medicare Payments.

Response: States have significant discretion in establishing payment methods across services, providers, and states, whereas Medicare uses national rates adjusted for geography for all services. While some states pay for services through rates based on Medicare fee structures, many services are reimbursed through cost reconciliation or other methodologies that do not follow Medicare approaches. Therefore, it would be difficult to standardize an analysis similar to the MedPAC approach for assessing adequate Medicare payments. As previously discussed, this final rule with comment period allows states considerable discretion to review access based

on a state's program and local considerations as long as the review is consistent with the standardized and transparent process described in this final rule with comment period.

Comment: Some commenters suggested that the framework described in the rule relies heavily on Medicaid provider reimbursement rates, beneficiary surveys, and provider engagement, with the latter two considerations being subjective and potentially at odds with one another.

Response: This final rule with comment period requires that states review access information focused on: the availability of care and providers, enrollee needs, and service utilization. In addition, states must consider information from beneficiaries and providers, as well as provider payments. We do not view this information as conflicting, but instead a comprehensive review of access to care that considers a number of factors that may indicate compliance with the statute.

Comment: We received many comments that were critical of the framework of the May 6, 2011 proposed rule which focused on the availability of care and providers, enrollee needs and service utilization. One commenter suggested that CMS should incorporate measures through future rulemaking and guidance, but only after Medicaid and CHIP Payment and Access Commission (MACPAC) completes its process of identifying a set of measures to determine and track access levels. The commenter further suggested that for purposes of the final rule, CMS should identify existing data and measures based on its experience and existing resources rather than the framework described in the proposed rule.

Response: While we appreciate the comment and intend to continue to work with states to identify appropriate access measures, the components of the broad framework that are described in this final rule with comment period are viewed by industry experts as good indicators of access to health care services. We are considering providing states with additional guidance through future rulemaking or subregulatory guidance and are reviewing ways to

standardize access monitoring and remediation efforts. In this rule, we require that states review data that considers enrollee needs, the availability of care and providers, and service utilization. Within the framework, this final rule with comment period continues to provide states with significant flexibility in reviewing data to demonstrate and monitor access to care which reflects their local healthcare delivery systems. States also have the ability to add to the framework to better represent access to services within the state.

Comment: Several commenters recommended that CMS consider identifying a set of uniform measures that states must collect data on or that CMS weighs more heavily in its analysis, based on CMS experience and existing studies. While some commenters suggested such uniform data elements would enable access comparisons across states and facilitate best practices, other commenters suggested that CMS provide flexibility to states by permitting the use of other measures based on the strength of the alternatives.

Response: We appreciate the value of common data sets to help compare access across states; however, we also recognize the importance of allowing states flexibility in designing and implementing appropriate access measures which reflect each state Medicaid program. Because each state Medicaid program faces unique challenges and it is difficult to create data sets that uniformly apply across all service categories, we are not at this time requiring specific access measures in the final rule with comment period. As discussed, we will continue to study and solicit feedback on standard data sets through a RFI process.

Comment: Several commenters suggested that consideration be given to race, ethnicity, rural, and urban, primary language spoken, eligibility subgroup, geography, age and income of Medicaid beneficiaries.

Response: We appreciate these suggestions. We have not specified the level of detail at which states are required to investigate access to care. States have the option to add the above

elements to their access monitoring efforts and we hope that the access monitoring review plans become more sophisticated over time.

2. Beneficiary information

Comment: Most commenters expressed support for the provisions requiring a mechanism to solicit feedback from beneficiaries on access issues. In addition to the feedback mechanisms for beneficiaries, many commenters also suggested mechanisms to gain feedback from service providers, caregivers, and advocates. A few commenters urged that we target feedback on specific issues (for example, mental health, and women's health) and mandate types of feedback mechanisms, while other commenters urged CMS to allow states flexibility to determine the best tools to obtain feedback. Commenters also requested clarification regarding the types of feedback mechanisms CMS would consider acceptable and the standards that CMS would use when reviewing beneficiary input.

Response: We appreciate the commenters' support for this provision and we are finalizing §447.203(b)(4) that requires states to have mechanisms for obtaining ongoing beneficiary feedback through hotlines, surveys, ombudsman, or other equivalent mechanisms. We continue to offer states the ability to implement feedback mechanisms tailored to their program characteristics and to use feedback mechanisms that are already in place and working to meet the objectives of this final rule with comment period. In consideration of comments from providers and provider groups, we are adding a requirement within the final rule with comment period that states have a mechanism for ongoing provider feedback. While CMS will not formally approve state feedback mechanisms, states are required in this final rule with comment period to maintain a record of the volume and nature of responses to beneficiary feedback.

Comment: One commenter suggested that CMS establish a mechanism for beneficiaries and stakeholders to raise concerns about access issues directly to CMS.

Response: Because each state designs and administers its own Medicaid program within

the federal framework, we believe it is most appropriate for beneficiaries and stakeholders to raise access concerns with the state directly, rather than to CMS. To the extent that a beneficiary or stakeholder's access concerns are not addressed by the state adequately, those concerns may be raised to CMS although we are not establishing a formal process at the federal level. As part of the final rule with comment period, states will be required to promptly respond to specific access problems, with an appropriate investigation, analysis, and response. In addition, we are exploring the feasibility of requiring a state level formal hearings process where access to care concerns will be independently heard by a hearings officer. We may propose this process through future rulemaking, which will include notice and opportunity for public comment.

Comment: One commenter encouraged CMS to work with state Medicaid agencies to collect Consumer Assessment of Healthcare Providers and Systems (CAHPS) data for FFS beneficiaries in a similar manner to what is collected for Medicare FFS beneficiaries.

Response: We are currently working with state Medicaid agencies to collect and use the CAHPS survey data for institutional and primary care settings and we will continue to assist states in collecting this or similar data in the future. To the extent possible, we will work with states to use the CAHPS survey data to support the analysis and oversight procedures described in this final rule with comment period.

Comment: Commenters suggested that states should also obtain provider and beneficiary feedback during the development of corrective action plans so that beneficiary and provider experience may better inform the state's actions.

Response: We are finalizing §447.203(b)(4), which requires states to have a mechanism for obtaining ongoing beneficiary feedback through hotlines, surveys, ombudsman, or other equivalent mechanisms. We are also adding a provision that requires states to have similar mechanisms in place for provider feedback. One mechanism that states could use is the Medical Care Advisory Committees that are already required in federal regulations. We believe that

states should solicit feedback during the development of corrective action plans or use the existing Medical Care Advisory Committees for input into the process.

3. Access review Medicaid payment data

Comment: We received numerous comments regarding which factors should or should not be included in the payment rate analysis. Many commenters requested CMS exclude Disproportionate Share Hospital (DSH) payments in the analysis, while other commenters stated these payments should be included. Commenters also suggested that uncompensated care pool payments, Health Information Technology (HIT) payments and other types of supplemental payments be excluded from the rate analysis. One commenter suggested that states should separately show percentiles with and without supplemental payments. Additional commenters stated the payment rate analysis should only include the net amount of payments, including supplemental payments, to the provider, and that payment data should appropriately deduct, or account for any taxes or assessments that are required to be paid by Medicaid providers. Some commenters even suggested a separate payment rate metric to reflect public hospitals and providers that pay the non-federal share of the Medicaid payments.

Response: Section 1902(a)(30)(A) of the Act describes payment rates for Medicaid care and services. Our regulatory purview is to review all state payment rate methodologies through the SPA process to ensure the payment rates are economic, efficient, and sufficient to assure access. The requirements contained in this final rule with comment period set forth a framework for states to use to demonstrate their payment rate methodologies are sufficient to ensure access. To the extent that payments are made to providers outside of a state plan rate methodology (for example, uncompensated care pool payments, Medicaid DSH, or HIT payments), such payments would not be directly included in the state's rate analysis. But rate analysis is only one part of an overall access analysis, and these other payments may affect provider's participation rates in Medicaid by providing additional incentive to serve Medicaid patients.

Comment: We received a significant number of comments regarding the proposed requirement to compare Medicaid rates to the rates of other payers; some commenters supported the proposed requirement while other commenters opposed it. One commenter suggested that the only way CMS could demonstrate that Medicaid access is at least comparable to that of the general population is through a comparison to commercial rates. Another commenter contended that it is difficult to determine actual commercial rates because often this information is considered proprietary. One state expressed concern about not being able to meet this requirement because there are no large commercial plans within the state. Other commenters suggested that it is ineffective to base rate comparisons on other payers' rates alone and some states may be relying on unsound data for comparisons. A few commenters cautioned against using Medicare rates as a comparison, citing that Medicare does not offer the same benefits as Medicaid (for example, comprehensive dental and pediatric) and that the Medicare payment rates do not reflect the costs incurred by the Medicare provider to provide the services. One commenter sought clarification on whether the review must include all three proposed comparisons or could be limited to at least one.

Response: The framework in the final rule with comment period recognizes that access to covered services may be affected by multiple factors. One such factor is the Medicaid payment rates in comparison to other payers. We maintain that a comparison can be a useful tool for states in determining the adequacy of their rates; however, it should not be relied upon without taking into account other factors that impact access. To the extent a state has issues making comparisons to private or public health payer rates because the data is not available for a particular service, we would expect the state to explain this as part of its analysis and conduct other appropriate reviews of Medicaid rates.

Comment: Some commenters expressed support for a two-pronged review: one comparing Medicaid FFS payments in relation to Medicare payment rates; and Medicaid FFS

payments in relation to the payment rates used by Medicaid managed care organizations within the state.

Response: The final rule with comment period requires that states include percentage comparisons of Medicaid payment rates to other public and private health coverage rates within the state for all services reviewed under the access monitoring review plan by provider type and site of service (e.g. primary care providers within office settings). We would expect the state to include Medicaid managed care payment rates in these comparisons to the extent practical.

Comment: Some commenters suggested CMS specify that children's access to primary care, specialty care and oral health services must be included in the first reviews conducted by states. Additionally, other commenters suggested that CMS should specify that children's access to dental services must be included in the first review conducted by states, as HHS has placed considerable emphasis on this issue and 5 years is an eternity in the lifetime of a child.

Response: This final rule with comment period requires that the access monitoring review plan include a review of primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery, home health services, and for services where either payment rates have been reduced or restructured or where a significantly higher than usual volume of beneficiary, provider, or stakeholder access complaints. Within primary care services, we are including dental care as one of the service categories states must review as part of the access monitoring review plan. We also agree that access needs may vary between pediatric and adult populations and we are requiring states to describe within their plans, the characteristics of the beneficiary populations, including considerations for care, services, and payment variations for pediatric and adult populations, as well as individuals with disabilities.

Comment: One commenter urged CMS not to require the publication of all payers' rates.

Response: This final rule with comment period does not require a state to publish the

rates used by other payers. Although we are finalizing the requirement for states to conduct a percentage comparison of Medicaid payment rates to other payers within the state, this is not intended to require the publication of other payers' specific rates.

Comment: Commenters offered that the May 6, 2011 proposed rule does not clarify that access reviews of Medicaid payment data should be collected and provided for each individual item or service rather than in the aggregate. Commenters requested that CMS require transparency of the state's analysis of provider rates and access determination for stakeholders to provide meaningful input of the changes to the state and CMS. The commenters noted that aggregate numbers would not allow an adequate review of potential access issues and would lack the specificity to identify any needed corrective action for individual types of Medicaid services. Some commenters suggested that CMS analyze rates for each code and that committees be established to determine if rates for each code are sufficient. Additionally, commenters stressed the importance that states gather and compare similar data sets from commercial insurers, Medicare, and other payers within their state.

Response: We approve states' rate methodologies for compliance with regulation and statute, but generally do not approve individual service rates unless a state presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule with comment period does not change that policy or imply that CMS will review individual rates for sufficiency. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are sufficient to enlist providers into the Medicaid program or not, since generally providers do not determine whether to provide care to an individual based on the rate for a single service. This final rule with comment period requires states to provide an analysis to compare Medicaid rates to other private and public health payer rates. This analysis will only serve as an indicator of whether low rates may be a source of access issues. A better determination of whether the rates are sufficient to enlist providers into the Medicaid program

will be the analysis of enrollee needs, the availability of providers and utilization trends, as well as beneficiary and stakeholder feedback that will be received through the processes described in this rule.

