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- *Email:* hebert.michael@epa.gov.
- *Mail:* Michael A. Hebert, Remedial Project Manager, EPA Region 6, Mail Code—6SEDRL, 1201 Elm Street, Suite 500, Dallas, Texas 75270–2102.
- *Hand delivery:*
 - Michael A. Hebert, Remedial Project Manager, EPA Region 6, Mail Code—6SEDRL, 5th Floor Reception Area, 1201 Elm Street, Suite 500, Dallas, Texas 75270–2102.
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Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at: Zimmerman Library, Government

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New Mexico Environment Department, Harold Runnels Building, 1190 St. Francis Drive, Santa Fe, NM 87505, 505.827.2855: Monday–Friday 8 a.m.–5 p.m.

In addition, documents concerning the site can be found at <https://www.epa.gov/superfund/south-valley>.

FOR FURTHER INFORMATION CONTACT: Michael A. Hebert, Remedial Project Manager, U.S. Environmental Protection Agency, Region 6, Mail Code—6SEDRL, 1201 Elm Street, Suite 500, Dallas, Texas 75270–2102, (214) 665–8315, email: hebert.michael@epa.gov.

SUPPLEMENTARY INFORMATION: The proposed rule published on July 31, 2018 at 83 FR 36838 provides information about NPL Deletion Criteria, NPL Deletion Procedures, and the Basis for the South Valley site partial deletion.

Dated: June 26, 2019.

David Gray,

Acting Regional Administrator, Region 6.
[FR Doc. 2019–14880 Filed 7–12–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2406–P2]

RIN 0938–AT41

Medicaid Program; Methods for Assuring Access to Covered Medicaid Services—Rescission

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would remove the regulatory text that sets forth the current required process for states to document whether Medicaid payments in fee-for-service systems are sufficient to enlist enough providers to assure beneficiary access to covered care and services consistent with the Medicaid statute. States have raised concerns over the administrative burden associated with the current regulatory requirements. While we believe the process described in the current

regulatory text is a valuable tool for states to use to demonstrate the sufficiency of provider payment rates, we believe mandating states to collect the specific information as described excessively constrains state freedom to administer the program in the manner that is best for the state and Medicaid beneficiaries in the state.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 13, 2019.

ADDRESSES: In commenting, please refer to file code CMS–2406–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three 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–2406–P2, 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–2406–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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 website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

Section 1902(a)(30)(A) of the Social Security Act (the Act) requires states 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. In the November 2, 2015 **Federal Register** (80 FR 67576), we published the “Medicaid Program; Methods for Assuring Access to Covered Medicaid Services” final rule with comment period (“2015 final rule with comment period”) that outlined a data-driven process for states to document their compliance with section 1902(a)(30)(A) of the Act. The 2015 final rule with comment period included a new § 447.203(b)(1) through (8), revisions to § 447.204, and a new § 447.205(d)(2)(iv). These regulations established that states must develop and submit to CMS an access monitoring review plan (AMRP), that is updated at least every 3 years, for the following services: (1) Primary care (including those provided by a physician, federally qualified health center, clinic or dental care); (2) physician specialist services (for example, cardiology, urology, radiology); (3) behavioral health services (including mental health and substance use disorder); (4) pre- and post-natal obstetric services, (including labor and delivery); (5) home health services; (6) any additional types of services for which a review is required under § 447.203(b)(6) because of a proposed payment rate reduction or restructuring; (7) additional types of services for which the state or CMS has received a significantly higher than usual volume of beneficiary, provider or other stakeholder access complaints for a geographic area; and (8) additional types of services selected by the state.

Furthermore, under § 447.204(a) through (c), when proposing to reduce or restructure Medicaid payment rates, states must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of proposed reduction or restructuring of Medicaid payment rates on beneficiary access to care. States must submit related analysis to CMS along with any proposed rate reduction or restructuring state plan amendment (SPA), and we may disapprove such proposed SPA that does not include documentation supporting compliance with the required AMRP review and public process. Under § 447.204(d), we may take a compliance action against a state to remedy an access issue. The initial AMRP submissions were due to us on October 1, 2016, as provided in the final

rule, “Medicaid Program; Deadline for Access Monitoring Review Plan Submissions,” published in the April 12, 2016 **Federal Register** (81 FR 21479). We received AMRP submissions from all states, and the submissions are available on the Medicaid.gov website at <https://www.medicaid.gov/medicaid/access-to-care/review-plans/index.html>.

