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Medicare Program; Methods for Assuring Access to Covered Medicaid Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS 2328-P]

RIN 0938-AQ54

Medicaid Program; Methods for Assuring Access to Covered Medicaid Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would 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 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). This proposed rule would also recognize, as States have requested, electronic publication as an optional means of communicating State plan amendments (SPAs) proposed rate-setting policy changes to the public.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. July 5, 2011.

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

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

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

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2328-P, P.O. Box 8016, Baltimore, MD 21244-8016. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human

Services, Attention: CMS-2328-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: 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://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as

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

I. Background

A. General Information

Title XIX of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to provide grants to States to help finance programs furnishing medical assistance (State Medicaid programs) to specified groups of eligible individuals in accordance with an approved State plan. “Medical Assistance” is defined at section 1905(a) of the Act as payment for part or all of the cost of a list of specified care and services, or the care and services themselves, or both.

Federal law provides a broad framework for State Medicaid programs, within which States have considerable flexibility. Details concerning the scope of covered services, the groups of eligible individuals, the payment methodologies for covered services, and all other information necessary to assure that the plan can be a basis for Federal Medicaid funding must be set forth in the approved Medicaid State plan. To be approved by the Department of Health and Human Services, the Medicaid State plan must comply with requirements set forth in section 1902(a) of the Act, as implemented and interpreted in applicable regulations and guidance issued by CMS. The Secretary has delegated overall authority for the Federal Medicaid program, including State plan approval, to CMS.

Medicaid services are jointly funded by the Federal and State governments in accordance with section 1903(a) of the Act. Section 1903(a)(1) of the Act provides for payments to States of a percentage of expenditures under the approved State plan for covered medical assistance. For general medical assistance, the “Federal medical assistance percentage” (FMAP) varies among the States based on a formula set forth in section 1905(b) of the Act that takes into consideration State specific information under a formula set forth in section 1905(b) of the Act. Beginning in 2014, the Federal Government will assume all or a higher share of costs for certain beneficiaries made eligible under the Patient Protection and Affordable Care Act of 2010, (Pub. L.

111–148, enacted March 23, 2010) (the Affordable Care Act).

The Medicaid statute requires that States provide coverage to certain groups of individuals, and also requires that such coverage include certain minimum benefits. In addition, States may elect to cover other populations and benefits. In order 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, as required by section 1902(a)(30)(A) of the Act. 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, and Medicaid service payment rates to providers.

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 fee-for-service 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 delivery systems 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.

As State delivery system models have evolved, so too have their provider payment systems. Many 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 supplemental or incentive payments that encourage providers to serve Medicaid populations. For instance, some States have authorized Medicaid providers to receive supplemental payments for care coordination and care management, or for achieving certain specified quality measures.

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 and 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 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 care in an effective and efficient manner consistent with quality of care, States are empowered to seek the best value through their rate-setting policies and may tailor their access strategies to take into account local conditions including geographic disparities in the availability of providers and demand for particular services. 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' ability to pursue that goal, or their ability to explore innovative approaches to providing services and lowering costs for other reasons. Indeed, the Secretary and CMS, including through the new Center for Medicare and Medicaid Innovation, is actively engaged in helping States achieve better value and better care while lowering per-person costs.

B. Discussion

Medicaid payment rate changes are a function of the State budget process in many States. We recognize that payment reductions or other adjustments to payment rates are legitimate tools to manage Medicaid program costs and achieve overall budget objectives. However, payment rate changes made

without consideration of the potential impact on access to care for Medicaid beneficiaries or without effective processes for assuring that the impact on access will be monitored, may lead to access problems. Payment rate changes are not in compliance with the Medicaid access requirements if they result in a denial of sufficient access to covered care and services.

Budget-driven payment changes have led to confusion 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 access provisions of section 1902(a)(30)(A) of the Act. Resulting court decisions have not offered consistent approaches to compliance with the access requirement. These decisions have left States without clear and consistent guidelines and have subjected them to considerable uncertainty as they move forward in designing service delivery systems and payment methodologies.

For instance, the United States Court of Appeals for the Ninth Circuit Court, in *Orthopedic Hospital v. Belshe*, 102 F.3d 1481, 1496 (1997), cert. denied, 522 U.S. 1044 (1998) required the State agency to set provider payment rates that "bear a reasonable relationship" to provider costs, based on "responsible cost studies." This ruling was reaffirmed by the Ninth Circuit in *Independent Living v. Maxwell-Jolly*, 572 F.3d 644 (2009). In contrast, the United States Court of Appeals for the Seventh Circuit, in *The Methodist Hospitals, Inc. v. Sullivan*, 91 F.3d 1026, 1030 (1996) did not find any requirement for prior cost studies or other procedural requirements. While other Federal Courts of Appeals have also addressed the issue, there is no consensus among the circuits.

Significantly, in 2009, the Congress created the Medicaid and CHIP Payment and Access Commission (MACPAC) (Pub. L. 111–3, section 506) specifically to study and make recommendations on beneficiary access to care in Medicaid and the Children's Health Insurance Program (CHIP). With members appointed by the non-partisan U.S. Comptroller General, MACPAC reviewed 30 years of research and consulted extensively with key stakeholders to develop a recommendation on how to measure access to care for Medicaid beneficiaries. This recommendation was in MACPAC's first report to the Congress, published on March 15, 2011.

The MACPAC report sets out the three-part framework for analyzing access to care which, as we discuss below in this section of the proposed rule, we propose to adopt as part of a State-level review strategy. The MACPAC-recommended framework considers: (1) Enrollee needs; (2) the availability of care and providers; and (3) utilization of services.

In this proposed rule, we recognize that States must have some flexibility in designing the appropriate measures to demonstrate and monitor access to care, which reflects unique and evolving State service delivery models and service rate structures. At this point, a singular approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act could prove to be ineffective given current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles. For these reasons, we are proposing 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. We are soliciting comments on this basic approach.

It is important to note that, if adopted, this proposed rule would not directly require States to adjust payment rates, nor to take any steps that would not be consistent with efficiency, economy, and quality of care. We believe that even if access issues are discovered as a result of the analysis that would be required under this rule, States may be able to resolve those issues through means other than increasing payment rates. Rather, these rules proposed to clarify that beneficiary access must be considered in setting and adjusting payment methodologies 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 always been within the regulatory authority of CMS to make SPA approval decisions based on sufficiency of beneficiary service access and this proposed rule merely provides a more consistent and transparent way to gather and analyze the necessary information to support such reviews.

II. Proposed State Level Review Strategy for Compliance With Access Requirements

We are not aware of any standardized, transparent methodology that is broadly accepted to definitively measure access to health care and services. Partly as a result, there has been no prior Federal rulemaking or guidance previously on

this subject. As a consequence, in implementing their programs, States lack the guidance that they need to understand the types of information that they are expected to analyze and monitor in determining compliance with statutory access requirements. This issue has come to light recently, both in litigation and in our review of proposed Medicaid State plan amendments (SPAs) that would reduce provider payment rates. Two Governors and several State Medicaid directors have sought Federal guidance in this area, and the Congress, by establishing MACPAC, has also expressed its interest in promoting more information analysis and guidance with respect to these important matters. MACPAC's March report is significant in that it offers the first Congressionally-authorized expert recommendation on standards and methodologies for defining access to health care and health services.

We have a responsibility under the Act to ensure sufficient beneficiary access to covered services and are aware of the uncertainties and problems that arise for States in the absence of Federal guidance on methods and standards for States to demonstrate compliance with this requirement. At the same time, we are mindful that the landscape of health care delivery systems and associated payment methodologies is undergoing significant change, the relevant data are not always available, and that MACPAC, the entity established by the Congress to consider these issues, may adapt its first set of recommendations.

As such, the strategy we are now proposing is designed to allow for State and Federal review of beneficiary access to evolve over time and for States to implement effective and efficient approaches and solutions that are appropriate to their local and perhaps changing circumstances. The proposed strategy would be a consistent and ongoing State-level review to demonstrate sufficient beneficiary access to services covered under the Medicaid State plan that is not solely focused on provider payment rate changes and the State plan process, but assesses ongoing performance.

We note that section 1902(a)(30)(A) of the Act, and the requirements of this proposed rule, discuss access to care for all Medicaid services paid through a State plan under fee-for-service and do not extend to services provided through managed care arrangements. Managed care entities are subject to separate access review procedures that are set forth in 42 CFR part 438 to ensure network sufficiency and procedures for beneficiaries to obtain needed services. We are currently undertaking a review

of State managed care access standards and are considering future proposals to address access issues under managed care delivery systems. The access requirements under section 1902(a)(30)(A) of the Act, apply equally to States that are not changing provider payment rates and those that are. The proposed State reviews, however, will provide an analytic framework to consider the impact of any proposed Medicaid State plan rate reductions on service access.