Comment: A commenter noted an error in the proposed regulatory text. Specifically, the May 6, 2011 proposed rule would have required that states calculate the "percentile" estimate which Medicaid payment represents of one, or more, of the following: Medicare payment rates, the average commercial rates, or the applicable Medicaid allowable cost of the service. The commenter notes that CMS likely intended states to calculate the "percentage" of which Medicaid payment represents the other payer or cost amounts.

Response: We agree with the commenter and we have corrected this in this final rule with comment period. We also note that, based on comments, we revised the payment analysis so that states are required to determine the percentage of which Medicaid payments represent other public or private payer rates for the services subject to the access monitoring review plan requirements by provider type and site of service.

Comment: Some commenters agreed that the proposed use of fee percentiles as an effective way of representing the distribution of fees charged by providers in a particular area.

Response: We are revising the regulations to require that states review percentage comparisons of Medicaid payment rates to other public or private health coverage rates within geographic areas of the state.

Comment: Many commenters suggested that CMS require states to compare Medicaid payment rates to the provider's actual cost as part of the access review. Some commenters stated CMS should specifically clarify that provider rates need not be tied to, or based on provider costs, while others suggested CMS should mandate that rates meet a certain percentage of provider cost. One commenter suggested that CMS should require the access reviews to account for average customary provider charges and also the extent to which providers in the geographic

area are requiring these charges to be paid in full. Still other commenters stated that healthcare charges have virtually no relationship to the true cost of procuring services, and therefore, are not a valid reference for comparison.

Response: The framework described in this final rule with comment period addresses how states can demonstrate and monitor sufficient access to care as required by section 1902(a)(30)(A) of the Act. Neither provider cost nor charges is a required review element in meeting the requirements of the final rule with comment period. We acknowledge and support states' efforts in working toward delivery system reforms that promote more effective care and lower cost. We have issued several guidance letters on reform models that can be supported under the Medicaid program and, within those letters, have cautioned that access to care should be considered as part of a reform model.

Comment: Commenters suggested that the regulations be revised to address "payment" as referring to both individual health care service rates, as well as payments for care and services on an aggregate basis such as total payments for all care and services or total payments for all acute hospital care and services.

Response: This rule only addresses how states can demonstrate and monitor sufficient access to care as required by section 1902(a)(30)(A) of the Act, which describes payment rates for Medicaid care and services. The requirements contained in this final rule with comment period set forth a framework for states to use to demonstrate their payment rate methodologies are sufficient to ensure access. We appreciate the comment but, as previously discussed, we are not requiring states to review access for each individual item, service, or procedure payment rate.

Comment: One commenter expressed concern that the proposed requirement in §447.203(b)(3) is unreasonable and impedes the efficient operation of the Medicaid program because all changes in payment policy can be considered "significant".

Response: Reviews of access to care are necessary to ensure the state Medicaid program

is providing sufficient services to its beneficiaries. We discussed the reasons for issuing this regulation at length in the May 6, 2011 proposed rule. Although there is some burden associated with the proposed requirements, we considered comments related to burden in developing this final rule with comment period. The requirements of the final rule with comment period are not predicated upon a significant change in payment policy, but whether the proposed changes could negatively impact access. Where there is confusion over whether a change may cause harm to access to care, we will work with states to make a determination.

Comment: Some commenters stated that Medicaid payment rates should be reviewed and analyzed as new technology is introduced into the medical community to determine whether access to the new technology is limited. Commenters also suggested that medical conditions affecting Medicaid populations may develop that substantially affect the need for certain covered items and services, such as the rise in HIV infection in the early 1980s. The commenters concluded that any similar health-related changes should require review of provider payments rates to ensure continued access to necessary items and services; this is not reflected in the proposed 5-year review structure.

Response: Our intent is to define a process by which states can effectively and consistently measure beneficiary access to medical services in the Medicaid program. To the extent that advances in technology and/or unforeseen challenges arise that have an impact on the delivery of care in the Medicaid program, we expect these types of changes to be considered when reviewing access to care but only to the extent that it increases or decreases access to services as established in section 1902(a)(30)(A) of the Act. As such, this final rule with comment period offers flexibility to states to demonstrate access within the context of each state's local health care delivery system.

Comment: We received some comments indicating that establishing a standard equivalent to commercial insurance would need to be established by the Congress and doing so

through the proposed rule is an administrative expansion of the Medicaid entitlement, one that may or may not be achievable even if substantial increases in state and federal program funding were possible.

Response: We did not propose to establish a standard equivalent to commercial insurance. Rather, this rule will require states to make comparisons of Medicaid service rates to private or public health payer rates. We are aware that a number of states already perform these types of calculations for varying administrative purposes.

4. Stratification Requirements

Comment: Some commenters supported the proposed stratification requirement for the access review, while other commenters opposed such a requirement.

Response: After careful consideration, we are not finalizing this requirement. Section 1902(a)(30)(A) of the Act does not specify that beneficiaries have access to care within specific provider ownership categories, but rather that access be viewed within the service categories as a whole and within associated geographic areas. We understand that payments do vary based on provider ownership status and we intend to review those differences outside of the scope of this final rule with comment period.

5. Access review timeframe

Comment: Several commenters addressed the timeframe of the on-going reviews and offered alternatives to the timeframe in the May 6, 2011 proposed rule. One commenter suggested requiring that each state complete a full program access review by the end of the second full calendar year following the effective date of the regulations, request that all services be reviewed every 3 years, and that one-third of all services be reviewed each year. Other commenters suggested that rates be reviewed more frequently than every 5 years and suggested various alternative for more frequent review. While other commenters suggested that yearly reviews are excessive without a change in payments and that it is more appropriate to monitor

access after implementation of rate changes to determine the impact of the change.

Response: The timeframe outlined in the May 6, 2011 proposed rule was designed to ensure a timely review of access, while accommodating the time, manpower, and data constraints of state Medicaid agencies. After considering the public comments, we have determined that a full program review over 5 years is too burdensome. Therefore, we have revised this requirement to include a review of: primary care services; physician specialist services; behavioral health services (including mental health and substance abuse disorder treatment); pre- and post-natal obstetric services including labor and delivery; and home health services; services where either payment rates have been reduced or restructured; and services for which a higher than usual volume of beneficiaries, providers, or stakeholders have raised access to care issues. The ongoing reviews will be conducted every 3 years and intend to measure the current status of access to services within the state. We chose to require that states conduct the ongoing reviews every 3 years based on comments indicating that the 5 year proposed review periods were too infrequent to adequately capture changes in access to care. In addition, SPAs reducing payment rates for the services other than those mentioned above must be submitted with an analysis of access to care and then reviewed for a minimum period of 3 years. States may also select additional services to review at their discretion.

Comment: Some commenters requested that CMS require states to post their access review online by January 15th each year since access reviews are to be completed by January 1st.

Response: We consider the completion date to be synonymous with the date the access monitoring review plan should be published or readily made available upon request. We have revised the final rule with comment period to require that states issue the access monitoring review plan by July 1 of each review year. This coincides with the beginning of most state fiscal years and allows states sufficient time after the issuance of this final rule with comment period to

conduct the first review for service categories subject to ongoing review.

Comment: Many commenters suggested revisions to the timeline for review that would require states to conduct access studies and monitor program changes on an annual basis. For example, commenters suggested CMS require states to conduct annual reviews and compare information from year-to-year and analyze trends, averages, and notations of changes in access to care over time.

Response: We agree that comprehensive studies of access are important. However, we have also considered concerns from states over the burden associated with the data requirements discussed in the May 6, 2011 proposed rule and the resources that states estimate would be required to collect and analyze access information for all covered Medicaid services. Therefore, to comply with section 1902(a)(30)(A) of the Act, we focus access review requirements on ongoing reviews of primary care services, physician specialist services, mental health services, pre- and post-natal obstetric services including labor and delivery, and home health services and to focus state efforts on review and monitoring access to care for all other Medicaid services specific to rate methodology changes made through SPAs, as well as ongoing feedback from beneficiaries, providers and other stakeholders.

Comment: Some commenters suggested as an alternative to the proposed timeline, that states should be required to conduct a comprehensive and public access review within 180 days prior to submission of the proposed payment rate change.

Response: We believe that the changes in access to care that occur within 180 days between a review and SPA submission and a year between review and submission would be negligible. Furthermore, states are required to monitor access ongoing for 3 years once a rate reduction goes into effect so any access to care issues that arise between the initial review and SPA submission will be detected through state monitoring procedures.

Comment: We received some comments suggesting that the regulation carve out a

separate effective date of January 1, 2013 for the first rate review required under the regulation and the subsequent rate reviews be conducted every 5 years thereafter. Other commenters stated that CMS should require states to begin the access reviews as soon as possible. Some commenters stated that CMS could require states to begin reviews on the sooner of the first day of the state fiscal year or the first day of the calendar year after the final rule with comment period becomes effective.

Response: We had proposed that states make available the first access data reviews beginning January 1 of the year beginning no sooner than 12 months after the effective date of the final rule with comment period. Based on comments regarding the delay in access review information, we are revising the proposed timeframe and will require states to publish the access monitoring review plans by July 1 after the effective date of this final rule with comment period. The access monitoring review plans must be updated by July 1st every 3 years thereafter. As discussed, this timeframe corresponds with the start of state fiscal years for the majority of states and provides states with time to gather the necessary data and resources to perform accurate and detailed access reviews.

Comment: Several commenters suggested that priority be given to certain services for which access problems have been documented. The list of services included physician services, dental services, mental health services, and many specialty care services.

Response: We agree with the commenters though the list of services that commenters suggested that states prioritize would have required levels of state effort similar to what we proposed. For the reasons discussed in more detail above, we will require that the access monitoring review plan include a review of primary care services; physician specialist services; behavioral health services, including mental health and substance abuse disorder treatment; pre- and post-natal obstetric services including labor and delivery; home health services, and for services where either payment rates have been reduced or restructured or where a significantly

higher than usual level of beneficiary, provider or stakeholder access complaints have been received. States may also select additional services to review at their discretion.

6. Special provisions for proposed provider rate reductions

Comment: We received many comments on the requirement that access monitoring review plans accompany SPAs that proposed rate reductions. Many commenters suggested that we modify the access review procedures to require baseline access analysis prior to taking action to reduce provider rates, ongoing monitoring processes to detect problems, and corrective action when problems are detected. Some of the commenters stated that CMS should suspend the rate reduction until corrective measures are taken. Other commenters requested that CMS eliminate the requirement that proposed rate changes be accompanied by an analysis of access or face disapproval.

Response: In the May 6, 2011 proposed rule, we discussed the basis and reasoning behind requiring access information in making SPA decisions. This final rule with comment period requires that states conduct baseline reviews and monitoring procedures when implementing rate reductions or restructuring rates in ways that may negatively affect access to care. Consistent with commenters' suggestions, this rule requires that states conduct baseline reviews and ongoing monitoring of access data to ensure compliance with section 1902(a)(30)(A) of the Act.

Based on feedback from states that ongoing 5-year access reviews for all services would overly burden state agencies, we determined a process similar to the commenters' to be the appropriate regulatory framework. Such a process will include a review of primary care services, physician specialist services, behavioral health services including mental health, pre- and post-natal obstetric services including labor and delivery, home health services and for services where either payment rates have been reduced or restructured or for which a significantly higher than usual level of beneficiary, provider or stakeholder complaints have been

received. While the suspension of a rate reduction may be an appropriate corrective action, we will not require a specific approach to addressing access issues within this rule, and we will work with states on appropriate remedies given the facts and nuances of particular situations. We intend to work with states to monitor access data and determine an appropriate course of action should access issues arise.

7. Compliance with access requirements

Comment: Some commenters suggested that CMS approve an access review within 90 days of receipt and if the review is deemed unacceptable, that CMS disapprove a SPA submittal or take corrective action to address inadequate access to care.

Response: While we will not formally approve or disapprove access reviews, all reviews must include the elements described in the regulations and we will review the plans using this standard. We will not approve SPAs that are unsupported by data and the processes described in this final rule with comment period, and will pursue compliance action should a state fail to conduct the baseline access data reviews.

8. Monitoring procedures

Comment: Some commenters suggested that we revise the access demonstration to state that states must "consider" the access impact and commit to ongoing monitoring when appropriate.

Response: We agree that states should conduct ongoing monitoring efforts on access to care and included oversight and monitoring procedures within this final rule with comment period. To the extent that states find access to care issues as part of the access monitoring review plan processes that are ongoing or associated with specific rate actions, we expect the state to take actions to remediate those issues. If a state does not take remediation actions, the state would not be in compliance with the statute and would be at risk of losing FFP.

