DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 438

[CMS-2402-P]

RIN 0938-AT10

Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems

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

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses changes, consistent with the CMCS Informational Bulletin (CIB) concerning "The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems," published on July 29, 2016, to the pass-through payment transition periods and the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). The changes prevent increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established in the final Medicaid managed care regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. [Insert Date 30 days after the date of publication in the **Federal Register]**.

ADDRESSES: In commenting please refer to file code CMS-2402-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-2402-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-2402-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

FOR FURTHER INFORMATION CONTACT:

John Giles, (410) 786-1255.

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://regulations.gov. Follow the search instructions on that website 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

In the June 1, 2015 **Federal Register** (80 FR 31098), we published the "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability" proposed rule ("June 1, 2015 proposed rule"). As part of the actuarial soundness proposals, we proposed to define actuarially sound capitation rates as those sufficient to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract, including furnishing of covered services and operation of the managed care plan for the duration of the contract. Among the proposals was a general rule that the state may not direct the MCO's, PIHP's, or PAHP's expenditures under the contract.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" final rule ("May 6, 2016 final rule"), which finalized the June 1, 2015 proposed rule. In the final rule, we finalized, with some revisions, the proposal which limited state direction of payments, including pass-through payments as defined below.

A. Summary of the Medicaid Managed Care May 6, 2016 Final Rule

We finalized a policy to limit state direction of payments, including pass-through payments at §438.6(d) in the May 6, 2016 final rule (81 FR 27587 through 27592). Specifically, under the final rule (81 FR 27588), we defined pass-through payments at §438.6(a) as any amount required by the state to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate, between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for the following purposes: a specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under §438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments. We noted that section 1903(m)(2)(A) of the Social Security Act (the Act) requires that capitation payments to managed care plans be actuarially sound; we interpret this requirement to mean that payments under the managed care contract must align with the provision of services to beneficiaries covered under the contract. We provided that these pass-through payments are not consistent with our standards for actuarially sound rates because they do not tie provider payments with the provision of services. The final rule contains a detailed description of the policy rationale (81 FR 27587 through 27592).

In an effort to provide a smooth transition for network providers, to support access for the beneficiaries they serve, and to provide states and managed care plans with adequate time to design and implement payment systems that link provider reimbursement with services covered under the contract or associated quality outcomes, we finalized transition periods related to pass-through payments for specified provider types to which states make most pass-through payments under Medicaid managed care programs: hospitals, physicians, and nursing homes (81 FR 27590

through 27592). As finalized, §438.6(d)(2) and (3) provide a 10-year transition period for hospitals, subject to limitations on the amount of pass-through payments. For MCO, PIHP, or PAHP contracts beginning on or after July 1, 2027, states will not be permitted to require pass-through payments for hospitals. The final rule also provides a 5-year transition period for pass-through payments to physicians and nursing facilities. For MCO, PIHP, or PAHP contracts beginning on or after July 1, 2022, states will not be permitted to require pass-through payments for physicians or nursing facilities. These transition periods provide states, network providers, and managed care plans significant time and flexibility to integrate current pass-through payment arrangements into allowable payment structures under actuarially sound capitation rates, including enhanced fee schedules or the other approaches consistent with §438.6(c)(1)(i) through (iii).

As finalized, §438.6(d) limits the amount of pass-through payments to hospitals as a percentage of the "base amount," which is defined in paragraph (a) and calculated pursuant to rules in paragraph (d)(2). Section 438.6(d)(3) specifies a schedule for the phased reduction of the base amount, limiting the amount of pass-through payments to hospitals. For contracts beginning on or after July 1, 2017, the state may require pass-through payments to hospitals under the contract up to 100 percent of the base amount, as defined in the final rule. For subsequent contract years (contracts beginning on or after July 1, 2018 through contracts beginning on or after July 1, 2026), the portion of the base amount available for pass-through payments decreases by 10 percentage points per year. For contracts beginning on or after July 1, 2027, no pass-through payments to hospitals are permitted. The May 6, 2016 final rule noted that nothing would prohibit a state from eliminating pass-through payments to hospitals before contracts beginning on or after July 1, 2027. However, the final rule provided for a phased reduction in the percentage of the base amount that can be used for pass-through payments,

because a phased transition would support the development of stronger payment approaches while mitigating any disruption to states and providers.

We believe that states will be able to more easily transition existing pass-through payments to physicians and nursing facilities to payment structures linked to services covered under the contract. Consequently, the May 6, 2016 final rule, in §438.6(d)(5), provided a shorter time period for eliminating pass-through payments to physicians and nursing facilities and did not require a prescribed limit or phase down for these payments; states have the option to eliminate these payments immediately or phase down these payments over the 5 year transition period if they prefer. As noted in the final rule, the distinction between hospitals and nursing facilities and physicians was also based on the comments from stakeholders during the public comment period (81 FR 27590).