More specifically, we propose to require States to determine appropriate data elements that focus on the MACPAC-recommended three-part framework, which include information on: Enrollee needs, availability of care and providers, and utilization of services. This and other information that the State believes to be relevant, will be periodically analyzed by States to demonstrate and monitor sufficient access to care. The data and analysis will be made available to the public and furnished to CMS as requested in the context of a SPA that reduces provider rates or restructures provider payments in circumstances that could result in access issues, or as part of ongoing program reviews.

The MACPAC-recommended framework does not focus on one particular data element, such as the relationship of provider payment rates to provider costs, but recognizes that access to covered services is affected by multiple factors. Though cost may be one consideration affecting access to care, there are other factors such as local market conditions, variable provider costs, administrative burden for providers, and demographic differences. Depending upon State circumstances, cost-based studies may not always be informative or necessary. In addition, because many State payment rates are not specifically calculated based on provider cost considerations, it can be burdensome and not particularly productive to rely solely on that one factor as a measure of access.

The proposed State-level review strategy would recognize an ongoing responsibility to conduct periodic reviews of compliance with access requirements for all Medicaid services and also a particular responsibility to review and monitor sustained service access after implementing a change in provider payment rates. While we are proposing to allow States some discretion to determine appropriate measures to demonstrate and monitor access to care within the three-part framework, this proposal provides consistent steps for States to follow in

demonstrating and monitoring Medicaid access.

To ensure continuing compliance review, we propose that States must conduct access reviews for a subset of services each calendar year and release the results through public records or a web site developed and maintained by the State, by January 1st of each year. We have chosen to base the requirement on the calendar year because State fiscal years vary. We note that States may issue the access reviews prior to, but no later than January 1 of each year, with the first review completed by no sooner than 12 months after the effective date of the final rule. States may determine the services that they will review each year, provided that each service is reviewed at least once every 5 years. The reviews must include the specific measures that the State used to analyze access to care by geographic location, discuss the measures in the context of the MACPAC three-part framework, discuss any issues with access that were discovered as a result of the review, and make a recommendation about the consistency with the requirements of section 1902(a)(30)(A) of the Act.

We propose that, prior to submission of a SPA to reduce rates or alter the structure of provider payment rates in circumstances that could result in access issues for a covered service, the State would need to submit information from an access review that had been conducted within the year prior to submission of the SPA as applicable. We are proposing this requirement so that CMS and the States will have the information necessary to assess consistency with section 1902(a)(30)(A) of the Act before a rate reduction or restructuring proposal is processed. Since it may be difficult to predict the impact that a provider rate reduction or restructuring of provider payments will have on access, we are also proposing that States develop special procedures to monitor access to services after such a change has been implemented. These procedures would result in a periodic review of State-determined indices that demonstrate sustained access to care that would be made available to CMS and the public.

To address potential issues that develop in service access, we are proposing that States implement an ongoing mechanism that allows beneficiary feedback. This feedback mechanism could be based on beneficiary hotlines or surveys, an ombudsman program, or other equivalent mechanisms. In addition, we are proposing that each State specify a process to address any access issues that are discovered through the ongoing

access reviews and monitoring, through a corrective action plan that would be submitted to CMS and would include specific steps and a timeline for State action to address such issues. As proposed under this proposed rule, States would need to submit their action plan to CMS within 90 days of discovering an access issue. Below, in section II.C. of this proposed rule, we offer some examples of actions that States may take to address access issues.

A. Data Measures To Demonstrate Sufficiency of Access

We propose to provide States with discretion in determining the appropriate data measures to demonstrate whether access is sufficient through access reviews and monitoring efforts in the context of the MACPAC-recommended framework. We are offering specific suggestions on trends and factors that States could use to measure enrollee needs, the availability of care and providers, and utilization, but we would allow States to develop alternative approaches and improve on these suggestions within each of these categories of required data. We are soliciting public comments on additional data measures that may be useful in measuring access in the context of the proposed framework and whether it is appropriate to require certain data measures as part of State access reviews.

We note at the outset that the data States would review under this rule will explicitly address Medicaid beneficiary access. However, the required statutory test is a comparison between Medicaid beneficiary access and access to medical services by the general population in the geographic area. While it is neither desirable nor feasible to require that States develop new data sources on general access to medical services, the data measures for Medicaid beneficiary fee-for-service access may, in some cases, require that States compare information from commercial insurance standards or Medicaid managed care. We welcome public comment on any existing data sources that address general access to medical services that might be relevant. In general, we are confident that the Medicaid data will implicitly address general access standards in the geographic area. For example, data on beneficiary experience and satisfaction will take into account expectations based on community standards, and the percentage of community providers enrolled and accepting Medicaid patients will necessarily indicate the availability of such providers in the community.

We believe the meeting of enrollee needs should be the primary driver to determine whether access to care is sufficient. Measurable data on the beneficiaries' experiences and needs, however, may be difficult for States to attain. States may need to rely upon qualitative information that is received through beneficiary surveys or other means, such as hotlines or beneficiary Ombudsman offices that some States may have in place, and may request that community-based organizations, primary care providers, hospitals, case management, and other providers assist in soliciting the information from beneficiaries. Once a State determines the most efficient means to reach beneficiaries, it has a number of options for data elements that could be significant in assessing whether their needs are met:

- Extent of knowledge that a service is covered by the Medicaid program;
- Success in scheduling a service appointment with a provider, including after hours as necessary;
- Satisfaction with the availability of service providers within a reasonable distance from home;
- Ability to obtain transportation to and from a scheduled appointment;
- Number and reasons for emergency room services received in the year;
- Number and reasons for missed appointments and means;
- Ability to either schedule an appointment or receive services in light of limited English language proficiency;
- Turnover in providers such as with homecare workers or personal care attendants; and
- Means and ability to seek help in scheduling service appointments.

The connection between the number of enrolled providers and the availability of services is seemingly obvious, but there are many qualifications that affect the meaningfulness of such data. It may be important to know the number of enrolled providers in relation to the overall number of providers in the community. And, in order to contribute to beneficiary access, it is significant to know whether enrolled providers have "open panels" which means that they are accepting Medicaid patients.

Data on the availability of care and providers is likely more easily obtainable by States, measurable and able to be monitored on a consistent basis. Many of the elements that we suggest below are likely available through current State information systems, while some of the information may require a survey of the providers within the State. With that in mind,

States could review the following data elements:

- The availability of care and services through Medicaid fee-for-service as compared to access standards established under Medicaid managed care;
- The availability of care and services through Medicaid fee-for-service as compared to commercial managed care or other commercial insurance access standards.
- The number of providers with open panels who are accepting new Medicaid patients;
- The extent to which timely follow-up visits occur after an emergency visit or inpatient stay;
- Provider Medicaid enrollment (with open panels) compared to licensed providers in the preceding rate year applicable to each covered service;
- Provider Medicaid enrollment compared to actual provider Medicaid participation (as measured by claims submitted) in the preceding rate year applicable to each covered service;
- Provider Medicaid enrollment (with open panels) compared to provider enrollment in one of the four largest commercial insurers in the State in the preceding rate year applicable to each covered service;
- Provider loss and retention in the preceding rate year applicable to each covered service;
- The average amount of time from provider application for enrollment to the approval of the provider agreement; and
- The average amount of time from provider claim submission to payment of the claim by the Medicaid agency.

Beneficiary service utilization data is relevant because changes in beneficiary service utilization can indicate access problems. In particular, drops in service utilization that coincide with payment changes may indicate access problems. In addition, patterns of beneficiaries obtaining access to care through hospital emergency rooms may be an indication of the access problems for certain categories of services.

Beneficiary utilization data is readily available through State information claims systems and relatively easy for States to review and monitor. For purposes of reviewing utilization, States could focus on Medicaid utilization of applicable covered Medicaid State plan services in the preceding rate year on a per capita basis and also take into account that some services apply to subsets of the population (such as pediatric services and obstetrics services). States could also look at avoidable emergency room visits and hospital admissions to determine if

there are issues with preventive hospital use that may suggest a corresponding access issue.