Comment: Commenters requested that CMS define access issues and action plans as

system-wide rather than case-by-case as identified by beneficiaries or providers, and that the requirement be comparability to the private sector.

Response: Section 1902(a)(30)(A) of the Act requires that payments 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. We expect states to address access issues, whether through a formal corrective action plan, or if more appropriate, on a case by case basis.

Comment: Some commentators requested more specific requirements for monitoring access after a rate reduction is implemented, including the request that CMS set specific timeframes for the required monitoring procedures.

Response: Section 447.203(b)(6)(ii) allows the state flexibility to develop access monitoring strategies. While monitoring procedures are required of states, each state may develop the monitoring plan that best accommodates its data and other resources, while still adequately monitoring access to services. This final rule with comment period incorporates a specified time period of 3 years for monitoring following the implementation of a SPA that reduces or restructures payment rates.

Comment: Some commenters suggested that we provide clear and broad discretion to states in managing rates, and a clear path toward expedient approval of a rate reduction, provided that the states have mechanisms in place to monitor and correct adverse impacts to access.

Response: This final rule with comment period continues to offer states broad discretion to manage rates and includes procedures to ensure that proposed changes in the program do not violate section 1902(a)(30)(A) of the Act.

Comment: Some commenters suggested that CMS should define in the regulation its role in post-implementation monitoring.

Response: We will review access to care data each time a state submits a rate reduction

or restructuring of payment SPA or any time the agency is made aware of access to care issues. The monitoring procedures in the regulation are intended to be used to inform the state and federal government of the overall status of access to care in their program. In addition, CMS may use the access to care data to monitor the adequacy of rates over time, and may use it to address areas in which access is insufficient.

Comment: One commenter requested that CMS clarify if the monitoring requirements apply to all payment methodology restructuring or only those that result in rate reductions.

Response: A state must develop procedures to monitor continued access to care after implementation of state plan service rate reduction or payment restructuring that may reduce access to care. The procedures must define a periodic review of state determined indices that will serve to demonstrate sustained service access, consistent with efficiency, economy, and quality of care.

Comment: One commenter requested that CMS clarify how a state would demonstrate sustained access after implementation of a SPA that reduces or restructures rates.

Response: The monitoring procedures required in §447.203(b)(6)(ii) require that a state develop procedures to monitor access after implementation of a SPA that results in rate reduction or payment restructuring. Such monitoring should include enrollee needs, availability of care and providers, utilization of services, and service payment information. States must conduct reviews periodically over a minimum 3-year period following implementation of a SPA that reduces or restructures rates.

Comment: Several commenters recommended changes to the review and monitoring requirements of the proposed rule. Some commenters requested that CMS provide additional flexibility to states in establishing appropriate methods for measuring and monitoring beneficiary access to services. Other commenters suggested that states should periodically review and monitor access and states determine the measures of access and beneficiary information included

in such reviews allowing states to take a more balanced approach to evaluating access.

Response: This final rule with comment period offers states significant flexibility in determining the measures of access and beneficiary information included in the review as the commenter suggests. However, we believe that a defined time period for completion of the access to care reviews allows the collected data to serve as an acceptable comparative analytical tool over a number of years whenever states proposes to restructure or reduce rates or when beneficiaries alert the agency to access to care issues. Timely reviews also allow states to demonstrate ongoing compliance with the section 1902(a)(30)(A) of the Act. Section 447.203(b)(6)(ii) will require states to develop ongoing monitoring procedures through which they periodically review indices to measure sustained access to care. Our goal is to provide a consistent path for all states to document access to care consistent with the Act but to also allow states flexibility to measure and monitor access within state means.

Comment: Some commenters stated that states should be required to use the same methodology to measure access once a rate reduction is put into place so that a fair comparison of the impact of the rate reduction may be made.

Response: We generally agree that consistency in a state's methodology may allow for better comparisons of access over a period of time; however, states may need to make adjustments and changes to the analysis based on modifications of service delivery systems, payment rates or other program changes that may affect access to care. States and CMS may also determine that an analysis is not feasible to conduct or does not accurately demonstrate access after conducting a review For these reasons, we are not restricting states from making modifications to their methodology when the changes intend to improve the analysis or present reasonable alternative approaches to reviewing access to care.

Comment: Some commenters suggested, as part of monitoring identified access issues, an annual review and public town hall meetings should be implemented.

Response: We considered requiring that states conduct a public process for monitoring activities similar to that which is described for the submission of SPA that reduce rate or restructure payment in circumstances when the changes could result in access issues. This final rule with comment period requires states to have mechanisms for ongoing beneficiary, provider, and other stakeholder feedback and those mechanisms should ensure that state monitoring activities are effective and were properly developed.

9. Mechanisms for ongoing input

Comment: Many commenters supported the requirement that states have ongoing mechanisms (hotlines, surveys, ombudsman, etc.) for beneficiary input on access to care. Some of the commenters suggested that we add a specific mechanism for feedback from tribes, tribal organizations, and Indian Health Providers.

Response: We appreciate the support for the requirement that states have an ongoing mechanism for beneficiary feedback. We have also considered comments from providers and provider organizations and will require that states have a similar mechanism for provider feedback. Tribes and Indian Health providers are an important part of the Medicaid community and both the beneficiary and provider feedback mechanisms must be available to Tribes and Indian Health providers. In addition, consistent with Executive Order 13175, HHS Policy, and the CMS Tribal Consultation Policy, states are required to consult with tribes to receive their input. We also encourage states to develop specialized mechanisms that would be responsive to input from beneficiaries from other populations that have particular access concerns.

Comment: Several commenters requested that states or CMS establish advisory groups to help determine whether state payment rates sufficiently provide for access to care. Commenters suggested that the groups be comprised of a variety of stakeholders, such as beneficiaries, beneficiary advocacy groups, clinicians, and provider trade organizations.

Response: Current §431.12 requires that state Medicaid agencies establish Medical care advisory committees that include provider and beneficiary participation. We are finalizing the requirement that states have a mechanism for ongoing provider feedback, similar to the process for ongoing beneficiary feedback. This could include the Medical care advisory committee required at §431.12.

Comment: Commenters requested that we clarify the decision to require ongoing beneficiary feedback when other requirements of the proposed rule, such as the public process, involve providers and other stakeholders. In addition, commenters requested that CMS clarify the standard against which we would require states to consider input from beneficiaries and other stakeholders. A commenter noted that the level of input and magnitude of proposed SPA changes are not always correlated.

Response: After considering the comments received, we are including in this final rule with comment period the requirement that states consider provider feedback similar to the requirement for ongoing beneficiary feedback. This could be accomplished through state Medical care advisory committees, logging of issues raised by providers, or other means. States must incorporate feedback from beneficiaries and providers are part of the access monitoring review plan procedures. There is no threshold or standard that we will apply to stakeholder feedback; rather, the requirements will assure that states understand access to care concerns from the community as they arise and consider that information as they make changes to their Medicaid program.

Comment: Some commenters suggested advocate groups should also have an opportunity for ongoing input which should be differentiated from the mechanism provided for public input.

Response: We understand that advocate groups currently have many opportunities to provide feedback to states on Medicaid issues and offer important insights for state

consideration. This final rule with comment period offers advocates and other stakeholders an opportunity to provide feedback on specific state rate actions through the public process procedures. In addition, we would expect that individuals advocating on behalf of a Medicaid beneficiary would have access to the mechanism for ongoing beneficiary feedback described in this rule.

10. Addressing access questions and remediation of access issues

Comment: We received several comments regarding the subsequent actions if an access issue is identified. Many commenters were in support of the requirement for states to submit a corrective action plan, while many commenters were opposed to such a requirement. Commenters stated opposition and expressed concern about the lack of "threshold" for the scope or severity of an access issue that would require the submission of a corrective action plan. While some commenters sought clarification from CMS, others implied that the state should be able to define such threshold, especially in instances that are clearly compliant with the statutory standard. Some commenters suggested that CMS should not approve a SPA or permit a payment reduction to be imposed until corrective action measures are taken. Other commenters suggested that CMS should affirmatively require states to suspend or reverse a payment reduction if an access issue is identified. A few commenters urged CMS to impose sanctions on states that fail to remedy access issues timely. Still other commenters requested that CMS remove any references to remedies for access issues that do not involve increasing payment rates. Commenters also discussed the 90-day timeframe to submit corrective action plan after discovery. Some concerns were raised that the 90-day timeframe was overly hasty, while others thought it appropriate.

Response: After careful consideration of all of the comments received, we are finalizing §447.203(b)(8) requiring a state to develop and submit a corrective action plan to CMS within 90 days of discovery of an access deficiency. The submitted action plan must aim to remediate the

access deficiency within 12 months. This requirement ensures that the access deficiency is addressed in a timely manner while allowing the state time to address underlying causes of the access issue, be it payment rates, provider participation, etc. Section 447.203(b)(8) clarifies that states have a number of options to address access to care issues. These remediation efforts can include but are not limited to: increasing payment rates; improving outreach to providers; reducing barriers to provider enrollment; providing additional transportation to services; or improving care coordination. This is an acknowledgement that access to care is not always about payment rates but rather that when enough providers are enlisted in the program, states may need to find ways to connect beneficiaries with the care and services they need.

Comment: Some commenters stated that states need more than 12 months to implement corrective action when access issues are discovered, whereas other commenters believed that allowing states 12 months to resolve the issue was too long. Commenters stated concerns that that the 12-month time frame attached to the corrective action plan could encourage longer-term measures, which may have an adverse effect on provider participation. One commenter stated the final rule should recognize the potential need for state legislative action to address identified access issues and the 12-month timeframe could potentially be too short for a state to make these changes, especially in states with biennial legislative sessions.

Response: We are finalizing §447.203(b)(8) that requires a state to develop and submit a corrective action plan to CMS within 90 days of discovery of an access issue. The submitted action plan must aim to remediate the access deficiency within 12 months. This timeframe has been developed to minimize the length of time beneficiaries may experience decreased access while realistically accommodating a state's resources and allowing sufficient time to address the underlying causes of identified access issues. Although longer-term measures may be needed to fully address the underlying causes of an access issue, it is imperative that a corrective action plan aim to resolve the access issue within 12 months, in the interest of preserving adequate

beneficiary access.

Comment: Commenters suggested that we require states to publicly report and address any decline in access to services following rate reductions.

Response: We are finalizing §447.203 that will require states to publish, or promptly make available upon request, the access monitoring review plan. Within the access monitoring review plan, a state must monitor continued access to care following rate reduction or payment restructuring.

Comment: A commenter suggested that CMS should implement a mechanism to fast-track any substantive access concerns that are uncovered during state-level review; states should not be permitted to wait until the start of the next calendar year to fix a substantive problem.

Response: Once access issues are identified, the state will have 90 days to submit to CMS for review a corrective action plan; the goal of this plan must be to resolve the identified access issues within 12 months. This timeframe has been developed to minimize the length of time beneficiaries may experience decreased access while realistically accommodating a state's resources, allowing sufficient time to address the underlying causes of identified access issues.

Comment: Commenters raised concerns that the remediation process could result in a SPA backlog because states would need to address access issues before moving forward with state plan changes.

Response: State plan changes must comply with statutory and regulatory requirements. To the extent a state identifies areas of inadequate access to Medicaid services, we could not approve any SPA that could potentially impede access further. We will work with states to address these issues on an as needed basis.

Comment: One commenter stated that the final rule should remove the requirement for data gathering and focus on monitoring and corrective action. The commenter further suggested that if, and when, access issues are found, a state should develop and implement a corrective

action plan. These activities would be supplemented through ongoing mechanisms for obtaining beneficiary input, using hotlines, surveys and other tools.

Response: We have revised the requirements of this final rule with comment period to have a greater focus on monitoring and corrective action. Data gathering is essential to these activities and, as previously discussed, we are focusing the data review efforts in consideration of state burden.

Comment: A commenter noted that the May 6, 2011 proposed rule states that CMS may disapprove a SPA if a rate is "modified" without an access review; however, the term "modified" is not defined in the rule.

Response: We believe that in the context of the regulatory language and we are confirming here that modified means to reduce or restructure Medicaid service payment rates in circumstances when the changes could result in access issues. To the extent that states are unsure whether a change could result in access issues, we will work with states individually to make a determination.

Comment: One commenter suggested that CMS outline the remedies that beneficiaries and providers will have if access issues are discovered and the state proceeds with implementing a SPA without regard to the issues.