B. Questions about the Final Rule

Since publication of the May 6, 2016 final rule, we have received inquiries about states' ability to integrate new or increased pass-through payments into Medicaid managed care contracts. As explained in the CMCS Informational Bulletin (CIB) published on July 29, 2016[1], adding new or increased pass-through payments for hospitals, physicians, or nursing facilities complicates the required transition of these pass-through payments to permissible provider payment models.

The transition periods under the final rule provide states, network providers, and managed care plans significant time and flexibility to move existing pass-through payment arrangements (that is, those in effect when the final rule was published) into different, permissible payment structures under actuarially sound capitation rates, including enhanced fee

[1] The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems; available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib072916.pdf. CMCS also noted in this CIB that it intended to further address in future rulemaking the issue of adding new or increased pass-through payments to managed care contracts.

schedules or the other approaches consistent with §438.6(c)(1)(i) through (iii). We did not intend states to begin additional or new pass-through payments, or to increase existing pass-through payments, notwithstanding the adjustments to the base amount permitted in §438.6(d)(2), after the final rule was published but before July 1, 2017; such actions are contrary to and undermine the policy goal of eliminating pass-through payments. We clarify that we would not permit a pass-through payment amount to exceed the lesser of the amounts calculated pursuant to paragraph (d)(3) of this proposed rule. For states to add new or to increase existing pass-through payments is inconsistent with longstanding CMS policy, the proposal made in the June 1, 2015 proposed rule, and the May 6, 2016 final rule, which reflects the general policy goal to effectively and efficiently transition away from pass-through payments.

Under the final rule, we provided a delayed compliance date for §438.6(c) and (d); we will enforce compliance with §438.6(c) and (d) no later than the rating period for Medicaid managed care contracts beginning on or after July 1, 2017. Our exercise of enforcement discretion in permitting delayed compliance was not intended to create new opportunities for states to add or increase existing pass-through payments before July 1, 2017. This delay was intended to address concerns articulated by commenters, among them states and providers, that an abrupt end to directed pass-through payments could cause damaging disruption to safety-net providers. As discussed in the final rule and this proposal, pass-through payments are inconsistent with our interpretation and implementation of the statutory requirement for actuarially sound capitation rates because pass-through payments do not tie provider payments to the provision of services under the contract (81 FR 27588). Further, such required payments reduce managed care plans' ability to control expenditures, effectively use value-based purchasing strategies, and implement provider-based quality initiatives. The May 6, 2016 final rule made clear our position on these payments and our intent that they be eliminated from

Medicaid managed care delivery systems, except for the directed payment models permitted by §438.6(c), or the payments excluded from the definition of a pass-through payment in §438.6(a), such as FQHC wrap payments.

The transition periods provided under §438.6(d) are for states to identify existing pass-through payments and begin either tying such payments directly to services and utilization covered under the contract or eliminating them completely in favor of other support mechanisms for providers that comply with the requirements in §438.6(c). The transition periods for current pass-through payments minimize disruption to local health care systems and interruption of beneficiary access by permitting a gradual step down from current levels of pass-through payments: (1) at the schedule and subject to the limit announced in the May 6, 2016 final rule for hospitals under §438.6(d)(3); and (2) at a schedule adopted by the state for physicians and nursing facilities under §438.6(d)(5). By providing states, network providers, and managed care plans significant time and flexibility to integrate current pass-through payment arrangements into different payment structures (including enhanced fee schedules or the other approaches consistent with §438.6(c)(1)(i) through (c)(1)(iii)) and into actuarially sound capitation rates, we intended to address comments that the June 1, 2015 proposed rule would be unnecessarily disruptive and endanger safety-net provider systems that states have developed for Medicaid.

Recent questions from states indicate the transition period and delayed enforcement date have caused some confusion regarding our intent for increased and new pass-through payments for contracts prior to July 1, 2017, because the final rule did not explicitly prohibit such additions or increases. While we assumed such a prohibition in the final rule, we believe that additional rulemaking is necessary to clarify this issue in light of these comments. Under this proposed rule, we are linking pass-through payments permitted during the transition period to the aggregate amounts of pass-through payments that were in place at the time the May 6, 2016 final

rule became effective on July 5, 2016, which is consistent with the intent under the final rule to phase out pass-through payments under Medicaid managed care contracts.

II. Provisions of the Current Proposed Rule

For reasons discussed above, we propose to revise §438.6(d) to better effectuate the intent of the May 6, 2016 final rule. First, we propose to limit the availability of the transition periods in §438.6(d)(3) and (5) (that is, the ability to continue pass-through payments for hospitals, physicians, or nursing facilities) to states that can demonstrate that they had such pass-through payments in either: (A) managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016, and that were submitted for our review and approval on or before July 5, 2016; or (B) if the managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016 had not been submitted to us on or before July 5, 2016, the managed care contract(s) and rate certification(s) for a rating period before July 5, 2016 that had been most recently submitted to us for review and approval as of July 5, 2016.