Consistent with the performance standard measures described under the Affordable Care Act, we are actively working, with input from State partners to develop a coordinated and streamlined data solution aimed at reducing redundancy, administrative burden, and to maximize business value. As we propose to have States review data to measure Medicaid access to care, we are mindful that our broader data improvement and streamlining efforts that aim to inform program performance and compliance may also be useful to States in informing access to care. As part of this proposed rule, we are asking States to consider how measures of access to care may align with current program oversight and review activities so that the access reviews build upon existing State data collection efforts that are used to improve overall program efficiency and quality. In addition, through our data efforts, we will work to identify and highlight data available within CMS and States that can inform the State access review under this proposed rule and monitor access on a national basis.

We also will offer States technical assistance in identifying available data resources and facilitate cross-State collaboration as they undertake the access review procedures proposed under this proposed rule. To initiate our technical assistance, we have worked with our Federal partners to develop a matrix of potential Federal and State data resources which may be helpful to States in developing their access reviews. These resources are listed below in section IV. of this proposed rule.

The resources presented in section IV. do not address each data element identified in this proposed rule and much of the data will need to be obtained from existing or developed State sources. We are soliciting public comments and suggestions on these and other existing sources of data that may help States inform their rate-setting policies and their efforts to ensure service access. We will also develop a standardized template for States to report and make publically available the data analysis identified under this proposed rule. The template will be designed to focus on the data elements that a State has reviewed to measure access to care within the MACPAC recommended framework, any issues that the State has identified as a result of the review, and the State agency's recommendation on the sufficiency of access to care based on the review. We

are soliciting public comments on the content of the access template and specifically, the important areas that States should address in their reviews. We believe the reviews should address, minimally, the data elements reviewed under the MACPAC recommended framework, including the information gathered on beneficiary experience, and the Medicaid payment rate comparison. However, we are interested in exploring additional topics that should be standardized through the template.

B. Public Process To Involve Stakeholders

In addition to the access rate review, we propose to require a public process that States would conduct prior to submitting State plan amendments that propose Medicaid provider payment rate reductions or changes in the provider payment structure. We are not prescribing a specific form for that public process, but we would require that the State describe the process that they have developed in their State plan. We are soliciting public comments on whether specific elements regarding that process should be required. We also encourage States to conduct the public process in any instance when the State data collection and monitoring process uncovers an access issue. The purpose of the public process would be to provide a meaningful opportunity for beneficiaries, providers, and other interested parties to provide input and feedback on the impact that the proposed rate reductions will have on efficiency, economy, and access to care, offer ideas to enhance service delivery models and other innovative solutions to address access issues, discuss strategies to encourage continued provider participation, and develop the procedures that States will use to monitor access to care after implementation of the proposed rate reductions.

We are proposing to require this public process in part because we have found that States that worked with affected stakeholders prior to implementing rate reductions often maintained a commitment from providers to continue to serve Medicaid beneficiaries. States have frequently held these discussions with the affected provider community. We are proposing that States also discuss the impact of proposed rate reductions with beneficiaries and other interested parties. As stated earlier in section II.A. of this proposed rule, we believe that beneficiaries' experiences in receiving services are a primary driver in determining the sufficiency of service access and it is important that their

views concerning changes that could directly affect their care be solicited.

Moreover, it is also important to have a public process that obtains feedback from all affected stakeholders because each may have unique approaches to mediating Medicaid service access issues, promoting provider participation in the program, and assuring the program operates in an efficient and economical way. As proposed, the public process requirements will solicit feedback from stakeholders in determining the monitoring and oversight procedures that a State will implement to ensure access is sustained after the implementation of a rate reduction.

C. Monitoring Access and Corrective Action To Address Access

As States review their service access data and monitor access after implementing rate reductions, it is important to have a process in place to address access issues that are uncovered through the new process. While we, through official compliance procedures, may address issues by requiring the State to develop a corrective action plan detailing action steps and timelines to address access issues, we are also proposing to allow States to identify access issues and submit a corrective action plan within 90 days of discovering the problem. When a State develops a corrective action plan on its own, we would not treat it as a finding of non-compliance, but as evidence of a good faith effort by the State to remain in compliance. Action plans may also be developed to improve the State's information base going forward, regardless of whether a particular access problem is identified.

While a corrective action plan may have longer term action steps, it should set a target for compliance with access requirements that is no longer than one year from the submittal of the plan to CMS. We are also encouraging States to work with stakeholders through the public process to develop monitoring indices to ensure sustained access to care and remediation plans that address known access issues. Stakeholders can provide valuable input and assistance in the identification and implementation of measurable efforts that could increase access as appropriate for their local health delivery infrastructure, service delivery system, and other factors.

The precise nature of needed corrective action depends on individual State circumstances. For instance, a State could submit action steps and a timeline to reduce administrative burdens on providers or to implement and oversee a program through which

beneficiaries receive assistance in finding a service appointment. We understand that some States have "ombudsman" programs to aid beneficiaries in finding service appointments as part of their managed care systems and we offer that these programs could serve as one step in alleviating fee-for-service access issues or could help pinpoint the access issues with great precision. Alternatively, or perhaps in addition, a State might seek to incentivize the development or expansion of clinics in underserved areas where access is of particular concern. States could also structure their service reimbursement rates to address particular geographic disparities in service access or to offer incentives for available evening and weekend appointments to working individuals who may not have flexible schedules to accommodate regular work hour appointments. A State could also review, modify or implement transportation, telemedicine or integrated models of care (such as health homes or primary care case management) policies that serve to make care available in efficient and effective ways.

In proposing to address access to care issues through any of these approaches, it would be important for States to describe their process for monitoring program effectiveness in improving or maintaining service access through use of these action steps so that the State will ultimately comply with the requirements at section 1902(a)(30)(A) of the Act.

D. Clarification and Electronic Publication of State Public Notice

In addition to establishing a framework for documenting access to covered Medicaid services, this proposed rule would update the public notice requirement in § 447.205 by recognizing electronic publication as a means to notify the public of payment policy changes. We are proposing this change at the request of States to relieve State burden. The current regulatory language, which requires publication in a State register similar to the **Federal Register**, the newspaper of widest circulation in each city with a population of 50,000 or more, or the newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more, was drafted prior to widespread accessibility of the web and development of State government web sites and we are updating the regulation to consider electronic methods of publication.

We are also soliciting public comment on the use of the term "significant" in

§ 447.205(a). The current public notice regulation calls for notice of "significant" changes in methods and standards, which has resulted in some confusion among States in determining when it is appropriate to publish notice. Because the term "significant" is not defined, and because the impact of payment changes is not always objectively clear, States are not always clear on when it is appropriate to notify the public of changes to rate-setting methods and standards.

Longstanding CMS policy has been to require public notice for any change in payment methods and standards because there is no definable threshold for a "significant" change that can apply across services, service providers, beneficiaries and other stakeholders. A change that may be significant for one individual or group of stakeholders may not be significant to another. Therefore, the historic interpretation has been applied because it is important for providers, beneficiaries and stakeholders to be aware of all changes in State rate policies and evaluate how those changes impact the delivery of Medicaid services. In addition, given that the process for amending the approved State plan to change provider payment rates is somewhat complex, we do not believe that States go through that process for changes that are not significant.

We are soliciting public comments to determine if it is appropriate to clarify the public notice requirement at this time. One option to clarify the requirement is to remove the reference to significance and clarify that any changes in rates, methods and standards require public notice as has been consistent with CMS policy. We could also establish a threshold for significance.

III. Specific Proposed Regulatory Changes

A. Existing Authorities

Section 1902(a)(30)(A) of the Act requires that, in order to receive Federal Financial Participation (FFP), States must set Medicaid service payment rates that are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that services are available to Medicaid eligible individuals to the extent that they are available to the general population in the geographic area. The regulations located at 42 CFR part 447 subpart B (Payment Methods: General Provisions) sets forth the implementation requirements that States must follow when establishing Medicaid payment rates.

Regulations at § 447.203 establish certain documentation requirements that the State Medicaid agency must maintain and make available to the Department of Health and Human Services upon request. Specifically, for any increase in payment rates, the State Medicaid agency is required to record an estimate of the percentile of the range of customary charges to which the revised payment structure applies, a description of the methods used to make the estimate and an estimate of the composite average percentage increase of the revised payment rates of the preceding rates. This information is recorded in State manuals or other official files and applies to individual practitioner services.