Response: This final rule with comment period requires that states monitor access to care after implementing Medicaid payment rate reductions and identify and remediate issues that are found as a result of the access review and monitoring efforts. The rule also requires an ongoing mechanism for beneficiaries, providers, and other stakeholders to raise concerns over access to care. States are required to maintain a record of the volume and nature of the response to those concerns. We expect that the monitoring procedures and mechanisms for ongoing input will work together to raise ongoing access concerns.

C. Medicaid provider participation and public process to inform access to care (§447.204)

We received several comments that discussed concerns over the proposed changes to the public process requirements.

Comment: One commenter stated that the public process requirements are not enforceable because they are not a specific requirement in statute.

Response: The purpose of this final rule with comment period is to provide states with standard processes that consider and document access to care in the Medicaid program consistent with section 1902(a)(30)(A) of the Act. We respectfully disagree that the proposed changes to the public process are not contemplated within the requirements of that section. The regulatory guidance within this rule relies upon public interaction to, in part, gauge and document whether beneficiaries and stakeholders raise concerns that proposed rate changes will have a meaningful effect on beneficiary needs and the availability of care and providers. We maintain that such information is necessary to understand state rate proposals and inform CMS approval actions.

Comment: Commenters noted that the May 6, 2011 proposed rule may create a timing problem for states by requiring the public process to occur prior to the submission of a SPA. Commenters anticipate that the public process does not allow sufficient time for states to prepare and submit SPAs. Commenters also stated that the public process requirement increases the time it takes to submit a SPA by at least 30 days. As an alternative, some commenters suggested that the public process occur prior to the effective date of the SPA consistent with the public notice requirement.

Response: Under the processes required by this final rule with comment period, to the extent that a state wishes to change payment rates that may affect access, the state will need to be up to date in following the access review procedures and public input mechanisms. If the state does not have the required access review data, or has not recently prepared an access analysis, there could be a delay in its ability to submit an approvable SPA submission. We note that this rule does not affect the timing provisions for SPA effective dates. States may make SPAs

effective as early as the first day within the quarter in which the SPA is submitted so even a 30-day delay should rarely change the proposed effective date of a state's SPA action. Furthermore, we also note that states are already subject to a similar process related to conducting notice prior to SPA submissions through the Tribal Notification processes established under section 1916 of the Act.

Comment: Commenters stated that the proposed changes were overly prescriptive and that CMS should allow individual states to determine how to interact with stakeholders on changes to Medicaid payment methodologies.

Response: We provided states with the flexibility to determine the appropriate mechanism to solicit input from beneficiaries and affected stakeholders. States that have these mechanisms in place are under no requirement to change their approach. This final rule with comment period requires that a state document beneficiary and stakeholder feedback and use that information to inform how they evaluate access to care to meet the statutory requirement. This information will both inform CMS's approval actions and serve as the state's public record for compliance with section 1902(a)(30)(A) of the Act.

Comment: We received many comments that requested states provide specific information as part of the public process. Commenters stated that public process should include: the proposed SPA; material submitted by the state Medicaid agency in connection with the proposed SPA; the information that CMS reviews to approve a SPA; and information on how interested parties may promptly obtain such materials. Commenters also requested that all state plans and proposed SPAs should be posted on state Web sites or the CMS Web site.

Response: This final rule with comment period does not address the public process under section 1902(a)(13)(A) of the Act that is required for institutional rate setting. This rule addresses only the procedures necessary to document compliance with section 1902(a)(30)(A) of the Act to assure that provider payment rates are sufficient for beneficiary access to care. Those

procedures must include a public input mechanism for comments on access to care. This final rule with comment period provides states with considerable flexibility to determine appropriate public input mechanisms. We suggest that interested parties work with states to ensure that these mechanisms are effective.

Comment: Commenters suggested that CMS be more prescriptive in how states should conduct the public process based upon a proven methodology. One commenter suggested a formal "Listserv" for comments similar to the federal proposed rule listserv for public access to comments. A commenter requested that families, caregivers, and providers be able to represent their concerns to the Medicaid agencies and have processes in place that allow them to represent the voice of Medicaid beneficiaries where appropriate.

Response: While we continue to allow for states to determine exact procedures for soliciting input from beneficiaries and stakeholders, we appreciate the suggestion that states could use a listserv to reach its intended audience. The mechanisms for ongoing beneficiary feedback required in this final rule with comment period will allow beneficiaries and stakeholders to voice concerns related to access to care in multiple forums, such as hotlines and ombudsman programs. We agree that beneficiary and stakeholder feedback is vital to understanding access to care both as it pertains to specific rate proposals and on an ongoing basis.

Comment: Some commenters offered concerns that the specific requirements of public input is an unclear process and that it is difficult for states to obtain stakeholder input on all services. Commenters further stated that public process creates a substantial administrative burden for the state to implement on an ongoing basis. To overcome these issues, commenters wrote that the final rule should clarify that states have flexibility in monitoring access to care and recommend that we remove the requirements of ongoing "beneficiary input" since the public process and ongoing beneficiary feedback mechanisms are duplicative.

Response: This final rule with comment period does not require a particular mechanism for states to receive feedback from beneficiaries and other stakeholders that are affected by Medicaid rate-setting. The preamble to the May 6, 2011 proposed rule specifically discussed state flexibilities and the ability of states to rely on current processes to demonstrate access to care to the extent that states already have such processes in place. In this rule, we are implementing a standard set of procedures, including feedback from stakeholders, that all states must follow to document access to care consistent with section 1902(a)(30)(A) of the Act. States develop the particular mechanisms to enact the procedures either consistent with current practices or in other ways that meet beneficiary needs and address access concerns within each state. The public process requirements for institutional rates and the ongoing public input mechanisms serve different purposes. The ongoing public input mechanisms apply to all services, are not limited to input regarding proposed changes in rates, and includes a clear opportunity for beneficiary feedback on access. The beneficiary feedback mechanism allows states to understand any access to care concerns in real time as they occur. We respectfully disagree that those efforts are duplicative.

Comment: Several commenters recommended that CMS strengthen the regulation to state that any SPAs submitted without having completed the public process requirement would be disapproved. A commenter specifically proposed that the regulatory text be modified so that CMS “must” disapprove a SPA if submitted without a state meeting the public process requirements described at §447.204(b).

Response: The regulations require that states provide a mechanism for public input when reducing or restructuring Medicaid payment rates in circumstances that could result in access issues. We retain the authority to consider the circumstances of and content of a SPA submittal to determine its compliance with statutory and regulatory requirements before making approval decisions.

Comment: One commenter wrote that discretionary language in §447.204(b) "the agency may disapprove a proposed SPA using the authority…or may take a compliance action" could enjoin a rate alteration or reduction based solely on the fact that the SPA is not yet CMS-approved.

Response: As we indicated above, we do not intend in this rulemaking to change the requirements relating to the effective date of approvable SPAs. How these requirements are applied and interpreted in judicial review in the federal courts is an issue that is beyond the scope of this rulemaking.

Comment: Several commenters suggested requiring states to implement an ongoing input process for every change, regardless of the scope. Other commenters noted the rule creates a significant administrative burden for states and stated it would be an inefficient use of limited resources in situations where states are making minor changes. The commenters requested that CMS work with states to define a threshold that would trigger the need for beneficiary input. The commenters also recommended that CMS adopt language for such a process similar to that contained in the proposed "Monitoring Access" provisions whereby the state is able to define the procedures and process.

Response: The requirements in this final rule with comment period for public input allow states flexibility to design public input mechanisms that are appropriate for state-specific circumstances. Considering that there is so much variability in the Medicaid program and the delivery of Medicaid services, CMS is concerned that defining the significance of a rate reduction or payment restructuring before a state institutes a beneficiary feedback mechanism would undermine the inclusion of the process in this regulation. Many states have indicated to CMS through other venues that the feedback mechanism is a primary indicator of access to care.

D. Public notice of changes in statewide methods and standards for setting payment rates (§447.205)

Comment: We received comments that suggested various thresholds for significant changes and removal of the term significant from the public notice requirement. Some commenters requested that states be allowed to define the term "significant" in the regulations, while others requested that CMS define both the terms "significant" and "change" in the final rule**.** A number of commenters suggested thresholds for issuing public notice, including: any reduction in payment; a reduction of 5 percent or more; a reduction of 10 percent or more, a CMS-defined threshold; or any rate reduction or alteration in reimbursement methods. Many commenters also suggested that CMS should delete the term "significant" altogether.

Response: The public notice requirement informs providers of changes in state plan methods and standards that have either a positive or negative impact on rate-setting. As discussed in the May 6, 2011 proposed rule, it is difficult to determine a threshold of a significant change in payment methods and standards since the determination to participate or continue to participate in Medicaid is provider specific. This final rule with comment period should reduce the administrative and financial burden of issuing notice by allowing states to publish on state agency Web site. In consideration of this and comments from providers requesting the removal of the term "significant" and the past ambiguity in interpreting whether notice is required, we are removing the term "significant" in this final rule with comment period. Aside from the specific exceptions described in the regulation, notice will be required for all changes in state plan methods and standards with the effective date of this final rule with comment period.

Comment: A commenter suggested that the public notice regulation describe requirements specific to tribal consultation.

Response: While the May 6, 2011 proposed rule did not address tribal consultation, the CMS tribal consultation requirements were detailed in policy in the November 17, 2011 document entitled "CMS Tribal Consultation Policy." The policy incorporates provision in the

American Recovery and Reinvestment Act of 2009 (Recovery Act) and the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). Additional information regarding the CMS Tribal Consultation Policy is available at http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Consultation.html. CMS will continue to consult with Tribal leaders on the delivery of health care for American Indians/Alaska Natives (AI/AN) served by the Marketplace, Medicare, Medicaid, Children's Health Insurance Program (CHIP), or any other health care program funded by CMS and make updates to the policy as necessary.

Comment: One commenter offered that the public notice requirement should be expanded so that a "change" includes both a change in payment rates and/or a change in the scope or definition of Medicaid benefits.

Response: We did not propose an expansion of the public notice requirement to include changes in coverage policy and the public notice regulation discusses notice of changes in statewide methods and standards for setting payment rates. Since this rule addresses policies related to section 1902(a)(30)(A) of the Act, which is specific to state plan service rates and access to care, we are not addressing changes to coverage policies at this time.

Comment: One commenter offered that the public notice requirement should be amended to tie in with the public process requirement described in the May 6, 2011 proposed rule. The commenter offered that since the new public process is required prior to a state submitting a SPA, the process should tie in with the requirements set forth in §447.205 as to how notice should be given.

Response: The public process and public notice requirements serve different purposes. The public notice applies to any changes in state plan methods and standards, and is published 1 day prior to the effective date of a Medicaid SPA. The public notice informs the public of a proposed change in Medicaid rate-setting or policy without necessarily considering public

feedback as part of the policymaking process. The public process requirement provides opportunity for the public to provide input into determining beneficiary access to care.

Comment: A few commenters objected to the use of web-based publications as an option to issue public notice. One commenter cited a number of reasons for the opposition, including: the benefit of printed notice over Internet notice; the fact that state Web sites do not have strong readership when compared to newspapers; limited access to the Internet in many poor and rural communities; potential problems that individuals with disabilities or illness may have with using the Internet; lack of assurance that states will maintain Internet sites sufficiently; and difficulty in archiving web-based publications for courts, historians, researchers and archivists. The commenter stated that the proposal would leave the public with large gaps in public information.

Response: We have addressed many of the issues raised in the comment in this final rule with comment period. For instance, the rule provides that a state's electronic publication must be regular and known. This offers significant advantages over paper-based publications that may appear on any day in the calendar year and should alleviate some concerns over access to the state Web sites. We agree that these Web sites must meet national standard to assure access to individuals with disabilities, and we are including this requirement in the final rule with comment period. Such standards are issued by the Architectural and Transportation Barriers Compliance Board, and are referred to as "section 508" standards. Alternatively, the World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG) 2.0 Level AA standards would also be considered as acceptable national standard for Web site accessibility. For more information, see the WCAG Web site at http://www.w3.org/TR/WCAG20/. We also note that states currently have the option to publish notice in a state register that is similar to the **Federal Register**. Like the **Federal Register**, many state registers are web-based and states already routinely use them to publish notice as an alternative to paper-based publication. Therefore, we do not view the proposed flexibility as a significant departure from the current

available options. Furthermore, we believe that web-based publication will be as accessible to poor and rural communities as publication in a state register.