Finally, under § 447.205(d)(2)(iv), states may provide the required public notice of any significant proposed change in its methods and standards for setting payment rates for services on a state public website that meets the standards specified in that paragraph.

A number of states expressed concern regarding the administrative burden associated with the regulatory requirements, particularly those states with very high beneficiary enrollment in managed care and a correspondingly limited number of beneficiaries receiving care through a fee-for-service delivery system. States have mentioned that they must utilize a significant amount of staff resources to develop the AMRPs and conduct the required analysis when, because of the relatively small population in fee-for-service, it will result in program data that is not reflective of the state’s overall care delivery system and therefore is not well suited to evaluating access for the entire population of Medicaid beneficiaries in the state. For instance, states have discussed that remaining fee-for-service populations are often dually eligible for Medicare and Medicaid with Medicaid only being the secondary payer for most services provided to these individuals. Similarly, remaining fee-for-service populations may reside in long-term care facilities and because Medicaid is often the primary payer of long-term care services, and as such, typically sets the market for these services, the types of data comparisons required by the AMRPs are of limited utility. Other populations remaining in fee-for-service may have reduced packages of services based on specific needs, and these populations are often so small or require such specialized care that their needs may not be meaningfully compared to the general population. Additionally, some states have noted that their managed care contracts require participating providers to also participate in their fee-for-service program. Even states with limited managed care enrollment have raised concerns about what they consider to be burdensome standards and unsustainable processes and, through the National Association of Medicaid Directors, have requested to work with CMS to develop meaningful standards

and a process that effectively implements section 1902(a)(30)(A) of the Act.

In attempt to address some of the states’ concerns regarding undue administrative burden, in the March 23, 2018 **Federal Register** (83 FR 12696), we published a proposed rule that would have exempted states with at least 85 percent of their Medicaid population enrolled in comprehensive, risk-based managed care from the regulatory requirements in §§ 447.203(b)(1) through (6) and 447.204(a) through (c). In addition, the proposed rule would have exempted from the regulatory requirements in §§ 447.203(b)(6) and 447.204(a) through (c) state proposals to reduce rates or restructure payments where the overall reduction is 4 percent or less of overall spending within the affected state plan service category for a single state fiscal year (SFY) and 6 percent or less over 2 consecutive SFYs. In the responses that we received during the public comment period, an overwhelming number of commenters raised concerns that the exemption thresholds were arbitrarily set without data to support them. While we maintain that the thresholds are supportable, we have decided not to finalize the proposed exemptions, and instead to set out a new approach to understanding access and ensuring statutory compliance while eliminating unnecessary burden on states.

We have relied on states to analyze access to care data and develop procedures to monitor data through updates to the AMRPs. While the AMRPs can serve as an overall structure for states to monitor access data, including after rate reductions or restructurings, similar information can be presented by states through the SPA submission process to demonstrate compliance with the statute without the need to develop and maintain AMRPs as currently required under the regulations. Additionally, apart from the SPA submission process, states continue to be obligated to ensure their rates are sufficient to maintain compliance with section 1902(a)(30)(A) of the Act. If the regulatory amendments in this proposed rule are finalized, we would expect to issue subregulatory guidance concurrently with the publication of the final rule through a letter to State Medicaid Directors to provide information on data and analysis that states will submit with SPAs to support compliance with section 1902(a)(30)(A) of the Act. We anticipate that this guidance would provide states flexibility to select the types of data they would use to demonstrate the sufficiency of payment rates. Such data

might include: Rate comparisons; ratios of participating providers to total providers in the geographic area; ratios of participating providers to beneficiaries in the geographic area; available transportation in the geographic area; direct comparisons of access for Medicaid beneficiaries to that of the general population in the geographic area; and provider, beneficiary, and other stakeholder complaints and recommendations for resolution of such complaints. We expect that the guidance would remind states of their ongoing obligation to ensure sufficient payment rates and that they must demonstrate with the information they provide through SPAs that the proposed rates or rate structure would satisfy the requirements of the statute, including section 1902(a)(30)(A) of the Act.