As currently described, § 447.203 requires that States document a comparison of increased payment rates to customary charges and preceding rates at the time that the increase occurs and only for practitioner service rates. The documentation requirement does not contemplate rate decreases or include a process or timeframe for States to update the methodology and make a rate comparison using contemporary data. Further, the documentation process does not account for all Medicaid provider payments and could be interpreted to exclude payment increases for hospital, clinic, long-term care facilities, hospice, home health care, durable medical equipment, and other Medicaid service rates that encompass costs beyond practitioner services. Clearly, the regulation was intended to document potential overpayments for a subset of Medicaid service rates and is insufficient, in its current scope, to ensure the collection of information on efficiency, economy, and adequacy of current payment rates across all services and to measure service access.

Regulations at § 447.204 implement, in part, section 1902(a)(30)(A) of the Act by adopting into the CFR the statutory requirement for comparable general population service availability. The regulation replicates the statute, stating that payments must be sufficient to enlist enough providers to ensure that services under the plan are available to recipients at least to the extent that those services are available to the general public. However, the regulation does not provide additional guidance to States on standards to demonstrate sufficient access to Medicaid services. Without specific guidance, States have attempted to comply with this regulation through a variety of methods. As discussed in more detail in section III.A. of this proposed rule, these methods include: stated assurances,

public processes, and/or data reviews, each of which may not fully demonstrate that rates are sufficient to provide for Medicaid service access equivalent to service access available to the general public consistent with the statute.

Regulations at § 447.205 require, with certain exceptions, that the State agency provide public notice of any significant proposed change in methods and standards for setting Medicaid payment rates. Prior to the effective date of a change in methodology, which must be submitted to CMS for review through a Medicaid SPA, States are required to notify the public of the proposed change through publication of a public notice that is published in: a State register similar to the **Federal Register**, or the newspaper of widest circulation in each city with a population of 50,000 or more. If there is no city with a population of 50,000 or more within the State, the publication must be made in the newspaper of widest circulation within the State. The regulation specifies that the content of the public notice describe the proposed change in methods and standards, explain the reason for the change, identify the local agencies where the changes are available for public review, provide an address where comments may be sent and reviewed by the public, and give the location, date and time for any public hearings on the change. The public notice requirement is meant to notify stakeholders of rate-setting policy changes that have already been determined and does not require that States examine and provide the public with any information on the resulting impact on service access that the proposed changes may have once such changes have taken effect.

B. State Plan Review Process Changes

Since 2008, as more States sought to amend Medicaid State plan payment methodologies by instituting significant provider rate changes, we have requested that States provide information to help the agency determine that the changes to rates resulting from State plan amendments will continue to provide for access to care consistent with the Act and the implementing regulations. As part of the SPA review process, we requested this information either informally or through a formal request for additional information. Though we did not develop a standard set of questions for all SPA information requests, similar concerns over adherence to the provisions of § 447.204 were raised in many of the rate reduction SPA reviews. Without clear standards or processes for

determining sufficient rates that will maintain access and encourage provider participation, States were offered a variety of means to satisfy the statutory requirement.

Based on our current review methods, all States that propose to implement rate reductions through a SPA submittal, or change payment rate structures during the rate year, respond with a statement assuring that access would not be affected by the changes in the amendment. When asked for additional detail on the methodology that States used to determine compliance with the access requirement, only a few States indicated that they relied upon actual data to make the determination. Of the States that relied upon data, most focused on historical levels of provider enrollment and their belief that providers would not disenroll based on a reduction in payments. A few States also looked at rates as compared to cost, Medicare rates, or payment rates in surrounding States to determine the impact of the reductions. Some States noted that historic reductions had no discernible impact on provider participation and so they did not anticipate access issues as a result of additional reductions.

Nearly every State held a public meeting that invited some or all of the providers to discuss the proposed changes or at least held informal discussions with providers and policy-makers. Approximately half of the States also included consumer groups and other affected stakeholders as part of the rate proposal hearings or discussions. Many of these public hearings, however, seemed focused on awareness of the coming rate changes, rather than a discussion on the potential impact to service access.

Finally, when asked how they intended to monitor the impact of the rate changes on access, a few States indicated that they would review data submitted to their Medicaid Management Information Systems to determine if services utilization or provider participation levels dropped after the changes were implemented. Some States have hotlines or other mechanisms to record consumer complaints, although it is not clear how widely known these mechanisms are among beneficiaries or how the complaints are considered or evaluated over time. The majority of States did not offer any plan to monitor the impact of the rate reduction on an on-going basis or to make rate adjustments or other changes based on the monitoring activities.

Absent data on the sufficiency of State efforts, including State plan rates, to

achieve access consistent with efficiency, economy, and quality and without a defined process for involving stakeholders in rate setting determinations, we have generally relied upon State assurances and these disparate State approaches to make decisions on proposed rate reduction SPAs. It should be noted that in one instance, we informed a State that based upon the persistent, widespread negative reaction by providers in response to a proposed significant rate reduction of an already low rate (by comparison to commercial rates and other State Medicaid rates for the same service), that we could not approve a reduction amendment as submitted because of concerns that Medicaid eligible individuals would no longer have adequate access to care. In a similar situation, where a State also failed to provide any information or analysis on whether the rate proposal would negatively impact access after the implementation of proposed reductions, we have denied the relevant SPAs.

We agree with MACPAC that it is more consistent with the statute to make such decisions in the context of a consistent framework for evaluating access, informative data and a transparent process that assures stakeholder involvement. Therefore, we are proposing clear guidelines on data collection efforts and public processes that all States must implement in order to demonstrate that rate-setting is informed by sustained access to services consistent with the requirements of section 1902(a)(30)(A) of the Act.

We are also proposing to require that States should submit to CMS, in support of State plan amendments that reduce payment rates or restructure provider payments in circumstance when the resulting changes could create access issues, an analysis based on access data collected during the prior year. The data itself would be available to CMS for review upon request.

C. Standards for CMS Review of Compliance With Access Requirements and State Plan Amendments Affecting Access

As discussed above, we are proposing a State-level ongoing access review process that will generate analysis and data concerning access issues, and will provide a framework for ongoing monitoring and corrective action. We would consider State compliance with these procedural requirements, including both the access review process and the need for identification of access issues and corrective action plans, to be essential to a demonstration of compliance when we review

proposed State plan amendments that affect access to services, such as provider payment reductions or restructuring. When a State has not complied with the access review requirements, we would not approve such a State plan amendment.

We have considered and declined to propose setting a single uniform Federal standard for reviewing substantive compliance with access requirements because we believe that determination of such compliance is very fact-specific and data-specific, taking into consideration local circumstances.

In our review of compliance with access requirements, we intend to focus on working with States to improve beneficiary access mindful of legitimate efforts to ensure that State policies are consistent with efficiency and economy, as well as to the potential advantages of innovative methods of service delivery, provider payment, and case management. However, we will have a perspective in reviewing State-level access reviews and underlying data that States themselves will not have. This is because we will have the advantage of having seen similar access reviews from other States and will recognize best practices and analytic methodologies based on that experience.

Federal review will be based on the statutory standard that the State must have methods and procedures "to assure that payments are consistent with efficiency, economy, and quality of care, and sufficient to enlist enough providers so that care and services under the plan 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 believe that application of this standard requires a review and analysis of data in light of local circumstances. Determinations of compliance will necessarily involve judgments as to how to weigh the data States develop on access measures, and at least without more experience and analysis we do not believe those judgments can be readily reduced to procedural or substantive formulas. We invite comment on possible national or State-specific access threshold tests, particularly given that the statutory requirement to measure access to care in relation to the availability of care and services to "the general population in the geographic area" suggests a State-specific CMS review.

In Federal oversight of State-level reviews to determine ongoing compliance with the statutory access requirement, we do not intend to develop independent analyses of beneficiary access to services, but instead will review State analyses to

ensure that the State-level review process operated to reasonably demonstrate substantive compliance with the access requirements. Our review will generally be limited to the issues of whether the State collected relevant data on each of the required elements, and reasonably analyzed that data to find substantive compliance with access requirements. While we intend to conduct a case-by-case review of these State-level reviews, we may also issue guidance on State-level review practices and may integrate such guidance into our Federal oversight review.

Such guidance may direct the State with respect to the analysis of the required data, and we may consider a State analysis to be deficient if those practices are not applied. For example, such guidance might inform States about how to appropriately weigh different types of data to ensure that the resulting analysis reflects overall access. If we conclude that a State-level review and analysis is deficient and therefore does not reasonably demonstrate compliance with the statutory access requirements, we intend to initiate a compliance process (which could involve requiring a corrective action plan pursuant to these regulations) or, for a pending SPA, we would disapprove the SPA. In that latter instance, we note that the State would have an opportunity during the reconsideration process to correct deficiencies in the State-level review and access analysis.