Comment: A commenter suggested that CMS reconsider the statement in §447.205(b) which allows states to change reimbursement as long as the change is made to conform to Medicare without public notice. The commenter stated that Medicare serves a significantly different population than Medicaid, has different conditions of participation, and may be a relative low payer of professional services in some locations.

Response: The May 6, 2011 proposed rule did not contemplate modifying the exception to public notice in instances where the change in Medicaid rates is consistent with Medicare. At this time we are not adopting the commenter's suggestion.

IV. Provisions of the Final Regulations

This final rule with comment period incorporates many of the provisions of the May 6, 2011 proposed rule but also makes substantial modifications based on responses to the public comments. Those provisions of this final rule with comment period that differ from the proposed rule are as follows:

- The term "access review" is replaced throughout by the term "access monitoring review plan" to emphasize that the regulation is intended to establish a process by which states monitor and measure access, rather than just the requirement that data is due to CMS.
- Section 447.203(b) is revised to clarify that the states' access monitoring review plans must be developed in consultation with the state's medical care advisory committee and submitted to CMS, and will be reviewed by CMS. This section has been revised to also indicate that the plans must be made available for public review and comment for a period of no less than 30 days prior to the finalization of the plan and submission to CMS. This allows stakeholders time to comment on the appropriateness of the specific measures the state will use to determine that there is adequate access to Medicaid services.

- Section 447.203(b)(1) is revised to state that the access monitoring review plan must include the items specified under the access review procedures, as well as data sources, methodologies, assumptions, trends and factors, and thresholds so that it is clear that measurable data and analysis are essential components of the access monitoring review plans.

- Section 447.203(b)(1) is revised by replacing the term "access review" with "access monitoring review plan" for the reasons described above. We made clarifying changes to the monitoring plan framework, specifying that reviews must measure whether beneficiary needs are fully met, that the providers analyzed as part of the review are enrolled in the program, and that the access analysis must demonstrate access to care within state specified geographic areas. This is consistent with the statutory requirements. We also added a requirement that the analysis describe the characteristics of the beneficiary population (including considerations for care, service, and payment variations for pediatric and adult populations and for individuals with disabilities). This is important to understand specific access needs within geographic areas.

- Section 447.203(b)(2) is revised to specify that beneficiary and provider input must be considered within the access monitoring review plans. We have also indicated potential sources of this information, such as the public rate-setting process, medical care advisory committees, and letters to state and federal officials. In addition to the data the state will review, ongoing input from beneficiaries and providers will help states understand access issues (and suggestions to improve access) on a real-time basis and potentially target access improvements and remediation strategies.

- Section 447.203(b)(3) changes the analysis of payments to compare Medicaid payments as a percentage of other public and private health payment rates within geographic areas of the state. We proposed that states compare Medicaid rates to provider charges and Medicare payments rates, the average commercial payment rates or the applicable allowable cost of Medicaid services. We also proposed that states stratify this information based on provider

ownership status. The final rule with comment period modified the requirement to streamline the information and allow states flexibility in demonstrating the comparative analysis of the Medicaid payment rates as now defined in §447.203(b)(1)(C). The analysis required in the final rule with comment reduces administrative burden associated with the proposed requirements while continuing to provide a basis to understand how Medicaid service payments compared to other health payer payments. The statute discusses the sufficiency of rates in ensuring access to services; however, as we have stated, rates may not be the only or most important determinant of access in the Medicaid program.

- Section 447.203(b)(4) provides details on the review plan standards and methodologies. To provide additional clarity on types of information that states can use for these reviews, we have described suggested data elements for state consideration including, but not limited to: time and distance standards, providers participating in the Medicaid program, providers with open panels, providers accepting new Medicaid beneficiaries, service utilization patterns, identified beneficiary needs, logs of beneficiary and provider feedback and suggestions for improvement, etc. While not specifically required, these data elements may be used by states to address the framework described in the final rule with comment and represents the scope of the analysis that states should conduct when reviewing access to care. This responds to state and provider concerns that the data reviews in the May 6, 2011 proposed rule lacked clear direction and standards for how CMS will evaluate the sufficiency of a state's access analysis.

- Section 447.203(b)(5) regarding the "Access Review Timeline" has been modified to clarify that states will need to comply with the provision of this final rule with comment period. We received many comments on the timing associated with the access data reviews. In the final rule with comment, states will be required to conduct the first review for the specified subset of ongoing services by July 1 after the effective date of the final rule with comment period and update the analysis every 3 years by July 1 of each review year. This corresponds with the start

of the fiscal year for most states and provides sufficient time to develop the baseline monitoring plan.

- Section 447.203(b)(5)(ii) was revised to change the requirement that states review all covered services within a 5-year period to require that states review a subset of service categories at least once every 3 years. Language has also been added to this section to clarify that the states are required to "complete a full review of the data collected through the monitoring plan methodology." Paragraphs (b)(5)(ii)A, (ii)(B), (ii)(C), (ii)(D), and (ii)(E) were added to define the specific categories of services that must be included in the access monitoring review plan. Paragraph (b)(5)(ii)(A) adds primary care services which includes physician, FQHC, clinic, dental care, etc. Paragraph (b)(5)(ii)(B) adds physician specialist services which includes services which are provided via a referral from a primary care provider, for example, cardiology, urology and radiology. Paragraph (b)(5)(ii)(C) adds behavioral health services which includes mental health, substance use disorder, etc. Paragraphs (b)(5)(ii)(D) adds pre- and post-natal obstetric services including labor and delivery. Paragraph (b)(5)(ii)(E) adds home health services. These categories were added because they are frequently used services in Medicaid, and access to these services indicates that an individual has primary sources of care, which may increase the likelihood of having their care needs met. Paragraph (b)(5)(ii)(F) has been added clarify that additional services are to be added to the access monitoring review plan when states reduce or restructure rates. Paragraph (b)(5)(ii)(G) was added to require states to review access for additional services based on a significantly higher than usual level of beneficiary, provider, or stakeholder access complaints. Paragraph (b)(5)(ii)(H) was added to allow additional types of services selected by the state. These modifications remove some burden from the states, particularly those that have continuously monitored Medicaid access to care and do not have widespread access issues. We are requesting comment on the revisions to paragraphs (b)(5)(ii)(A) through (ii)(E).

● Section 447.203(b)(6)(i) was revised to clarify that access monitoring review plans shall be updated to incorporate an access review as described under paragraph (b)(1) of this section when a state submits a SPA to reduce payment or restructure payment in circumstances when the changes could result in diminished access for the service or services affected by the SPA. We have further clarified in this paragraph that a state must update the access monitoring review plan within 12 months of the effective date of the submitted SPA.

● Section 447.203(b)(6)(ii) which describes monitoring procedures, has been retitled "Monitoring procedures." The monitoring process has been modified to require incorporation of access monitoring review plans and procedures, including period review protocols and clearly defined measures and thresholds, into the Medicaid state plan reimbursement methodology and to require the first monitoring review to occur within a year after the effective date of a SPA rate change and continue periodically for a period of at least 3 years after the effective date of the SPA authorizing the payment reduction or restructuring.

● Section 447.203(b)(7) describes that states must have mechanisms for ongoing beneficiary input on access to care (through hotlines, surveys, ombudsman, or another equivalent mechanism). In response to concerns over individual access issues, we revised the provision to require states to promptly respond to public input with an appropriate investigation, analysis, and response. The state is also required to maintain records of the input and the nature of the state's responses. While CMS recognizes that services provided through home and community-based waivers or 1115 demonstrations are not bound by the procedural requirements of this rule, states may understand through these feedback mechanisms access issues that may also arise for individuals receiving services through those delivery systems.

● Section 447.203(b)(8) is revised to clarify that states have a number of options to address access to care issues that are identified through the access monitoring review plans. These remediation efforts can include but are not limited to: modifying payment rates;

improving outreach to providers; reducing barriers to provider enrollment; providing additional transportation to services; improving care coordination; or changing provider licensing or scope of practice polices. This is an acknowledgement that access to care is not determined by payment rates alone but rather that when enough providers are enlisted in the program states may need to find ways to connect beneficiaries with the care and services that they need.

- In §447.204(a), the term “recipients” is changed to “beneficiaries.”

- Section 447.204(a)(1) is revised to incorporate the baseline data review requirement and as part of the information that states consider prior to the submission of a SPA that proposes to reduce or restructure Medicaid service payment rates. The results of the baseline data should inform states on compliance with section 1902(a)(30)(A) of the Act and project the potential impact of rate policies on access to care.

- Section 447.204(a)(2) is revised to indicate that prior to the submission of a SPA that proposes to reduce or restructure Medicaid service payment rates, states must consider input from providers, as well as input from beneficiaries and other affected stakeholders. This change was added based on public comments that requested that feedback from providers be considered in addition to beneficiaries as part of the public process.

- Section 447.204(b) is modified to more clearly state that with any proposed SPA affecting payment rates, states must provide the most recent access monitoring review plan, if any, together with an analysis of the effect of the change in payment rates on access, and a specific analysis of the information and concerns expressed in input from affected stakeholders. With this change, is more clearly delineated that states must furnish the information gathered under the procedures of the final rule with comment to CMS as part of the SPA submission process. We will use this information to inform our SPA approval decisions.

- Section 447.204(c) and (d) were edited to more clearly describe CMS’s enforcement process if a state does not submit the supporting documentation described in the final rule with

comment period along with SPAs. If a state does not submit the supporting documentation, then the SPA would be disapproved. Likewise, if a state submits a SPA and the access analysis does not demonstrate adequate access, the SPA would be disapproved. To address access deficiencies, CMS may also take a compliance action using the procedures described at §430.35 of this chapter which is specified at 447.204(d). These edits were made for clarity and did not alter the agency's proposed approach to enforcing the provisions of the final rule with comment period.

● Section 447.205(iv) was proposed to allow states to issue public notice on Web sites maintained by the single state agency. We revised this section to provide some additional parameters around notice publications, requiring that publication Web site must be easily reached from a hyperlink that provides general information to beneficiaries and providers and the state specific page on the federal Medicaid Web site and that the state ensures compliance with national standards to ensure access to individuals with disabilities (that is, section 508 standards). Further, we clarified that the notice must be issued as part of regular and known provider bulletin updates and maintained on the state's Web site for no less than 3 years. These changes are necessary to ensure that notices are easily accessible to the public (and CMS) and will remain available for a sufficient period of time.

V. 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.

In the May 6, 2011, proposed rule (76 FR 26352 – 26359), we solicited public comments 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 in section C under "Comments Associated with the Collection of Information Requirements."

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	33.69	33.69	67.38
Computer and Information Analyst	15-1120	42.25	42.25	84.50
General and Operations Manager	11-1021	56.35	56.35	112.70
Management Analyst	13-1111	43.68	43.68	87.36
Social Science Research Assistant	19-4061	20.71	20.71	41.42

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Carried Over from the Proposed Rule (May 6, 2011; 76 FR 26352 – 26359)

1. ICRs Regarding Access Monitoring Review Plans (§447.203(b))

Section 447.203(b) requires that states develop and make public an access monitoring review plan that considers, at a minimum: beneficiary needs, the availability of care and providers, utilization of services, characteristics of the beneficiary population, and provider payment rates. States are also required under this provision to monitor data and beneficiary and provider input on an ongoing basis and address known access issues through corrective action.

This final rule with comment period provides states with the discretion to determine appropriate data sources that will be used to conduct the review. We believe most of the data that will be used to inform access is available to states and may already be collected by states as part of Medicaid program reviews and payment rate-setting procedures. We also note that states have flexibility to compare Medicaid rates to one or more of Medicare rates, commercial rates, or Medicaid cost, as may be appropriate to the service under review. The burden associated with these requirements is the time and effort associated with analyzing this information, making it available to the public, and periodically updating the information relative to activities states are already undertaking. We have attempted to mitigate any new burden by identifying data that states are likely to currently possess, identifying other data sources that might be informative to state access reviews, and limiting the categories of services states will be required to review.

a. Access Monitoring Review Plan Timeline

Section 1902(a)(30)(A) of the Act requires states to ensure that Medicaid beneficiaries

have access to care and services that is equivalent to care provided to the general population within a geographic area. Based on public comments received we are revising the requirements of §447.203(b) to limit the scope of Medicaid services that states must review on an ongoing basis. This final rule with comment period stipulates that states must develop an access monitoring review plan for the specified service categories and update the plan every 3 years. States will also be required to develop an access monitoring review plan when a state submits a SPA to reduce or restructure payment rates in circumstances where the changes could result in access issues for the service or services affected by the SPA. In this way, states would consider the impact that such proposals may have on access to care and demonstrate compliance with section 1902(a)(30)(A) of the Act. States may complete this review within the prior 12 months of the SPA submission.

b. Access Monitoring Review Plan Framework

The data analysis activities described in this final rule with comment period are claimable as administrative claiming activities and are reimbursable at the general 50 percent FFP rate for administrative expenditures, insofar as they are necessary for the proper and efficient administration of the Medicaid state plan as described at section 1903(a)(7) of the Act. More specifically, utilization review is identified as an allowable Medicaid administrative activity in guidance that was issued in the form of a SMD letter dated December 20, 1994 (www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD122094.pdf). We also believe that states may be collecting some of this information as part of current review efforts for various purposes, including program administration and oversight, quality activities, integrity and payment, and as part of other performance standards and measures required under the Affordable Care Act.