In addition, in partnership with states, we are renewing our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program across fee-for-service and managed care delivery systems, as well as in home and community-based services waiver programs. This new strategy will focus on developing a more uniform methodology for analyzing Medicaid access data for all states and will be led by us working in partnership with states and other stakeholders. We will use this analysis to inform our approval decisions and to set out new policies, as necessary, to improve beneficiary access to care and services in the Medicaid program. In conjunction with the 2015 final rule with comment period, we also published a Request for Information (RFI) in the **Federal Register** (80 FR 67377) in which we sought public input to inform the potential development of standards with regard to Medicaid beneficiaries' access to covered services under the Medicaid program. The majority of responses to the RFI were supportive of the concept of more standardized access measures across states and delivery systems, at that time however, we did not believe we had the necessary data at the federal level to move forward with developing such measures. Since 2015, we have improved data available at the federal level through the Transformed Medicaid Statistical Information System (T-MSIS), which is a significant expansion of the previously available information

from the Medicaid Statistical Information System (MSIS) and have a better understanding of how such data may be used to monitor access in Medicaid. Additionally, we have been working extensively with states, through a vendor, to identify best practices and develop standardized templates that can be used to analyze access. We hope to build upon these efforts as part of the new strategy.

II. Provisions of the Proposed Regulations

We are proposing to remove § 447.203(b), but leave in place the requirement in § 447.203(a) for states to maintain documentation of payment rates and make that available to us upon request. In addition, we propose to remove § 447.204(b) through (c) to remove the regulatory requirements for the process states must follow prior to the submission of a SPA that proposes to reduce or restructure Medicaid service payment rates. We are also proposing to remove § 447.204(d), which specifies actions we could take to remedy an access issue, as this provision was intended to address issues that arose based on the state's access monitoring review procedures that we are now proposing to no longer require. We would continue to have authority to take compliance action or other remedial action if we determine that a state is not in compliance with section 1902(a)(30)(A) of the Act. The proposal would leave in place the opening sentence of the current requirement in § 447.204(a), which is a restatement of the statutory language of section 1902(a)(30)(A) of the Act.

Although this proposed rule would remove the regulatory process requirements for states to develop and update an AMRP and to submit certain access analysis when proposing to reduce or restructure provider payment rates, states still would be obligated by the statute to ensure Medicaid payment rates are sufficient to enlist enough providers to assure that beneficiary access to covered care and services are available under the plan at least to the extent such care and services are available to the general population in the same geographic area, particularly when reducing or restructuring Medicaid payment rates through SPAs. States would still be required to submit information and analysis to demonstrate compliance with section 1902(a)(30)(A)

of the Act when submitting payment SPAs, and as discussed above, we would expect to issue subregulatory guidance to inform states on the types of information and data that we would consider to be acceptable.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this rule that would rescind certain "collection of information" requirements as defined under 5 CFR 1320.3 of the PRA's implementing regulations.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). Note, this is updated wage information from the currently approved information collection request (CMS-10391; OMB 0938-1134), which used 2015 National Occupational Employment and Wage Estimates. In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. This updated adjusted hourly wage information is used for all of the estimated burden calculations in this proposed rule.

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	35.14	35.14	70.28
Computer and Information Analyst	15-1120	45.10	45.10	90.20
General and Operations Manager	11-1021	59.35	59.35	118.70
Management Analyst	13-1111	44.92	44.92	89.84
Social Science Research Assistant	19-4061	23.57	23.57	47.14

We adjusted our employee hourly wage estimates by a factor of 100 percent. This was necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost was a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

This rule does not propose any new collection of information requirements. Instead, in the interest of consistency with Executive Order 13771 (January 30, 2017), entitled, “Reducing Regulation and Controlling Regulatory Costs,” this rule proposes to rescind the collection of information requirements and burden that are set out under the 2015 final rule with comment period (80 FR 67576). The requirements and burden (with modification, as explained below) were approved by OMB on April 29, 2016, under control number 0938–1134 (CMS–10391). As noted previously, while we believe the process described in the current regulatory text can be a valuable tool for states to use to demonstrate the sufficiency of provider payment rates, because we have no basis for determining how many states would continue to follow the current AMRP process in whole or in part, we are assuming that all states would opt to provide alternate evidence of compliance with section 1902(a)(30)(A) of the Act and are therefore removing the burden of the current AMRP requirements in its entirety. States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. As the requirements and burden estimate under control number 0938–1134 (CMS–10391) only accounted for new burden associated with 2015 final rule with comment period, we are not accounting for burden associated overall

compliance with section 1902(a)(30)(A) of the Act and information states may submit to demonstrate statutory compliance as part of the SPA submission process if the proposal to rescind the 2015 requirements is finalized. Information and documentation states submit in support of SPAs are covered within the procedural requirements defined in 42 CFR part 430.