We note that Federal oversight of State reviews will likely be more stringent when the State proposes changes in provider payment of significant magnitude, or when we have other evidence, either through data or other sources, of an access problem.

While we are not proposing any single Federal standard for reviewing access issues, we are inviting public comment on whether there should be particular indicators that we would regard as an irreducible minimum standard. We have not proposed such a minimum standard for several reasons. First, it is not clear whether any particular indicator is going to be determinative of access issues in every circumstance. The access reviews will examine a number of indicators, and we believe they are best examined in the aggregate. In most cases, we believe that the different indicators that a State examines will confirm each other, but in some cases there may actually be a reason for a variation in the results that is based on a State-specific characteristic. In any case, we believe that the overall access review process should make serious

access problems obvious and easily addressed in a case-by-case review. We also invite comment from States and others on whether a single or small set of Federally determined indicators is preferable administratively to a broader set of State determined indicators.

IV. State Use of National Data Resources To Fulfill Proposed Data Requirements

As discussed previously in this proposed rule, we have worked closely with our partners within the Federal Government, the MACPAC, and a number of experts in an attempt to identify potential sources of data that States may use to fulfill their responsibilities under the proposal. We recognize that much of the information necessary to evaluate access may require States to use existing State data or develop or implement new resources, such as a beneficiary survey. We also recognize that data from different sources have distinct definitions, timeframes for collection, and therefore, challenge and limitations exist to trending data reliably. We are soliciting public comments on existing sources of data that States may use to ensure that they are fulfilling their responsibility to assure access to care and, if States are already analyzing data to measure access to care, that they share their sources and methods of data collection with other States either through public comment to this proposed rule or through MACPAC.

At the Federal level, the Health Resources and Services Administration (HRSA) publishes the Uniform Data System, which includes patient count, diagnosis and expense data at the grantee, State and national levels for HRSA's Federally Qualified Health Center grantees, which are funded under section 330 of the Public Health Service Act. This information is available at <http://www.hrsa.gov/data-statistics/health-center-data/index.html#what>. The HRSA also publishes State data on shortages in primary care, dental and mental health providers on the Health Areas Shortage Designation web site (<http://hpsafind.hrsa.gov/HPSASearch.aspx>). This information may be of particular use to States in targeting specific State locations where access problems are a known issue in that geographic area, without regard to payer. The Agency for Healthcare Research and Quality (AHRQ) has developed a Medical Expenditures Panel Survey, available at http://www.meps.ahrq.gov/mepsweb/data_stats/onsite_datacenter.jsp, which offers surveys of families and individuals, medical providers, and

employers to document cost and use of health care and health insurance coverage. The Centers for Disease Control and Prevention (CDC), produces the National Ambulatory Medical Care Survey, which describes data on utilization and the provision of ambulatory care services in hospital emergency and outpatient departments, (<http://www.cdc.gov/nchs/ahcd.htm>), and the National Health Interview Survey, which tracks health status and health care access: (<http://www.cdc.gov/nchs/nhis.htm>).

We publish a number of Medicare and Medicaid data measures through a contractor, the Research Data Assistance Center (RESDAC), (<http://www.resdac.org/>). In addition, we have developed the Medicare Current Beneficiary Survey, which States may find of use in developing surveys that track beneficiary experience (<https://www.cms.gov/>). States may also find the U.S. Census Bureau's Current Population Survey of use for developing beneficiary questionnaires, <http://www.census.gov/>.

For external resources, the State Health Access Data Assistance Center (SHADAC) Web site, <http://www.shadac.org/>, which includes access data measures for each State. Finally, as part of MACPAC's three part approach to measuring access to care, the Commission offers a number of useful survey resources that States may find helpful in their first published report to the Congress, which was issued on March 15, 2011, (<http://www.macpac.gov/reports>).

We are working to improve upon Medicaid data collection and analyses more generally and will be soon reaching out to States to help us identify the data and measures that are most important to guide State and Federal administration of the Medicaid program. We believe these broader data and performance measures will ultimately provide new resources for States to use as they carry out their important responsibilities to assure access to care consistent with the principles of efficiency, economy, and quality of care.

V. Provisions of the Proposed Regulations

The provisions of this proposed rule aim to create a consistent national approach to analyze and document Medicaid service access that allows States to formulate their own processes, metrics, and approaches in light of the range of local factors and circumstances that influence access in their State. In addition, the provisions seek to clarify and modernize the public notice regulation. As discussed previously in

this proposed rule, we are proposing to address State processes for setting payment rates by amending existing regulations at § 447.203, § 447.204, and § 447.205. Together, these changes better inform States and CMS on beneficiary access as States develop their service delivery and payment policies and potentially implement initiatives to address access issues.

A. Documentation of Access to Care and Service Payment Rates

The proposed revisions at § 447.203(b) would require State Medicaid agencies to demonstrate access to care by considering: Enrollee needs, the availability of care and providers, and the utilization of services. We believe that the experiences of beneficiaries should be a primary determinant of whether access is sufficient and we are soliciting public comments that will serve to help States narrow the focus of the data review to core elements that will demonstrate sufficient access to care. If beneficiaries are able to gain access to care (as required by the Act as equivalent to the general population in a geographic area), then clearly the standards of the Act have been met regardless of other factors, including payment levels. However, if beneficiaries experience difficulty in scheduling service appointments or otherwise accessing needed care, then data on rates of provider participation and retention, analyses of care delivery systems, as well as other relevant factors, including levels of payment are important for States to review and potentially adjust.

We have structured this proposed rule to require that States collect information on each of three parts of the MACPAC-recommended framework, leaving States the discretion to determine which particular metrics they can and should examine. However, we are soliciting public comments as to whether the data review should be required on an ongoing basis if the beneficiary data demonstrates adequate access to care. In part, this may depend on how accurate the beneficiary data may be, and we are particularly interested in public comments on the most reliable ways to gather beneficiary input across diverse groups of people, some with significant physical and mental health problems, language and other barriers.

As proposed, States would be required to review these data elements on an ongoing basis and specifically with respect to an affected service prior to submitting a Medicaid SPA that proposes service payment rate reductions. In terms of the ongoing review, we are proposing that States

would develop a schedule for reviewing each covered service at least once every 5 years, looking at a subset of services each calendar year. We considered a mandatory schedule for all States to follow to promote cross State collaborations and so that comparative data would be available. For example, all States would examine access to physician services in year one, and hospital services in year two. However, in this proposed rule, we are allowing States the discretion to determine the timeline and the organization of the review in recognition of unique State delivery systems and to allow States to prioritize their reviews based on their own sense of urgency, potential issues, or anticipated rate modifications. Further, this proposed rule proposes that all States have some process in place to hear from beneficiaries on access issues, for example, beneficiary survey, a hotline, or an ombudsman that is either internal to the agency or a contracted community partner. In addition, in this proposed rule, we are proposing that States set procedures for their review that will be informed by a public process, to monitor sustained access to care after a rate reduction is implemented and submit a corrective action plan to CMS to address access issues within 90 days of their discovery.

The data collection requirements are discussed in the proposed regulation text at § 447.203(b)(1)(i) through (iii). These provisions would require 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 have proposed that States review this data by State designated geographic location.

The proposed changes to the regulation text at § 447.203(b)(1)(iii)(B) would require that the review must include: (1) An estimate of the percentile which Medicaid payment represents of the estimate 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 have developed this list of comparable payment structures based on our experience in how States set rates and the availability of the data in the interest of easing the administrative burden associated with the data collection effort. In our

experience, most States set Medicaid rates based on one of the three above-noted structures to which we are requiring a comparison and the comparable data should be easily obtained. We believe that the payment comparisons are consistent with the MACPAC-recommended framework and particularly may be informative of the availability of providers, though as discussed, may not be the primary indicator or provider participation. We are soliciting public comments on these measures.

We have further clarified the regulation text, at § 447.203(b)(1)(iii)(B)(3), to state that the Medicaid payment rates must include both base and supplemental payments for Medicaid services. It is important to include supplemental payments because the supplements are tied to the provision of a Medicaid service and will more accurately reflect total provider reimbursement. Should States target a subset of providers with supplemental payments, this should be noted and the targeted amounts recorded in the methodology required at § 447.203(b)(1)(iii)(B). Since States often reimburse service providers according to different payment schedules based on governmental status, we have included a provision at § 447.203(b)(1)(iii)(C) that has States stratify the access review data by State government owned or operated, non-State government owned or operated and private providers. Presenting the data in this manner should inform States as to whether payments are consistent with efficiency, economy, and quality and sufficient to enlist providers consistent with the availability of care and services in the geographic area.