The provisions at §447.203(b)(1) through (3) require that states develop and make publically available an access monitoring review plan using data trends and factors that

considers: beneficiary needs, availability of care and providers, and changes in beneficiary utilization of covered services. Consistent with the statutory requirement, we have clarified that states demonstrate access to care within specific geographic regions. After careful consideration of the comments received, we are finalizing the review framework with some modifications in an effort to minimize the administrative burden associated with the requirement. Though we recognize that no methodology to gauge access to care is flawless, we believe that the framework, as supported by state data sources, is appropriate to inform whether the Medicaid access requirements are met.

Section 447.203(b)(1) and (2) describes the minimum factors that states must considered when developing an access monitoring review plan. Specifically, we require the review to include feedback from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data, and a description of the specific measures the state will use to analyze access to care. We recommend that states use existing provider feedback mechanism such as medical care advisory committees described in §431.12 to ease burden on states rather than create new requirements.

Section 447.203(b)(3) requires that states include percentage comparisons of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) or private health coverage rates within geographic areas of the state. This requirement was modified based on comments received to allow states maximum flexibility in comparing Medicaid payment rates to the rates of other payers.

Section 447.203(b)(4) describes the minimum content that must be in included in the monitoring plan. States are required to describe: the measures the state uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the state Medicaid agency’s recommendations on the sufficiency of access to care based on the review.

Section 447.203(b)(5) describes the timeframe for states to develop and complete its access monitoring review plan the data review and make the information available to the public through accessible public records or Web sites on an on-going basis for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health services and additional services as determined necessary by the state or CMS. The initial access monitoring review plans are to be completed by July 1 after the effective date of this final rule with comment period. The plan must be updated at least every 3 years, but no later than July 1 of the update year. We estimate that the requirements to develop and make the access monitoring review plans publically available under §447.203(b)(1) through (4) will affect all states. We have defined specific categories of services that states must develop access monitoring review plans for, while allowing states to include additional service categories as necessary. We assume states will conduct reviews in the context of rate reductions or restructuring payment rates and we consider the burden associated with rate reduction or restructuring reviews as part of the ongoing estimated burden.

The one-time burden associated with the requirements under §447.203(b)(1) through (5) is the time and effort it would take, on average, each of the 50 state Medicaid programs and the District of Columbia (51 total respondents) to develop and make publically available an access monitoring review plan for the specific categories of Medicaid services. The uniform nature of the initial menu of services required for the access monitoring review plans are the reason we present average impacts.

We estimate that it will take 5,100 hr to develop the access monitoring review plan, 8,160 hr to collect and analyze the data, and 2,040 to publish the plan and 510 hr for a manager to review and approve the plan (15,810 total hours). We also estimate a cost of $22,631,80 per state and a total of $1,154,221.80.

In deriving these figures we used the following hourly labor rates and time to complete each task: 80 hr at $41.42/hr for a research assistant staff to gather data, 80 hr at $84.50/hr for an information analyst staff to analyze the data, 100 hr at $87.36/hr for management analyst staff to develop the content of the access monitoring review plan, 40 hr at $67.38/hr for business operations specialist staff to publish the access monitoring review plan, and 10 hr at $112.70/hr for managerial staff to review and approve the access monitoring review plan.

TABLE 1: Access Monitoring Review Plan – One-time Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Monitoring Plan ($/State)
Gathering Data	Social Science Research Assistant	80	41.42	3,313.60
Analyzing Data	Computer and Information Analyst	80	84.50	6,760
Developing Content of Access Monitoring Review Plan	Management Analyst	100	87.36	8,736
Publishing Access Monitoring Review Plan	Business Operations Specialist	40	67.38	2,695.20
Reviewing and Approving Access Monitoring Review Plan	General and Operations Manager	10	112.70	1,127.00
Total Burden Per State…	……	310	…	22,631.80

TABLE 2: Access Monitoring Review Plan—One-Time Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
51	15,810	22,631.80	1,154,221.80

The ongoing burden associated with the requirements under §447.203(b)(1) through (5) is the time and effort it would take each of the 50 state Medicaid programs and the District of Columbia (51 total respondents) to develop and make publically available an access monitoring review plan for the specific categories of Medicaid services. The access monitoring review plans must be updated at least every 3 years.

We anticipate that the average initial and ongoing burden is likely to be the same since

states will need to re-run the data, determine whether to add or drop measures, consider public feedback, and write-up new conclusions based on the information they review. In this regard, we estimate it will take 5,100 hr to develop the access monitoring review plan, 8,160 hr to collect and analyze the data, and 2,040 to publish the plan, and 510 hr for a manager to review and approve the plan (15,810 total hours). We also estimate a cost of $22,631,80 per state and a total of $1,154,221.80.

In deriving these figures we used the following hourly labor rates and time to complete each task: 80 hr at $41.42/hr for a research assistant staff to gather data, 80 hr at $84.50/hr for an information analyst staff to analyze the data, 100 hr at $87.36/hr for management analyst staff to update the content of the access monitoring review plan, 40 hr at $67.38/hr for business operations specialist staff to publish the access monitoring review plan, and 10 hr at $112.70/hr for managerial staff to review and approve the access monitoring review plan.

TABLE 3: Access Monitoring Review Plan–Ongoing Burden Per State (annual)

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Monitoring Plan ($/State)
Gathering Data	Social Science Research Assistant	80	41.42	3,313.60
Analyzing Data	Computer and Information Analyst	80	84.50	6,760
Updating Content of Access Monitoring Review Plan	Management Analyst	100	87.36	8,736
Publishing Access Monitoring Review Plan	Business Operations Specialist	40	67.38	2,695.20
Reviewing and Approving Access Monitoring Review Plan	General and Operations Manager	10	112.70	1,127.00
Total Burden Per State…	……	310	…	22,631.80

TABLE 4: Access Monitoring Review Plan—Ongoing Total Burden (annual)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
51	15,810	22,631.80	1,154,221.80

The requirements and burden will be submitted to OMB under control number 0938-1134

(CMS-10391). Annualized over the three-year reporting period, we estimate 17 responses, 5,270 hr, $7,543.93 (per state), and $384,740.60 (aggregate).

2. ICRs Regarding Monitoring Procedures (§447.203(b)(6)(ii))

Section 447.203(b)(6)(ii) requires states to have procedures within the access monitoring review plan to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures must be in place for at least 3 years following the effective date of a SPA that reduces or restructures payment rates.

The ongoing burden associated with the requirements under §447.203(b)(6)(ii) is the time and effort it would take each of the 50 state Medicaid programs and the District of Columbia to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. The requirements will affect all states that implement a rate reduction or restructure payment rates. We estimate that in each SPA submission cycle, 22 states will implement these rate changes based on the number of states that proposed such reductions in FY 2010. Please note that we are using FY 2010 as the basis for our estimate because of the unusual high volume of rate reduction SPAs that states submitted during this period. By basing our estimate on FY 2010 data, we anticipate the highest potential for burden associated with this final rule with comment period.

We estimate that it will take, on average, 880 hr to develop the monitoring procedures, 528 hr to periodically review the monitoring results, and 66 hr for review and approval of the monitoring procedures (1,474 total hours). We also estimate an average cost of $5,929.14 per state and a total of $130,441.08.

In deriving these figures we used the following hourly labor rates and time to complete each task: 40 hr at $87.36/hr for management analyst staff to develop the monitoring procedures,

24 hr at $87.36/hr for management analyst staff to periodically review the monitoring results, and 3 hr at $112.70/hr for management staff to review and approve the monitoring procedures.

TABLE 5: Access Monitoring Procedures Following Rate Reduction SPA--Burden Per State (annual)

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Data Review ($/State)
Develop Monitoring Procedures	Management Analyst	40	87.36	3,494.40
Periodically Review Monitoring Results	Management Analyst	24	87.36	2,096.64
Approve Monitoring Procedures	General and Operations Manager	3	112.70	338.10
Total Burden Per State…	……	67	…..	5,929.14

TABLE 6: Access Monitoring Procedures Following Rate Reduction SPA--Total Burden (annual)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
22	1,474	5,929.14	130,441.08

The requirements and burden will be submitted to OMB under control number 0938-1134 (CMS-10391).

3. ICRs Regarding Ongoing Input (§447.203(b)(7))

Section 447.203(b)(7) requires that states have a mechanism for obtaining ongoing beneficiary, provider and stakeholder input on access to care issues, such as hotlines, surveys, ombudsman, or other equivalent mechanisms. States must promptly respond to public input with an appropriate investigation, analysis, and response. They must also maintain records of the beneficiary input and the nature of the state response.

We estimate that the requirement will affect all states that do not currently have a means of beneficiary feedback. Since we currently do not know which states have implemented these mechanisms, we are assuming in our estimate that all states will need to develop new mechanisms. The one-time burden associated with the requirements under §447.203(b)(7) is the time and effort it would take, on average, for each of the 50 state Medicaid programs and the District of Columbia (51 total respondents) to develop and implement beneficiary feedback

mechanisms.

We estimate that it will take an average 5,100 hr to develop the feedback effort and 255 hr to approve the feedback effort (5,355 total hours). We also estimate an average cost of $9,299.50 per state and a total of $474,274.50.

In deriving these figures we used the following hourly labor rates and time to complete each task: 100 hr at $87.36/hr for management analyst staff to develop the feedback effort and 5 hr at $112.70/hr for managerial staff to review and approve the feedback effort.

TABLE 7: Beneficiary Feedback Mechanism--—One-time Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Data Review ($/State)
Developing Feedback Effort	Management Analyst	100	87.36	8,736
Approve Feedback Effort	General and Operations Manager	5	112.70	563.50
Total Burden Per State…	……	105	…..	9,299.50

TABLE 8: Beneficiary Feedback Mechanism—One-time Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
51	5,355	9,299.50	474,274.50

The ongoing burden associated with the requirements under §447.203(b)(7) is the time and effort it would take each of the 50 state Medicaid programs and the District of Columbia (51 total respondents) to monitor beneficiary feedback mechanisms.

The overall effort associated with monitoring the feedback will primarily be incurred by analysts who will gather, review and make recommendations for and conduct follow-up on the feedback. We do not estimate that the approval of the recommendations will not require as significant effort from managers. We estimate that it will take an average of 3,825 hr to monitor the feedback results, and 255 hr to approve the feedback effort (4,080 total hours). We also estimate an average cost of $7,115.50 per state and a total of $362,890.50.

In deriving these figures we used the following hourly labor rates and time to complete each task: 75 hr at $87.36/hr for management analyst staff to monitor feedback results and 5 hr at

$112.70/hr for managerial staff to review and approve the feedback effort.

TABLE 9: Beneficiary Feedback Mechanism—Ongoing Burden Per State (annual)

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Data Review ($/State)
Monitoring Feedback Results	Management Analyst	75	87.36	6,552.00
Oversee Feedback Effort	General and Operations Manager	5	112.70	563.50
Total Burden Per State…	……	80	…..	7,115.50

TABLE 10: Beneficiary Feedback Mechanism—Ongoing Total Burden (annual)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
51	4,080	7,115.50	362,890.50

The requirements and burden will be submitted to OMB under control number 0938-1134 (CMS-10391).

4. ICRs Regarding Corrective Action Plan (§447.203(b)(8))

Section 447.203(b)(8) institutes a corrective action procedure that requires states to submit to CMS a corrective action plan should access issues be discovered through the access monitoring processes. The requirement is intended to ensure that states will oversee and address any future access concerns.