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

Current provisions at § 447.203(b) require that states develop and make publicly available an access monitoring review plan that considers: Beneficiary needs, availability of care and providers, and changes to beneficiary utilization of covered services.

Section 447.203(b)(1) and (2) describes the minimum factors that states must consider when developing an access monitoring review plan, while § 447.203(b)(3) requires that states include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) or private health coverage rates within their state’s geographic areas.

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

Section 447.203(b)(5) describes the timeframe for states to develop the access monitoring review plan and complete the data review for the following categories of services: Primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the state has submitted a state

plan amendment to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the state or CMS. While the initial access monitoring review plans have been completed, the plan must be updated at least every 3 years, but no later than October 1 of the update year.

In our currently approved information collection request (CMS–10391; OMB 0938–1134), we estimated that the requirements to develop and make the access monitoring review plans publicly available under § 447.203(b) and (b)(1) through (b)(5) for the specific categories of Medicaid services will affect each of the 50 state Medicaid programs and the District of Columbia (51 total respondents). Using the previously derived estimates of burden hours and updated adjusted hourly wage information, we now estimate that it will take: 80 hr at \$47.14/hr for a research assistant staff to gather data, 80 hr at \$90.20/hr for an information analyst staff to analyze the data, 100 hr at \$89.84/hr for management analyst staff to update the content of the access review monitoring plan, 40 hr at \$70.28/hr for business operations specialist staff to publish the access monitoring review plan, and 10 hr at \$118.70/hr for managerial staff to review and approve the access monitoring review plan. As demonstrated below in Tables 2A and 2B, we estimate a burden reduction or savings of 15,810 hr (total) at a cost of \$1,222,439 (total) or \$23,969 (per state).

Please note that the 2015 final rule with comment period set out a burden of 5,270 hr which divided the total number of respondents (51 states) across 3 years (17 states per year) to equal 17 states × 310 hr per response. In this rule we propose to adjust the number of respondents from 17 to 51 to capture the total number of respondents across the 3 year period, resulting in a difference of –10,540 hr (5,270 hr – 15,810 hr).

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TABLE 2A: Access Monitoring Review Plan: Reduced One-time Burden (Per State)

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Monitoring Plan (\$/State)
Gathering Data	Social Science Research Assistant	-80	47.14	-3,771.20
Analyzing Data	Computer and Information Analyst	-80	90.20	-7,216.00
Developing Content of Access Review Monitoring Plan	Management Analyst	-100	89.84	-8,984.00
Publishing Access Review Monitoring Plan	Business Operations Specialist	-40	70.28	-2,811.20
Reviewing and Approving Access Review Monitoring Plan	General and Operations Manager	-10	118.70	-1,187.00
TOTAL		-310	Varies	-23,969.40

TABLE 2B: Access Monitoring Review Plan: Reduced One-Time Burden (Total)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
51	-15,810 [-310 hr x 51 reviews]	-23,969	-1,222,439

Based on this rule’s proposal to rescind the requirement for states to update the access monitoring review plan at least every 3 years, we are also removing the on-going or annual burden

associated with the access monitoring review plan. Consistent with our currently approved estimates, we believe that the average ongoing burden is likely to be the same as the average

initial burden since states will need to re-run the data, determine whether to add or drop measures, consider public feedback, and write-up new conclusions based on the information they review.

TABLE 3: Access Monitoring Review Plan: Reduced On-Going Burden (Total)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
51	-15,810 [-310 hr x 51 reviews]	-23,969	-1,222,439

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

Section 447.203(b)(6)(ii) requires that states have procedures within the access monitoring review plan to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures must be in place for a period of at least three years following the effective date of the SPA. The ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it would take each

of the state Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates.

In our currently approved information collection request (CMS–10391; OMB 0938–1134), we estimated that in each SPA submission cycle, states would submit 22 SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010.

Using the previously approved estimates of burden hours and updated

adjusted hourly wage information, we now estimate that it will take, on average: 40 hr at \$89.84/hr for management analyst staff to develop the monitoring procedures, 24 hr at \$89.84/hr for management analyst staff to periodically review the monitoring results, and 3 hr at \$118.70/hr for management staff to review and approve the monitoring procedures. As demonstrated below in Tables 4A and 4B, we estimate a burden reduction or savings of 1,474 hr (total) at a cost of \$134,329 (total) or \$6,106 (per state).