In the proposed regulation text at § 447.203(b)(1)(iii)(D), we have described the minimum content that must be included in the rate review. Specifically, we 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. We also require that States discuss any access issues that were discovered as a result of the review and the State agency's recommendation on the sufficiency of access to care based on the data review.

The proposed regulation text at § 447.203(b)(2) describe 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

propose such annual reviews begin no later than 2013, so that States would have the discretion to determine a timeframe to review each covered Medicaid service, as long as the State reviews 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 describe at § 447.203(b)(3)(i) that States will need to conduct its review relevant to the affected service prior to submission of a State plan amendment implementing a reduction. We believe this is appropriate so that States consider the impact that such proposals may have on access to care and demonstrate compliance with section 1902(a)(30)(A) of the Act. If the State has 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 maintains an ongoing monitoring mechanism with respect to beneficiary complaints, its review relative to the rate reduction can reference the previous review.

In order to ensure sustained access to care, we have included provisions at § 447.203(b)(3)(ii) that require States to develop ongoing monitoring procedures through which they periodically review indices to measure sustained access to care. The periodic reviews helps a State to fulfill its ongoing responsibility to assure access to covered services consistent with the Act and forms a solid, informed basis by which a State and CMS can consider how any proposed changes might impact access. Along with monitoring the review data, it is important for States to continue to engage beneficiaries to understand their concerns and access issues on an ongoing basis. We have proposed to require States to have a mechanism for beneficiary input on access to care, such as hotlines, surveys, ombudsman or other equivalent mechanisms, at § 447.203(b)(4). Additionally, proposed regulation text at § 447.203(b)(5) would institute 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 intend to ensure that States will oversee and address any future access concerns.

After careful consideration, we developed the data elements discussed in this provision based on coordination with our Federal partners, in light of the MACPAC-recommended three-part

approach, and 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 these measures are appropriate to inform whether the Medicaid access requirements are met and that the MACPAC-recommended framework has been developed after study and based on public and expert input. We are soliciting public comments and alternatives to the framework and data elements that we have proposed in this proposed rule, the timeline for the data review and the process for monitoring and remediating access issues.

We note that the data analysis activities are claimable as administrative claiming activities, and 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 we issued in a State Medicaid Director Letter dated December 20, 1994. 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 are likely to be collecting such information by 2014 as part of other performance standards and measures required under the Affordable Care Act.

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

Regulations at § 447.204 implement the statutory requirement that Medicaid rates must be consistent with efficiency, economy, and quality 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. As discussed, the sufficiency requirement has been difficult to measure due to lack of consistent data, variables in delivery systems, and inconsistent State approaches to involving stakeholders in the rate development process.

To address these issues, we are proposing to amend the regulation text at § 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. We have also clarified, at § 447.204(b) that we may disapprove a proposed rate reduction or restructuring SPA that does not include or consider the data review and a public process. As an alternative, we may take a compliance action, in accordance with regulation text at 42 CFR 430.35 in these instances.

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

We are also taking this opportunity to propose clarifying and modernizing changes the public notice requirement at § 447.205. The substance of the notice is not affected by this action. However, a few States have expressed confusion in the past as to when a notice is required insofar as the current regulation calls for notice of “significant” changes in payment methods and standards. At this time we are soliciting public comments on whether it is advisable to delete the term “significant” from the paragraph at § 447.205(a) and explicitly state that notice is required for any change in rates. Alternatively, we are soliciting comments on whether to adopt a threshold for significance and what that threshold might be.

Further, we are proposing to recognize electronic publication as an optional means of publishing payment notice. To do so, we are 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.

Given the dynamic nature of electronic media, we are proposing the following requirements for Internet notices: The notices are published on a regular and known basis; the issued notice includes the date that it was released to the public on the web site, and that the content of the notice is not altered after the initial publication. Based on discussions with States, we believe this will reduce State costs and allow for a more efficient means to notify the public of changes to Medicaid payment methods and standards.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Documentation of Access to Care and Service Payment Rates (§ 447.203(b))

Section 447.203(b) would require that States review and make public information that demonstrates sufficient Medicaid access to care, through a review of: Enrollee needs, the availability of care and providers, utilization of services and service payment rates. States would also be required under this provision to monitor data and beneficiary input on an ongoing basis and address known access issues through corrective action. Through this proposed rule, we would provide States with the discretion to determine appropriate data sources that will be used to conduct the review. We believe that 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 would 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 would be 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 associated with this section by identifying data that States are likely to currently possess, by identifying other data sources that might be informative to State access reviews, and by phasing in the broader service review over 5-year intervals.

1. Access to Care Review Timeline

Section 1902(a)(30)(A) of the Act requires that States ensure that access to care is available to Medicaid beneficiaries equivalent to care provided to the general population in a geographic area. Since this obligation is ongoing and service access may change over time, § 447.203(b)(2) requires that States conduct their reviews for a subset of services each calendar year and review all covered Medicaid services at least once every 5 years. States would have the discretion to determine the appropriate services to review each year over the 5-year period in order to manage their review priorities and resources. As an exception to the 5-year timeline, § 447.203(b)(3)(i) would require States to conduct the access review in the context of a SPA to reduce payment rates or restructure provider payments in circumstance when the resulting changes could create access issues prior to the submission of a SPA that implements the changes. 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.

2. Access to Care Review Framework

The data analysis activities described under the proposal are claimable as administrative claiming activities, and 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 we issued in a State Medicaid Director Letter dated December 20, 1994. 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 are likely to be collecting such information by 2014 as part of other performance standards and measures required under the Affordable Care Act.

The provisions at § 447.203(b)(1) through (3) would require States to review and make publically available, data trends and factors that measure: Enrollee needs, availability of care and providers, utilization of services, and service payment information. Consistent with the statutory requirement, we have proposed that States review this data by

State designated geographic location.

After careful consideration, we developed the review framework based on coordination with our Federal partners, in light of the MACPAC-recommended three-part approach, and 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, are appropriate to inform whether the Medicaid access requirements are met.

Section 447.203(b)(1)(iii)(B) would require that the review include: (1) An estimate of the percentile which Medicaid payment represents of the estimate 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 have developed this list of comparable payment structures based on our experience in how States set rates and the availability of the data in the interest of easing the administrative burden associated with the data collection effort. In our experience, most States set Medicaid rates based on one of the three above-noted structures and the comparable data should be easily obtained. We believe that the payment comparisons are consistent with the MACPAC-recommended framework and particularly may be informative of the availability of providers, though as discussed, may not be the primary indicator or provider participation.

In § 447.203(b)(1)(iii)(B)(3), we clarified that both base and supplemental payments for Medicaid services must include supplemental payments because the supplements are tied to the provision of a Medicaid service and will more accurately reflect total provider reimbursement. Should States target a subset of providers with supplemental payments, this should be noted and the targeted amounts recorded in the methodology required at § 447.203(b)(1)(iii)(B).

Since States often reimburse service providers according to different payment schedules based on governmental status, we have included a provision at § 447.203(b)(1)(iii)(C) that has States stratify the access review data by State government owned or operated, non-State government owned or operated and private providers.

Presenting the data in this manner should inform States as to whether payments are consistent with efficiency, economy, and quality and sufficient to enlist providers consistent with the availability of care and services in the geographic area.

In § 447.203(b)(1)(iii)(D), we describe the minimum content that must be included in the rate review. Specifically, we 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. We also require that States discuss any access issues that were discovered as a result of the review and the State agency's recommendation on the sufficiency of access to care based on the data review.

Section 447.203(b)(2) describes 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 propose such annual reviews begin no later than 2013, so that States would have the discretion to determine a timeframe to review each covered Medicaid service, as long as the State reviews 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.

We estimate that the requirements to review and make publically available, data trends and factors that measure: Enrollee needs, availability of care and providers, utilization of services, and Medicaid rate comparisons under § 447.203(b)(1) through (3) would affect all States. We have allowed States the flexibility to choose the services that they review annually based on available resources and State priorities. As such, we assume that States will conduct reviews in the context of rate reductions or restructuring payment rates as part of their annual ongoing reviews and we consider the burden associated with rate reduction reviews as part of the ongoing estimate burden.