This is a new requirement and thus we have no past data to use to determine how many states will identify access issues as they conduct their data reviews and monitoring activities. We assume that many states currently have mechanisms in place to monitor access to care and identify issues. While we are careful not to under-estimate the burden associated with this provision, we believe that a maximum of 10 states may identify access issues per year. The on-time burden associated with the requirements under §447.203(b)(7) is the time and effort it would take 10 state Medicaid programs to develop and implement corrective action plans.

We estimate that it will take an average of 200 hr to identify issues requiring corrective action, 400 hr to develop the corrective action plans, and 30 hr to review and approve the corrective action plans (630 total hours). We also estimate an average cost of $5,579.70 per state

and a total of $55,797.00.

In deriving these figures we used the following hourly labor rates and time to complete each task: 20 hr at $87.36/hr for management analyst staff to identify issues requiring corrective action, 40 hr at $87.36/hr for management analyst staff to develop the corrective action plans, and 3 hr at $112.70/hr for managerial staff to review and approve the corrective action plans.

TABLE 11: Corrective Action Plan--Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per Data Review ($/State)
Identifying Issues for Action	Management Analyst	20	87.36	1,747.20
Developing the Corrective Plan	Management Analyst	40	87.36	3,494.40
Approve Corrective Plan	General and Operations Manager	3	112.70	338.10
Total Burden Per State…	……	63	…..	5,579.70

TABLE 12: Corrective Action Plan--Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
10	630	5,579.70	55,797.00

The requirements and burden will be submitted to OMB under control number 0938-1134 (CMS-10391).

5. ICRs Regarding Public Process to Engage Stakeholders (§447.204)

Sections 447.204(a)(1) and (a)(2) require that states consider (when proposing to reduce or restructure Medicaid payment rates) the data collected through §447.203 and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid service payment rates on beneficiary access to care. In §447.204(b), we have also clarified that we may disapprove a proposed rate reduction or restructuring if the SPA does not include or consider the data review and a public process. As an alternative, or additionally, we may take a compliance action in accordance with §430.35.

We are estimating, annually, that for each SPA revision approximately 22 states will develop and implement these rate changes that would require a public process based on the

number of states that proposed such reductions in FY 2010. Again, we are using FY 2010 as the estimate due to the high number of rate reduction proposals submitted by states in that year.

We estimate that it will take an average of 440 hr to develop the public process and 66 hr for review and approval of the public process (506 total hours). We also estimate an average cost of $2,085.30 per state and a total of $45,876.60.

In deriving these figures we used the following hourly labor rates and time to complete each task: 20 hr at $87.36/hr for management analyst staff to develop the public process and 3 hr at $112.70/hr for managerial staff to review and approve the public process.

TABLE 13: Public Process—One-Time Burden Per State Per SPA

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per SPA ($)
Develop the Public Process	Management Analyst	20	87.36	1,747.20
Approve Public Process	General and Operations Manager	3	112.70	338.10
Total Burden Per State…	……	23	…..	2,085.30

TABLE 14: Public Process—One-Time Total Burden

Anticipated number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
22	506	2,085.30	45,876.60

The ongoing burden associated with the requirements under §447.204 is the time and effort it would take 22 state Medicaid programs to oversee a public process.

The overall effort associated with developing the public process will primarily be incurred by analysts who develop and initiate public process activities. We do not estimate that efforts associated with review and approval of the activities will increase for overseeing managers. We estimate it will take an average of 880 hr to oversee the public process and 66 hr for review and approval of the public process (946 total hours). We also estimate an average cost of $3,832.50 per state and a total of $84,315.00

In deriving these figures we used the following hourly labor rates and time to complete

each task: 40 hr at $87.36/hr for management analyst staff to oversee the public process and 3 hr at $112.70/hr for managerial staff to review and approve the public process.

TABLE 15: Public Process—Ongoing Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage ($/hr)	Cost Per SPA ($)
Oversee the Public Process	Management Analyst	40	87.36	3,494.40
Approve Public Process	General and Operations Manager	3	112.70	338.10
Total Burden Per State…	……	43	…..	3,832.50

TABLE 16: Public Process—Ongoing Total Burden (annual)

Anticipated number of State Reviews	Total Hours	Cost of Review per State ($)	Total Cost Estimate ($)
22	946	3,832.50	84,315.00

The requirements and burden will be submitted to OMB under control number 0938-1134 (CMS-10391).

6. ICRs Regarding Public Notice of Changes in Statewide Methods and Standards for Setting Payment Rates (§447.205)

The provisions at §447.205 clarify when states must issue public notice to providers and allow for the electronic publication of those notices. Section 447.205(d)(2)(iv)(A) through (D) allow those notices to be published on the single state Medicaid agency or other state-developed and maintained Web site that is accessible to the general public via the Internet. The burden associated with developing and issuing public notice at §447.205 is not affected by this requirement since the revision would simply address an additional (in this case, electronic) means of notification. Consequently, we do not include the electronic notice activity in our burden analysis.

C. Comments Associated with the Collection of Information Requirements

Comment: Several commenters noted that it could take a state up to 6 months and

consume many resources to conduct ongoing access reviews (in conjunction with a SPA) and have the documentation, including rate reduction SPA documents ready to submit to CMS. These commenters were concerned that the efforts would create a significant backlog of SPAs.

Response: As previously discussed, we have considered concerns related to the proposed burden and have modified the ongoing regulatory requirements to reduce the burden. We also note that the challenges presented by initial access reviews, including time constraints, were considered in the finalizing this rule. Though initial access reviews, either triggered by the routine, rotating review process, or by submission of a SPA, will require a significant time investment, subsequent reviews are expected to be more manageable, due to pre-established metrics and review mechanisms. We have conducted a regulatory impact analysis as part of this final rule with comment period. We do not believe that there is potential for this regulation to surpass the threshold for economic significance.

D. Summary of Annual Burden Estimates

TABLE 17: Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($/hr)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
447.203(b)(1) – (4) (one-time requirement)	0938-1134	51	17	80	1,360	41.42	56,331.20	0	56,331.20
				80	1,360	84.50	114,920.00	0	114,920.00
				100	1,700	87.36	148,512.00	0	148,512.00
				40	680	67.38	45,818.40	0	45,818.40
				10	170	112.70	19,159.00	0	19,159.00
Subtotal		*51*	*17*	*310*	*5,270*	--	*384,740.60*	*0*	*384,740.60*
447.203(b)(1) – (4) (on-going requirement)	0938-1134	51	51	80	4,080	41.42	168,993.60	0	168,993.60
				80	4,080	84.50	344,760.00	0	344,760.00
				100	5,100	87.36	445,536.00	0	445,536.00
				40	2,040	67.38	137,455.20	0	137,455.20
				10	510	112.70	54,477.00	0	54,477.00
Subtotal		*51*	*51*	*310*	*15,810*	_	*1,154,221.80*	*0*	1,154,221.80
447.203(b)(6) (ii)	0938-1134	22	22	64	1,408	87.36	123,002.88	0	123,002.88
				3	66	112.70	7,438.20	0	7,438.20
Subtotal		*22*	*22*	*67*	*1,474*	_	*130,441.08*	*0*	*130,441.08*
447.203(b)(7) (one-	0938-1134	51	17	100	1,700	87.36	*148,512.00*	0	
				5	85	112.70	*9,579.50*	0	

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($/hr)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
time requiremen t)									
Subtotal		*51*	*17*	*105*	*1,785*	_	*158,091.50*	*0*	*158,091.50*
447.203(b)(7) (on-going requirement)	0938-1134	51	51	75	3,825	87.36	334,152.00	0	334,152.00
				5	255	112.70	28,738.50	0	28,738.50
Subtotal		*51*	*51*	*80*	*4,080*	_	*362,890.50*	*0*	*362,890.50*
447.203(b)(8) (one-time requirement)	0938-1134	10	3.3	60	198	87.36	17,297.28	0	17,297.28
				3	9.9	112.70	1,115.73	0	1,115.73
Subtotal		*10*	*3.3*	*63*	*207.9*	_	*18,413.01*	*0*	*18,413.01*
447.204(a)(1) and (2) (one-time requiremen t)	0938-1134	22	7.3	20	146	87.36	12,754.56	0	12,754.56
				3	21.9	112.70	2,468.13	0	2,468.13
Subtotal		*22*	*7.3*	*23*	*167.9*	--	*15,222.69*		*15,222.69*
447.204(a)(1) and (2) (on-going requirement)	0938-1134	22	22	40	880	87.36	76,876.80	0	76,876.80
				3	66	112.70	7,438.20	0	7,438.20
Subtotal		*22*	*22*	*43*	*946*	_	*84,315.00*	*0*	*84,315.00*
SUB-TOTAL (One Time Requirements)		--	44.6	568	8,905	--	706,908.88	0	706,908.88
SUB-TOTAL (On-Going Requirements)		--	146	433	20,836	--	1,601,427.30	0	1,601,427.30
TOTAL		**--**	**381.2**	**896**	**27,956**	**--**	**2,150,244.68**	**0**	**2,150,244.68**

E. Submission of PRA-Related Comments

We submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. The 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 collections discussed above, please visit CMS' Web site at 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 wish to comment, please identify the rule (CMS-2328-FC) and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: 202-395-5806 OR

E-mail: OIRA_submission@omb.eop.gov.

ICR-related comments are due [INSERT DATE 30-DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

VI. Response to Comments

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

VII. Regulatory Impact Statement

A. Statement of Need

This final rule with comment period revises regulatory provisions in §447.203 and §447.204 to create a standardized, transparent process for states to follow as part of their broader efforts to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area, as required by section 1902(a)(30)(A) of the Act. This rule also clarifies and amends §447.205, which require states to issue public notice to their providers when changing Medicaid payment methods and standards. The changes to the public notice requirement will alleviate confusion on when states must issue notice to providers and recognize electronic media as a means to issue the notices.

B. Overall Impact

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

Executive Order 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We do not believe that there is potential for this provision to surpass the threshold for economic significance because the proposed data analysis effort is generally consistent with current state oversight and review activities and states have flexibility within the reviews to use their existing data or build upon that data when reviewing access to care.

In fact, the guidance provided under this rule intends to focus disparate state efforts in monitoring and overseeing data and beneficiary concerns, which offers a clear framework to comply with section 1902(a)(30)(A) of the Act. In the absence of federal guidance, states have likely misspent resources in efforts to interpret and comply with section 1902(a)(30)(A) of the Act. We will also make every effort, in collaboration with state and federal partners, to identify resources and tools that states may use to review and monitor access to care within their state Medicaid programs. In this final rule with comment period, we are soliciting public comments to begin identifying data sources and will continue to provide assistance as states develop their reviews and monitoring procedures.

Based on our analysis above, we estimate that even if these data collection efforts were totally new to a state and each state were to either bid a contract to gather and publish the data collection effort and public process required under this rule or conduct the collection and public process with state agency resources, the economic effects would not surpass $100 million or more in any 1 year.

Further, we are not requiring states to directly adjust payment rates as a result of the provisions of this final rule with comment period, nor to take any steps that would not be consistent with efficiency, economy, and quality of care. Rather, these rules propose to clarify that beneficiary access must be considered in setting and adjusting payment methodology for Medicaid services. If a problem is identified, any number of steps might be appropriate, such as redesigning service delivery strategies, or improving provider enrollment and retention efforts. It has historically been within our regulatory authority to make SPA approval decisions based on sufficiency of beneficiary service access and this rule merely provides a more consistent and transparent way to gather and analyze the necessary information to support such reviews.

The RFA requires agencies to analyze options for regulatory relief for 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 organizations, and small government jurisdictions. For details, see the Small Business Administration's Web site at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we and the Secretary have determined that this final rule with comment period will not have a significant economic 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 604 of the RFA. For purposes

of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we and the Secretary have determined that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This final rule with comment period will not impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $144 million in any one year.

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. Since the estimated total cost associated with the provisions in this final rule with comment period is around $2.3 million annually, it will not impose significant costs on state or local governments, the requirements of E.O. 13132 are not applicable. We also note that the costs associated with this final rule with comment are allocated across 51 state governments. To the extent that costs are for the proper and efficient administration of the Medicaid state plan, many of the activities required under this final rule are likely available at the Medicaid matching rate for administrative expenditures.