TABLE 4A: Access Monitoring Procedures Following Rate Reduction SPA: Reduced Burden Per State (annual)

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Develop Monitoring Procedures	Management Analyst	-40	89.84	-3,593.60
Periodically Review Monitoring Results	Management Analyst	-24	89.84	-2,156.16
Approve Monitoring Procedures	General and Operations Manager	-3	118.70	-356.10
TOTAL		-67	varies	-6,105.86

TABLE 4B: Access Monitoring Procedures Following Rate Reduction SPA: Reduced Total Burden (annual)

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
22	-1,474 [-67 hr x 22 responses]	-6,106	-134,329

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

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

In our currently approved information collection request (CMS-10391; OMB

0938-1134), we estimated that the requirement to develop mechanisms for ongoing feedback would affect each of the 50 state Medicaid programs and the District of Columbia (51 total respondents).

Using the previously approved estimates of burden hours and updated adjusted hourly wage information, we now also estimate that it would take an average of: 100 hr at \$89.84/hr for management analyst staff to develop the feedback effort and 5 hr at \$118.70 for managerial staff to review and approve the feedback effort. As demonstrated below in Tables 5A and 5B, we estimate

a burden reduction or savings of 5,355 hr (total) at a cost of \$488,453 (total) or \$9,578 (per state).

Please note that the 2015 final rule with comment period had set out a burden of 1,785 hr which divided the total number of respondents (51 states) across 3 years (17 states per year) to equal 17 states × 105 hr per response. In this rule, we propose to adjust the number of respondents from 17 to 51 to capture the total number of respondents across the 3-year period, resulting in a difference of -3,570 hr (1,785 hr - 5,355 hr).

TABLE 5A: Beneficiary Feedback Mechanism: Reduced One-Time Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Develop Feedback Effort	Management Analyst	-100	89.84	-8,984.00
Approve Feedback Effort	General and Operations Manager	-5	118.70	-593.50
TOTAL		-105	varies	-9,577.50

TABLE 5B: Beneficiary Feedback Mechanism: Reduced One-Time Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
51	-5,355 [-105 hr x 51 responses]	-9,578	-488,453

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

associated with monitoring the feedback is primarily incurred by the analysts who will gather, review and make recommendations for and conduct follow-up on the feedback. We estimate that it will take an average of: 75 hr at \$89.84/hr for management analyst staff

to monitor feedback results and 5 hr at \$118.70/hr for managerial staff to review and approve the feedback effort. As demonstrated below in Tables 6A and 6B, we estimate a burden reduction or savings of 4,080 hr (total) at a cost of \$373,907 (total) or \$7,332 (per state).

TABLE 6A: Beneficiary Feedback Mechanism: Reduced On-going Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Develop Feedback Effort	Management Analyst	-75	89.84	-6,738.00
Approve Feedback Effort	General and Operations Manager	-5	118.70	-593.50
TOTAL		-80	varies	-7,331.50

TABLE 6B: Beneficiary Feedback Mechanism: Reduced On-going Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
51	-4,080 [-80 hr x 51 responses]	-7,332	-373,907

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

Current § 447.203(b)(8) requires that states submit to CMS a corrective action plan should access issues be discovered through the access monitoring processes.

In our currently approved information collection request (CMS-10391; OMB 0938-1134), we estimated that a maximum of 10 states may identify access issues per year. The one-time

burden is the time and effort it would take 10 state Medicaid programs to develop and implement corrective action plans.

Using the previously approved estimates of burden hours and updated adjusted hourly wage information, we estimate that it would take an average of: 20 hr at \$89.84/hr for management analyst staff to identify issues requiring corrective action, 40 hr at \$89.84/hr for management analyst staff to develop the corrective action plans, and 3 hr at

\$118.70/hr for managerial staff to review and approve the corrective action plans. As demonstrated below in Tables 7A and 7B, we estimate a burden reduction or savings of 630 hr (total) at a cost of \$57,465 (total) or \$5,747 (per state).

Please note that the 2015 final rule with comment period had set out a burden of 208 hr which was corrected in the Supporting Statement (approved by OMB on February 2, 2016) to reflect 630 hr, resulting in a difference of plus 422 hr.