An employee equivalent to the Federal Salary Classification of GS 13 Step 1 could be responsible for gathering review data and developing and publishing the content of the data review. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for overseeing and approving the data

review. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our

cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an

appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 1 and 2.

TABLE 1—ACCESS DATA REVIEW: BURDEN PER STATE
[Annual]

Proposed requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per data review
Gathering Review Data	GS 13 Step 1	160	\$42.66	\$15.35	\$9,281.60
Developing Content of Review	GS 13 Step 1	100	42.66	15.35	5,801.00
Publishing Content of Review	GS 13 Step 1	40	42.66	15.35	2,320.40
Reviewing and Approving Review	GS 15 Step 1	10	59.30	21.35	806.50
Total Burden per State	310	18,209.50

TABLE 2—ACCESS DATA REVIEW: TOTAL BURDEN
[Annual]

Anticipated number of State reviews	Total hours	Cost of review per State	Total cost estimate (\$)
50	15,500	\$18,209.50	\$910,475.00

B. ICRs Regarding Monitoring Access (§ 447.203(b)(3)(ii))

Section 447.203(b)(3)(ii) would require States to develop ongoing monitoring procedures after reducing or restructuring payments through which they periodically review measures of sustained access to care for the affected service(s). The periodic reviews are intended to help a State fulfill its ongoing responsibility to assure access to covered services consistent with the Act and form a solid, informed basis by which a State and CMS can consider how any proposed changes might affect access. Along with monitoring the review data, it is important for States to

continue to engage beneficiaries to understand their concerns and access issues on an ongoing basis.

We estimate that the requirement under § 447.203(b)(3)(ii) would affect all States that implement a rate reduction or restructure payment rates. We are estimating that approximately 22 States will implement these rate changes based on the number of States that proposed such reductions in FY 2010. An employee equivalent to the Federal Salary Classification of a GS 13 Step 1 could develop the monitoring procedures and periodically review the monitoring results. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would

be responsible for overseeing and approve the monitoring process. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 3 and 4.

TABLE 3—ACCESS MONITORING PROCEDURES: BURDEN PER STATE
[Annual]

Proposed requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per data review
Develop Monitoring Procedures	GS 13 Step 1	40	\$42.66	\$15.35	\$2,320.40
Periodically Review Monitoring Results	GS 13 Step 1	24	42.66	15.35	1,392.24
Approve Monitoring Procedures	GS 15 Step 1	3	59.30	21.35	241.95
Total Burden per State	67	3,954.59

TABLE 4—ACCESS MONITORING PROCEDURES: TOTAL BURDEN
[Annual]

Anticipated number of State reviews	Total hours	Cost of review per State	Total cost estimate (\$)
22	1,474	\$3,954.59	\$87,000.98

C. ICRs Regarding Beneficiary Feedback (§ 447.203(b)(4))

Section 447.203(b)(4) would require States to have a mechanism for obtaining beneficiary feedback on access to care, such as hotlines, surveys, ombudsman or other equivalent mechanisms.

We estimate that the requirement under § 447.203(b)(4) would 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. An employee equivalent to the Federal Salary Classification of a GS 9 Step 1 could develop and oversee the feedback effort. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for approving the feedback effort. We have taken these employee assumptions and utilized the corresponding employee

hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 5 and 6.

TABLE 5—BENEFICIARY FEEDBACK MECHANISM: BURDEN PER STATE
[Annual]

Proposed requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per data review
Developing Feedback Effort	GS 9 Step 1	100	\$24.74	\$8.90	\$3,364.00
Monitoring Feedback Results	GS 9 Step 1	24	24.74	8.90	807.36
Approve Feedback Effort	GS 15 Step 1	5	59.30	21.35	403.25
Total Burden per State	129	4,574.61

TABLE 6—BENEFICIARY FEEDBACK MECHANISM: TOTAL BURDEN
[Annual]

Anticipated number of State reviews	Total hours	Cost of review per State	Total cost estimate (\$)
50	6,450	\$4,574.61	\$228,730.50

D. ICRs Regarding Corrective Action Plan (§ 447.203(b)(5))

Section 447.203(b)(5) would institute a corrective action procedure that requires States to submit to CMS a remediation plan should access issues be discovered through the access review or monitoring processes. The requirement is intended to ensure that States will oversee and address any future access concerns.

We estimate that the requirement under § 447.203(b)(5) would affect all States that identify access issues. We are estimating that approximately 10 States will identify access issues and submit corrective action plans to CMS. This is

a new requirement and we have no basis to determine how many States will identify access issues as they conduct the data reviews and monitoring activities. We assume that many States currently have mechanisms in place to monitor access to care and identify issues. However, we are careful not to under-estimate the burden associated with this provision and we believe that a maximum of 10 States may identify access issues per year. An employee equivalent to the Federal Salary Classification of a GS 13 Step 1 could identify issues that require corrective action and develop the plan to submit to CMS. An employee equivalent to the Federal Salary Classification of a GS 15

Step 1 would be responsible for review and approving the plan. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 7 and 8.

TABLE 7—CORRECTIVE ACTION PLAN: BURDEN PER STATE
[Annual]

Proposed requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per data review
Identifying Issues for Action	GS 13 Step 1	20	\$42.66	\$15.35	\$1,160.20
Developing the Corrective Plan	GS 13 Step 1	40	42.66	15.35	2,320.40
Approve Corrective Plan	GS 15 Step 1	3	59.30	21.35	241.95
Total Burden Per State	63	\$3,722.55

TABLE 8—CORRECTIVE ACTION PLAN: TOTAL BURDEN
[Annual]

Anticipated number of state reviews	Total hours	Cost of review per state	Total cost estimate (\$)
10	630	\$3,722.55	\$37,225.50

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

Section 447.204 implements the statutory requirement specifying that Medicaid rates must be consistent with efficiency, economy, and quality and must also be 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. As discussed in section I. of this proposed rule, the sufficiency requirement has been difficult to measure due to lack of consistent data, variables in delivery systems, and inconsistent State approaches to involving stakeholders in the rate development process.

To address these issues, § 447.204(a)(1) and (a)(2) would require that States consider (when proposing to

reduce 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. We have also clarified, at § 447.204(b) that we may disapprove a proposed rate reduction or restructuring SPA that does not include or consider the data review and a public process. As an alternative, we may take a compliance action, in accordance with regulation text at § 430.35 in these instances.

We are estimating that approximately 22 States will implement these rate changes that would require a public process based on the number of States that proposed such reductions in FY 2010. An employee equivalent to the Federal Salary Classification of a GS 9

Step 1 could develop and oversee the public process effort. An employee equivalent to the Federal Salary Classification of a GS 15 Step 1 would be responsible for approving the public process effort. We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC as published by the U.S. Office of Personnel Management, to calculate our cost estimates. We have also calculated the cost by assuming that a State expends 36 percent of an employee's hourly wages on benefits for the employee. We have concluded that a 36 percent expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 9 and 10.

TABLE 9—PUBLIC PROCESS: BURDEN PER STATE

Proposed requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per data review
Develop the Public Process	GS 9 Step 1	20	\$24.74	\$8.90	\$672.80
Oversee the Public Process	GS 9 Step 1	40	24.74	8.90	1345.60
Approve Public Process	GS 15 Step 1	3	59.30	21.35	241.95
Total Burden Per State	63	2,260.35

TABLE 10—PUBLIC PROCESS: TOTAL BURDEN
[Annual]

Anticipated number of state reviews	Total hours	Cost of review per state	Total cost estimate (\$)
22	1,386	\$2,260.35	\$49,727.70

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

The proposed provisions at § 447.205 would clarify when States must issue public notice to providers and would allow for the electronic publication of

those notices. Section 447.205(d)(2)(iv)(A) through (C) would 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 proposed action since the revision would simply allow for an additional (in this case, electronic) means of notification. Consequently, we do not include the electronic notice activity in our burden analysis.