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

C. Regulatory Alternatives Considered

This section provides an overview of regulatory alternatives that CMS considered for this

final rule with comment period. In determining the appropriate approach to guide states in their efforts to meet the requirements of section 1902(a)(30)(A) of the Act and demonstrate sufficient access to Medicaid services, we consulted with SMDs, federal agency policy officials and the MACPAC. Based, in part, on these discussions we arrived at the provisions discussed in this rule, which seek to balance state obligations to meet the statutory requirement of section 1902(a)(30)(A) of the Act and potential new burden associated with the proposal. To achieve this balance, we have set forth a process that provides a framework for states to demonstrate access to Medicaid services using available data resources and in consideration of unique and evolving health care delivery systems. We have also emphasized the importance of considering beneficiary input in determining and monitoring access to Medicaid services throughout the process as discussed in this final rule with comment period.

1. Access Monitoring Review Plan

The process for documenting access to care and service payment rates described at §447.203 will require states to develop and make publically available access monitoring review plans that address the extent to which beneficiary needs are met, the availability of care and providers, and changes in beneficiary utilization of covered services and other factors. The access monitoring review plan would also include percentage comparisons of Medicaid payment rates to other public or private health coverage rates within geographic areas of the state. The access monitoring review plans are to be developed for a subset of Medicaid service categories and updated at least every 3 years or, in the context of a SPA proposal to reduce provider rates or restructure provider rates in circumstance that may negatively impact access to care, within 12 months of implementing the SPA.

As an alternative to the proposed framework for reviewing access to care, we considered requiring states to report standard data measures to demonstrate sufficient access to care and section 1902(a)(30)(A) of the Act. We also considered setting national access thresholds or

requiring states to establish and demonstrate access thresholds. As we have highlighted throughout this final rule with comment period, there are no standardized, transparent methodologies for demonstrating access to care that would be appropriate to adopt at this time.

Rather than prescribe data measures that may not align with all services or set threshold standards, we have adopted a general framework, which sets forth a three-part review that applies across services and delivery systems and will allow states the flexibility to determine, through current or new data sources, appropriate measures of access to care. As states analyze their existing data sources and those that we identify through work with MACPAC and our federal partners, we believe that states may arrive at best practices for determining sufficient Medicaid access to care which could be replicated across state delivery systems and will evolve with new approaches to delivering health care to Medicaid beneficiaries. In addition, we are issuing an RFI to solicit feedback from stakeholders on whether data exists to develop core access measures and thresholds would provide additional information or approaches that would be useful to us and states in ensuring access to care to Medicaid beneficiaries.

2. Access Review Timeframe and Monitoring Procedures

States will be required to develop access monitoring review plans for the following service categories: primary care; physician specialist services; behavioral health; pre- and post-natal obstetric services, including labor and delivery; home health services and other service categories as determined necessary based on beneficiary, provider or stakeholder complaints; the access monitoring review plans must be reviewed and updated at least every 3 years. States must also submit an access review, completed within the 12 months prior, with any SPA that proposes to reduce or restructure provider payments for each of the impacted services. We have arrived at this subset of service categories because they are frequently used services in Medicaid and they are considered gateway services, meaning if a beneficiary has access to these services, it is likely that the majority of the beneficiary’s needs are being met.

We considered requiring the review for all services on an annual basis or a review period that is more frequent than 5 years. After careful consideration of the burden associated with annual reviews, which were a foremost concern for some commenters, we determined 3 year ongoing reviews as an appropriate frequency period. The final rule with comment period provides for more frequent reviews for fewer high demand services and requires additional review and monitoring over three years for services subject to rate reductions or restructuring of payments or when the Medicaid agency receives a significantly higher than usual level of complaints about access to care from beneficiaries, providers, or other stakeholders. In this way, the final rule with comment period ensures that access to care reviews for most services will be conducted as potential issues arise or circumstances change. We believe that, absent rate reductions or restructuring of payments, the 3-year review and monitoring periods combined with ongoing solicitation of information about access from beneficiaries are sufficient to identify access issues that may occur over time.

This final rule with comment period will require states to develop monitoring procedures after implementing provider rate reductions or restructuring rates in ways that may negatively impact access to care. We require these monitoring procedures because the impact of rate changes on access to care may not be apparent at the time the changes are adopted. We considered not requiring states to monitor access after implementing the changes and to continue to rely on the 5-year reviews to ensure that access is maintained. However, we believe that it is important for states to identify and address access issues that arise from specific SPA actions, such as reimbursement rate reductions or restructuring.

3. Beneficiary Input on Access to Care

The requirements of §447.203 and §447.204 emphasize the importance of involving beneficiaries in determining access issues and the impact that state rate changes will have on access to care. Specifically, we require that states implement an ongoing mechanism for

beneficiary input on access to care (through hotlines, surveys, ombudsman, or another equivalent mechanism) and receive input from beneficiaries (and affected stakeholders) on the impact that proposed rates changes will have through a public process. We believe that beneficiaries' experiences in accessing Medicaid services is the most important indicator of whether access is sufficient and beneficiary input will be particularly informative in identifying access issues.

We also considered a requirement that states consult with beneficiaries when developing their corrective action plans in instances when the access data reviews or monitoring procedures identify access issues. While we encourage states to solicit beneficiary input on corrective action plans, we did not make this a specific regulatory requirement and we leave it to the states' discretion to develop the corrective action plans as part of their current policy development methods.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and 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 447—PAYMENTS FOR SERVICES

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

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

2. Section 447.203 is amended by revising the section heading and paragraph (b) to read as follows:

§447.203 Documentation of access to care and service payment rates.

* * * * *

(b) In consultation with the medical care advisory committee under §431.12 of this chapter, the agency must develop a medical assistance access monitoring review plan and update it, in accordance with the timeline established in paragraph (b)(5) of this section. The plan must be published and made available to the public for review and comment for a period of no less than 30 days, prior to being finalized and submitted to CMS for review.

(1) Access monitoring review plan data requirements. The access monitoring review plan must include an access monitoring analysis that includes: data sources, methodologies, baselines, assumptions, trends and factors, and thresholds that analyze and inform determinations of the sufficiency of access to care which may vary by geographic location within the state and will be used to inform state policies affecting access to Medicaid services such as provider payment rates, as well as the items specified in this section. The access monitoring review plan must specify data elements that will support the state's analysis of whether beneficiaries have sufficient access to care. The plan and monitoring analysis will consider:

(i) The extent to which beneficiary needs are fully met;

(ii) The availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service;

(iii) Changes in beneficiary utilization of covered services in each geographic area.

(iv) The characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and

(v) Actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.

(2) Access monitoring review plan beneficiary and provider input. The access monitoring review plan must include an analysis of data and the state's conclusion of the sufficiency of access to care that will consider relevant provider and beneficiary information, including information obtained through public rate-setting processes, the medical care advisory committees established under §431.12 of this chapter, the processes described in paragraph (b)(7) of this section, and other mechanisms (such as letters from providers and beneficiaries to State or Federal officials), which describe access to care concerns or suggestions for improvement in access to care.

(3) Access monitoring review plan comparative payment rate review. For each of the services reviewed, by the provider types and sites of service (e.g. primary care physicians in office settings) described within the access monitoring analysis, the access monitoring review plan must include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) and private health insurer payment rates within geographic areas of the state.

(4) Access monitoring review plan standards and methodologies. The access monitoring review plan and analysis must, at a minimum, include: the specific measures that the state uses to analyze access to care (such as, but not limited to: time and distance standards, providers participating in the Medicaid program, providers with open panels, providers accepting new Medicaid beneficiaries, service utilization patterns, identified beneficiary needs, data on

beneficiary and provider feedback and suggestions for improvement, the availability of telemedicine and telehealth, and other similar measures), how the measures relate to the access monitoring review plan described in paragraph (b)(1) of this section, baseline and updated data associated with the measures, any issues with access that are discovered as a result of the review, and the state agency's recommendations on the sufficiency of access to care based on the review. In addition, the access monitoring review plan must include procedures to periodically monitor access for at least 3 years after the implementation of a provider rate reduction or restructuring, as discussed in paragraph (b)(6)(ii) of this section.

(5) Access monitoring review plan timeframe. Beginning July 1, 2016 the State agency must:

(i) Develop its access monitoring review plan by July 1 of the first review year, and update this plan by July 1 of each subsequent review period;

(ii) For all of the following, complete an analysis of the data collected using the methodology specified in the access monitoring review plan in paragraphs (b)(1) through (4) of this section, with a separate analysis for each provider type and site of service furnishing the type of service at least once every 3 years:

(A) Primary care services (including those provided by a physician, FQHC, clinic, or dental care).

(B) Physician specialist services (for example, cardiology, urology, radiology).

(C) Behavioral health services (including mental health and substance use disorder).

(D) Pre- and post-natal obstetric services including labor and delivery.

(E) Home health services.

(F) Any additional types of services for which a review is required under paragraph (b)(6) of this section;

(G) Additional types of services for which the state or CMS has received a significantly higher than usual volume of beneficiary, provider or other stakeholder access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with paragraph (b)(7) of this section; and

(H) Additional types of services selected by the state.

(6) Special provisions for proposed provider rate reductions or restructuring—(i) Compliance with access requirements. The State shall submit with any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, an access review, in accordance with the access monitoring review plan, for each service affected by the State plan amendments as described under paragraph (b)(1) of this section completed within the prior 12 months. That access review must demonstrate sufficient access for any service for which the state agency proposes to reduce payment rates or restructure provider payments to demonstrate compliance with the access requirements at section 1902(a)(30)(A) of the Act.

(ii) Monitoring procedures. In addition to the analysis conducted through paragraphs (b)(1) through (4) of this section that demonstrates access to care is sufficient as of the effective date of the State plan amendment, a state must establish procedures in its access monitoring review plan to monitor continued access to care after implementation of state plan service rate reduction or payment restructuring. The frequency of monitoring should be informed by the public review described in paragraph (b) of this section and should be conducted no less frequently than annually.

(A) The procedures must provide for a periodic review of state determined and clearly defined measures, baseline data, and thresholds that will serve to demonstrate continued sustained service access, consistent with efficiency, economy, and quality of care.

(B) The monitoring procedures must be in place for a period of at least 3 years after the effective date of the state plan amendment that authorizes the payment reductions or restructuring.

(7) Mechanisms for ongoing beneficiary and provider input. (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanisms), consistent with the access requirements and public process described in §447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the state responded to this input. This record will be made available to CMS upon request.

(8) Addressing access questions and remediation of inadequate access to care. When access deficiencies are identified, the state must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The state's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, proving additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

3. Section 447.204 is revised to read as follows:

§447.204 Medicaid provider participation and public process to inform access to care.

(a) The agency's payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that services under the plan are available to

beneficiaries at least to the extent that those services are available to the general population. In reviewing payment sufficiency, states are required to consider, prior to the submission of any state plan amendment that proposes to reduce or restructure Medicaid service payment rates:

(1) The data collected, and the analysis performed, under §447.203.

(2) Input from beneficiaries, providers and other affected stakeholders on beneficiary access to the affected services and the impact that the proposed rate change will have, if any, on continued service access. The state should maintain a record of the public input and how it responded to such input.

(b) The state must submit to CMS with any such proposed state plan amendment affecting payment rates:

(1) Its most recent access monitoring review plan performed under §447.203(b)(6) for the services at issue;

(2) An analysis of the effect of the change in payment rates on access; and

(3) A specific analysis of the information and concerns expressed in input from affected stakeholders.

(c) CMS may disapprove a proposed state plan amendment affecting payment rates if the state does not include in its submission the supporting documentation described in paragraph (b) of this section, for failure to document compliance with statutory access requirements. Any such disapproval would follow the procedures described at part 430 Subpart B of this title.

(d) To remedy an access deficiency, CMS may take a compliance action using the procedures described at §430.35 of this chapter.

4. Section 447.205 is amended by adding paragraph (d)(2)(iv) to read as follows:

§447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

* * * * *

(d) * * *

(2) * * *

(iv) A Web site developed and maintained by the single State agency or other responsible State agency that is accessible to the general public, provided that the Web site:

(A) Is clearly titled and can be easily reached from a hyperlink included on Web sites that provide general information to beneficiaries and providers, and included on the State-specific page on the Federal Medicaid Web site.

(B) Is updated for bulletins on a regular and known basis (for example, the first day of each month), and the public notice is issued as part of the regular update;

(C) Includes the actual date it was released to the public on the Web site; or

(D) Complies with national standards to ensure access to individuals with disabilities; and

(E) Includes protections to ensure that the content of the issued notice is not modified after the initial publication and is maintained on the Web site for no less than a 3-year period.

Dated: September 17, 2015.

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 22. 2015.

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Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2015-27697 Filed: 10/29/2015 11:15 am; Publication Date: 11/2/2015]