TABLE 7A: Corrective Action Plan: Reduced Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Identifying Issues for Action	Management Analyst	-20	89.84	-1,796.80
Developing the Corrective Action	Management Analyst	-40	89.84	-3,593.60
Approve Corrective Action Plan	General and Operations Manager	-3	118.70	-356.10
TOTAL		-63	varies	-5,746.50

TABLE 7B: Corrective Action Plan: Reduced Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
10	-630 [-63 hr x 10 responses]	-5,747	-57,465

5. ICRs Regarding Public Process To Engage Stakeholders (§ 447.204(a)(1) and (2))

Current § 447.204(a)(1) and (2) require that states consider (when proposing to reduce or restructure Medicaid payment rates) the data collected through current § 447.203 and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid service payment rates on beneficiary access to care.

In our currently approved information collection request (CMS-10391; OMB 0938-1134), we estimated that approximately 22 states would develop and implement rate changes that would require a public process. Using the previously approved estimates of burden hours and updated adjusted hourly wage information, we also estimate that it would take an average of: 20 hr at \$89.84/hr for management analyst staff to develop the public process and 3 hr at \$118.70/hr for

managerial staff to review and approve the public process. As demonstrated below in Tables 8A and 8B, we estimate a burden reduction or savings of 506 hr (total) at a cost of \$47,364 (total) or \$2,153 (per state).

Please note that the 2015 final rule with comment period had set out a burden of 168 hr which was corrected in the Supporting Statement (approved by OMB on February 2, 2016) to reflect 506 hr, resulting in a difference of plus 338 hr.

TABLE 8A: Public Process: Reduced One-time Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Develop the Public Process	Management Analyst	-20	89.84	-1,796.80
Approve the Public Process	General and Operations Manager	-3	118.70	-356.10
TOTAL		-23	varies	-2,152.90

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

that it would take an average of: 40 hr at \$89.84/hr for management analyst staff to oversee the public process and 3 hr at \$118.70/hr for managerial staff to review and approve the public process.

As demonstrated below in Tables 9A and 9B, we estimate a burden reduction or savings of 946 hr (total) at a cost of \$86,893 (total) or \$3,950 (per state).

TABLE 9A: Public Process: Reduced On-going Burden Per State

Requirement	Occupation Title	Burden Hours	Adjusted Hourly Wage (\$/hr)	Cost Per Data Review (\$/State)
Oversee the Public Process	Management Analyst	-40	89.84	-3,593.60
Approve the Public Process	General and Operations Manager	-3	118.70	-356.10
TOTAL		-43	varies	-3,949.70

TABLE 9B: Public Process: Reduced On-going Total Burden

Anticipated Number of State Reviews	Total Hours	Cost of Review per State (\$)	Total Cost Estimate (\$)
22	-946 [-43 hr x 22 responses]	-3,950	-86,893

C. Summary of Proposed Collection of Information Requirements and Burden

TABLE 10A: Summary of Proposed One-time Collection of Information Requirements and Burden Reduction

Regulation Section(s)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
§447.203(b)(1) - (5)	51	51	80	4,080	47.14	192,331.20	0	192,331
			80	4,080	90.20	368,016.00	0	368,016
			100	5,100	89.84	458,184.00	0	458,184
			40	2,040	70.28	143,371.20	0	143,371
			10	510	118.70	60,537.00	0	60,537
<i>subtotal</i>	<i>51</i>	<i>51</i>	<i>310</i>	<i>15,810</i>	<i>Varies</i>	<i>1,222,439.40</i>	<i>0</i>	<i>1,222,439</i>
§447.203(b)(7)	51	51	100	5,100	89.84	458,184.00	0	458,184
			5	255	118.70	30,268.50	0	30,267
			<i>subtotal</i>	<i>51</i>	<i>51</i>	<i>105</i>	<i>5,355</i>	<i>Varies</i>
§447.203(b)(8)	10	10	60	600	89.84	53,904.00	0	53,904
			3	30	118.70	3,561.00	0	3,561
			<i>subtotal</i>	<i>10</i>	<i>10</i>	<i>63</i>	<i>630</i>	<i>Varies</i>
§447.204(a)(1) and (2)	22	22	20	440	89.84	39,529.60	0	39,530
		3	3	66	118.70	7,834.20	0	7,834
		<i>subtotal</i>	<i>22</i>	<i>22</i>	<i>23</i>	<i>506</i>	<i>Varies</i>	<i>47,363.80</i>
TOTAL*	51	134	501	22,301	Varies	1,815,720.70	0	1,815,721