TABLE 11: 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 (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
447.203(b)(1) – (3)	0938-NEW	50	50	300	15,000	58.01	870,150	0	870,150
Subtotal				10	500	80.65	40,325	0	40,325
447.203(b)(3)(ii)	0938-NEW	22	22	64	1,408	58.01	81,678.08	0	81,678.08
Subtotal				3	66	80.65	5,322.90	0	5,323.90
447.203(b)(4)	0938-NEW	50	50	124	6,200	33.64	208,568	0	208,568
Subtotal				5	250	80.65	20,162.50	0	20,162.50
447.203(b)(5)	0938-NEW	10	10	60	600	58.01	34,806	0	34,806
Subtotal				3	30	80.65	2,419.50	0	2,419.50
447.204(a)(1) and (2)	0938-NEW	22	22	60	1,320	33.64	44,404.80	0	44,404.80
Subtotal				3	66	80.65	5,322.90	0	5,322.90
TOTAL		154	154	632	25,440	--	1,313,159.68	0	1,313,159.68

If you comment on these information collection and recordkeeping

requirements, please do either of the following:

1. Submit your comments electronically as specified in the

ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-2328-P Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov

VII. Response to Comments

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

VIII. Regulatory Impact Statement

A. Statement of Need

This proposed rule would revise 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 proposed rule would also clarify and amend the regulations at § 447.205, which require States to issue public notice to their providers when changing Medicaid payment methods and standards. The proposed changes to the public notice requirement intend to 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 the proposal 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 mispent 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 proposed rule, we are soliciting public comments to begin identifying data sources and will continue to provide assistance as States develop their reviews and monitoring procedures.

We estimate that even if these data collection efforts were, in fact, 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 proposed 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 that States directly adjust payment rates as a result of the provisions of this proposed rule, nor to take any steps that would not be consistent with efficiency, economy, and quality of care. Rather, these rules propose to make clear 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 always been within the regulatory authority of the CMS to make SPA approval decisions based on sufficiency of beneficiary

service access and this proposed 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. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. For details, see the Small Business Administration's Web site at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>. 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 proposed rule would 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area 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 proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2011, that threshold is approximately \$136 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose costs above \$135 million or more on

State or local governments, the requirements of E.O. 13132 are not applicable.

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 proposed rule. 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 State Medicaid directors, Federal agency policy officials and the MACPAC. Based, in part, on these discussions we arrived at the provisions proposed in this proposed 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 proposed rule.

1. Access Data Review

The process for documenting access to care and service payment rates described at § 447.203 would require States to publish access data reviews that discuss, as recommended by MACPAC, the extent to which enrollee needs are met, the availability of care and providers, and changes in beneficiary utilization of covered services. The review would also include a comparison of Medicaid payment rates to customary charges and Medicare, commercial payments, or provider cost. The reviews are to be conducted over 5-year periods for all services covered in a State's Medicaid State plan or, in the context of a State plan amendment proposal to reduce provider rates or restructure provider rates in circumstance that may negatively impact access to care, within 12 months of implementing the State plan amendment.

As an alternative to the MACPAC-recommended 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 proposed rule, there are no standardized, transparent methodologies for demonstrating access to care that would be appropriate to adopt at this time. A singular approach to demonstrating access may not consider differences in Medicaid benefits and State or local delivery models. For instance, the appropriate data to measure access to Medicaid long-term care services provided through personal care providers could be very different from data used to measure access to acute care services delivered in a hospital facility that offers outpatient care.

Rather than prescribe data measures that may not align with all services or set threshold standards, we have adopted the MACPAC-recommended 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.

2. Access Review Timeframe and Monitoring Procedures

In this proposed rule, we are proposing that access data reviews be conducted over 5-year periods for all services covered in a State's Medicaid State plan or, in the context of a provider rate reduction or restructuring of provider rates that may negatively affect access to care, within 12 months of implementing the State plan amendment. We have arrived at the 5-year ongoing review to allow States to determine the best use of available State resources in conducting the access review and to prioritize the review in light of program changes or particular access concerns.

We considered requiring the review on an annual basis or a review period that is more frequent than 5 years. However, the burden associated with an annual review would likely be high and may not demonstrate any changes in access to care if the payment rates and service delivery systems remain stable. We believe that, absent rate reductions

or restructuring of payments, the 5-year review periods, combined with ongoing solicitation of information about access from beneficiaries, are sufficient to identify access issues that may occur over time, while also allowing the States the flexibility to prioritize the reviews. We also considered prescribing the services that States would be required to review each year so that there is national consistency in the access reviews. However, since the objective of this proposed rule is to provide States with a framework to demonstrate access to care consistent with section 1902(a)(30)(A) of the Act rather than to conduct a national study of access, we determined it appropriate to allow States the flexibility to choose which services to review each year based on their priorities.

This proposed rule would require that States 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.

3. Beneficiary Input on Access to Care

The proposed changes to § 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 this 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 would amend 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).

Subpart B—Payment Methods: General Provisions

2. Section 447.203 is amended by—

A. Revising the section heading.

B. Revising paragraph (b).

The revisions read as follows:

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

* * * * *

(b) The agency must record and update, medical assistance access reviews for each covered benefit, in accordance with timeline describe in paragraph (c) of this section. Such reviews must be published or promptly made available upon request to the public and furnished, upon request, to CMS. The access reviews must include the items specified in this section, as well as trends and factors, which may vary by geographic location within the State, which will be used to inform State policies affecting access to Medicaid services, such as provider payment rates.

(1) *Access review data requirements.* States must document in their access review, using data trends and factors, an analysis that demonstrates sufficient access to care, considering, at a minimum:

(i) The extent to which enrollee needs are met;

(ii) The availability of care and providers; and

(iii) Changes in beneficiary utilization of covered services. The access review must also include the following information:

(A) *Beneficiary information.* Relevant beneficiary information as described in paragraph (b)(4) of this section.

(B) *Access review medicaid payment data.* The review must include all of the following:

(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.

(3) An estimate of the composite average percentage increase or decrease resulting from any proposed revision in payment rates. The review must also include a description of the methods used to make the estimates described above. The data on Medicaid payment rates must include all base and supplemental payments to providers described under the Medicaid State plan.

(C) *Stratification requirement.* Data on provider payment rates in the access review must be stratified to the extent that payments vary by the following categories of providers: State government-owned or operated, non-State government owned or operated, privately owned or operated.

(D) *Content of the review.* The review must, at a minimum, describe: the specific measures that the State uses to analyze access to care, how the measures relate to the framework described in paragraph (b)(1) of this section, 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.

(2) *Access review timeframe.* Beginning January 1 of the year beginning no sooner than 12 months after the effective date of the final rule, for all covered services, the State agency must complete the access review on a State-determined timeframe, provided that:

(i) The State completes its reviews a subset of services each calendar year by January 1 of each year;

(ii) All covered services undergo a full review at least once every 5 years; and

(iii) The results of the review are made available to the public (which could include a web site developed and maintained by the single State agency or other responsible State agency), and to CMS upon request through public records.

(3) *Special provisions for proposed provider rate reductions or restructuring—*(i) *Compliance with*

access requirements. To demonstrate compliance with the access requirements at section 1902(a)(30)(A) of the Act, the State must submit with any State plan amendment that would reduce provider payment rates or restructure provider payments in circumstance when the changes could result in access issues, an access review 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 in circumstance when the changes could result in access issues.

(ii) *Monitoring procedures.* A State must develop procedures to monitor continued access to care after implementation of State plan service rate reduction or payment restructuring. 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.

(4) *Mechanisms for ongoing input.* States must have ongoing mechanisms for beneficiary input on access to care (through hotlines, surveys, ombudsman or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204 of this subpart. States must maintain a record of the volume and nature of the response to such input.

(5) *Addressing access questions and remediation of access issues.* If a State's access review or monitoring procedures determine access issues, regardless of whether the issue would indicate non-compliance with the statutory standard, the State agency is responsible for submitting a corrective action plan to CMS with specific steps and timelines to address the issue within 90 days of discovery. While the corrective action plan may include longer-term measures, the goal for remediation of the access deficiency should be no longer than 12 months.

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 recipients 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 through the process described in § 447.203 of this subpart.

(2) Input from beneficiaries and affected stakeholders in determining the extent of 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 volume and nature of the response to such input.

(b) The State must submit to CMS with any such proposed State plan amendment, an analysis reflecting consideration of the information and procedure described in paragraph (a) of this section. If CMS determines that service rates are modified without such

an analysis, the agency may disapprove a proposed State plan amendment using the authority and procedures described at part 430 Subpart B of this title or may take a compliance action using the authority and procedures described at § 430.35 of this title.

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:

(A) The site is updated for bulletins on a regular and known basis (for example, the first day of each month);

(B) The issued notice includes the actual date it was released to the public on the web site; or

(C) The content of the issued notice is not modified after the initial publication.

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

Dated: April 13, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: April 27, 2011.

Kathleen Sebelius,
Secretary, Health and Human Services.

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