*The 2015 final rule with comment period had set out a burden of 8,905 hr (80 FR 67608). As previously explained, we propose to change the number of respondents from 17 to 51 under §447.203(b)(1) through (5) and (7), resulting in a difference of 14,110 hr (10,540 hr + 3,570 hr) and a subtotal of 23,015 hr (8,905 hr + 14,110 hr). Under §§ 447.203(b)(8) and 447.204(a)(1) and (2) the burden was corrected in the Supporting Statement (approved by OMB on February 2, 2016) by 422 and 338 hr, respectively. Additionally, the rule had inadvertently included 1,474 hours of on-going burden related to § 447.203(b)(6)(ii). The error was identified and corrected in the approved Supporting Statement which set out an on-going burden of 8,191 hours (8,905 hr - 1,474 hr + 422 hr + 338 hr). The end result is a burden of 22,301 hr (8,191 hr + 14,110 hr).

TABLE 10B: Summary of Proposed On-going Collection of Information Requirements and Burden Reduction

Regulation Section(s)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
447.203(b)(1) - (5)	51	51	80	4,080	47.14	192,331.20	0	192,331
			80	4,080	90.20	368,016.00	0	368,016
			100	5,100	89.84	458,184.00	0	458,184
			40	2,040	70.28	143,371.20	0	134,371.20
			10	510	118.70	60,537.00	0	60,537
<i>subtotal</i>	<i>51</i>	<i>51</i>	<i>310</i>	<i>15,810</i>	<i>Varies</i>	<i>1,222,439.40</i>	<i>0</i>	<i>1,222,439</i>
447.203(b)(6)(ii)	22	22	64	1,408	89.84	126,494.72	0	126,495
			3	66	118.70	7,834.20	0	7,834
<i>subtotal</i>	<i>22</i>	<i>22</i>	<i>67</i>	<i>1,474</i>	<i>Varies</i>	<i>134,328.92</i>	<i>0</i>	<i>134,329</i>
447.203(b)(7)	51	51	75	3,825	89.84	343,638.00	0	343,638
			5	255	118.70	30,268.50	0	30,269
<i>subtotal</i>	<i>51</i>	<i>51</i>	<i>80</i>	<i>4,080</i>	<i>Varies</i>	<i>373,906.50</i>	<i>0</i>	<i>373,907</i>
447.204(a)(1) and (2)	22	22	40	880	89.84	79,059.20	0	79,059
			3	66	118.70	7,834.20	0	7,834
<i>subtotal</i>	<i>22</i>	<i>22</i>	<i>43</i>	<i>946</i>	<i>Varies</i>	<i>86,893.40</i>	<i>0</i>	<i>86,893</i>
TOTAL*	51	146	500	22,310	Varies	1,817,568.22	0	1,817,568

*The 2015 final rule with comment period had set out a subtotal of 20,836 hr which had inadvertently excluded 1,474 hr of on-going burden related to § 447.203(b)(6)(ii) requirements. The error was identified and corrected in the Supporting Statement (approved by OMB on February 2, 2016) which set out an on-going burden of 22,310 hr (20,836 hr + 1,474 hr).

TABLE 10C: Summary of Proposed Collection of Information Requirements and Total Burden Reduction

Regulation Section(s)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
Subtotal: One-time Requirements	51	134	501	22,301	Varies	1,815,720.70	0	1,815,721
Subtotal: On-going Requirements	51	146	500	22,310	Varies	1,817,568.22	0	1,817,568
TOTAL	51	280	1,001	44,611	Varies	3,633,288.92	0	3,633,289

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D. Submission of PRA-Related Comments

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

We invite public comments on these information collection requirements, and particularly on submission frequency and burden hours per response. If you wish to comment, please identify the rule (CMS-2406-P2), the CMS ID number (CMS-10391), and the OMB control number (0938-1134).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and->

Guidance/Legislation/Paperwork Reduction Act of 1995/PRA-Listing.html.

2. Email your request, including your address, phone number, OMB control number, and CMS document identifier (CMS-10391), to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786-1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

IV. Response to Comments

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

V. Regulatory Impact Statement

A. Statement of Need

We are concerned about the unnecessary administrative burden experienced by state Medicaid agencies in meeting the requirements of § 447.203(b)(1) through (8) and § 447.204(b) through (d), when we believe that similar information could be presented by states when necessary to demonstrate compliance with the statute without the need to develop and maintain AMRPs as currently required under the regulations. This proposed rule impacts states' documentation of compliance with section 1902(a)(30)(A) of the Act and would provide burden relief to all states. Although this proposed rule would remove the regulatory process requirements for states to develop and update an AMRP and to submit an access analysis when proposing to reduce or restructure provider payment rates in circumstances that could result in

diminished access, states are still obligated by the statute to ensure Medicaid payment rates are sufficient to enlist enough providers to assure that beneficiary access to covered care and services are available under the plan at least to the extent such care and services are available to the general population in the same geographic area, particularly when reducing or restructuring Medicaid payment rates through SPAs. This proposed rule would not remove, or otherwise limit, the states' obligation to comply with the statute, but would allow states greater flexibility in the way in which they demonstrate such compliance.

B. Overall Impact

We have examined the impacts of this proposed 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 (Pub. L. 96–354, enacted on September 19, 1980) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, enacted on March 22, 1995) (UMRA), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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

the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule is not economically significant with an overall estimated reduced reporting burden of \$3,633,289.

C. Anticipated Effects

1. Effects on State Medicaid Programs

We anticipate effects on state Medicaid programs as they would no longer be required to maintain and update the access monitoring review plans required under the current regulations. Importantly, the provisions of this proposed rule remove the regulatory procedural requirements for demonstrating access to care. However, states would not be exempt from the statutory requirements under section 1902(a)(30)(A) of the Act and would continue to be required to ensure access is consistent with the Act generally, and especially when seeking to reduce or restructure Medicaid payment rates.

2. Effects on Small Business and Providers

We do not anticipate effects on small businesses and providers because states are still required to comply with section 1902(a)(30)(A) of the Act and will need to demonstrate such compliance when they submit a SPA to reduce or restructure payment rates. We do not anticipate our SPA approval decisions will be impacted by removing the process requirements included in these regulations, as states will still need to demonstrate compliance with the Act.

3. Effects on the Medicaid Program

The estimated fiscal impact on the Medicaid program from the implementation of the proposed rule is estimated to be a net savings to Medicaid state agencies. This will have an effect on state administrative expenditures, which have been quantified in the collection of information requirements described previously in this proposed rule. While we acknowledge there will still be some level of state administrative burden associated with documenting compliance with the statute, we believe it is likely to be significantly less than the burden associated with carrying out the procedural requirements included in the current regulations, and are seeking comment specifically on this issue. We do not anticipate implementing this proposed rule would have an impact on a state’s Medicaid rates.

The RFA requires agencies to analyze options for regulatory relief of small

entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any one year). Individuals and states are not included in the definition of a small entity. As previously stated, we do not anticipate any effect on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This rule does not contain mandates that will impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, in excess of the threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule does not have a substantial direct cost impact on state or local governments.

D. Alternatives Considered

We considered, and previously proposed, setting a threshold for exemption from certain regulatory requirements for states with at least an 85 percent enrollment rate in comprehensive risk-based managed care. We also considered setting a threshold for proposed payment rate reductions that would be considered “nominal” and not subject to these regulatory requirements. After further consideration of these alternatives, we determined that neither alternative provided sufficient administrative

burden relief for states and that implementing the thresholds could be administratively challenging for both states and CMS, particularly in marginal cases where the state's managed care enrollment percentage or the percentage rate change approached the applicable threshold. Therefore, we believe that removing the regulatory requirements is the best course of action as we move forward in the development and implementation of a comprehensive approach to monitoring access across Medicaid delivery systems.

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule is expected to be an E.O. 13771 deregulatory action. We estimate that this rule generates \$3.63 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated cost savings of this rule can be found in the preceding analyses.

G. Conclusion

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

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, Rural areas.

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

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302.

§ 447.203 [Amended]

■ 2. Section 447.203 is amended by removing and reserving paragraph (b).

■ 3. Section 447.204 is revised to read as follows:

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

The agency's payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that those services are available to the general population in the geographic area.

Dated: January 28, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: February 13, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Editorial Note: This document was received by the Office of the Federal Register on July 10, 2019.

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