Second, we propose to prohibit retroactive adjustments or amendments, notwithstanding the adjustments to the base amount permitted in §438.6(d)(2), to managed care contract(s) and rate certification(s) to add new pass-through payments or increase existing pass-through payments defined in §438.6(a). In this proposed rule, we clarify that we would not permit a pass-through payment amount to exceed the lesser of the amounts calculated pursuant to paragraph (d)(3).

Third, we propose to establish a new maximum amount of permitted pass-through payments for each year of the transition period. For hospitals, a state would be limited (in the total amount of permissible pass-through payments) during each year of the transition period to the lesser of either: (A) the percentage of the base amount applicable to that contract year; or (B) the pass-through payment amount identified in proposed paragraph (d)(1)(i). Thus, the amount

of pass-through payments identified by the state in order to satisfy proposed paragraph (d)(1)(i) would be compared to the amount representing the applicable percentage of the base amount that is calculated for each year of the transition period. For pass-through payments to physicians and nursing facilities, we also propose to limit the amount of pass-through payments during the transition period to the amount of pass-through payments to physicians and nursing facilities under the contract and rate certification identified in proposed paragraph (d)(1)(i). In making these comparisons to the pass-through payments under the managed care contract(s) in effect for the rating period covering July 5, 2016 as identified in proposed paragraph (d)(1)(i)(A), or the rating period before July 5, 2016 as identified in proposed paragraph (d)(1)(i)(B), we will look at total pass-through payment amounts for the specified provider types. Past aggregate amounts of hospital pass-through payments will be used in determining the maximum amount for hospital pass-through payments during the transition period; past aggregate amounts of physician pass-through payments will be used in determining the maximum amount for physician pass-through payments during the transition period; and past aggregate amounts of nursing facility pass-through payments will be used in determining the maximum amount for nursing facility pass-through payments during the transition period.

Under our proposed rule, the aggregate amounts of pass-through payments in each provider category would be used to set applicable limits for the provider type during the transition period, without regard to the specific provider(s) that receive a pass-through payment. For example, if the pass-through payments in the contract identified under paragraph (d)(1)(i) were to 5 specific hospitals, the aggregate amount of pass-through payments to those hospitals would be relevant in establishing the limit during the transition period, but different hospitals could be the recipients of pass-through payments during the transition. As an alternative, we also considered whether the state should be limited by amount and recipient during the transition

period; in our example, this would mean that only those 5 hospitals that received pass-through payments could receive such payments during the transition period. However, we believe this narrower policy would be more limiting than originally intended under the May 6, 2016 final rule when the transition periods were finalized. We request comment on our proposed approach. To implement our proposal, we propose to amend the existing regulation text to revise paragraph (d)(1) (including new (d)(1)(i) and (ii)), revise paragraph (d)(3) (including new (d)(3)(i) and (ii)), and revise paragraph (d)(5) as described below.

We propose to revise paragraph (d)(1) to clarify that a state may continue to require an MCO, PIHP, or PAHP to make pass-through payments (as defined in §438.6(a)) to network providers that are hospitals, physicians, or nursing facilities under the contract, provided the requirements of paragraph (d) are met. We are proposing to retain the regulation text that provides explicitly that states may not require MCOs, PIHPs, or PAHPs to make pass-through payments other than those permitted under paragraph (d).

Under proposed paragraph (d)(1)(i), a state would be able to use the transition period for pass-through payments to hospitals, physicians, or nursing facilities only if the state can demonstrate that it had pass-through payments for hospitals, physicians, or nursing facilities, respectively, in both the managed care contract(s) and rate certification(s) that meet the requirements in either proposed paragraph (d)(1)(i)(A) or (B). We recognize that states may have multiple managed care plans and therefore multiple contracts and rate certifications that are necessary to establish the existence and amount of pass-through payments. We propose in paragraph (d)(1)(i)(A) that the managed care contract(s) and rate certification(s) must be for the rating period that includes July 5, 2016 and have been submitted for our review and approval on or before July 5, 2016. If the state had not yet submitted MCO, PIHP, or PAHP contract(s) and rate certification(s) for the rating period that includes July 5, 2016, we propose in paragraph

(d)(1)(i)(B) that the state must demonstrate that it required the MCO, PIHP, or PAHP to make pass-through payments for a rating period before July 5, 2016 in the managed care contract(s) and rate certification(s) that were most recently submitted for our review and approval as of July 5, 2016. We propose to use the date July 5, 2016 for the purpose of identifying the pass-through payments in managed care contract(s) and rate certification(s) that are eligible for the pass-through payment transition period because it is consistent with the intent of the May 6, 2016 final rule that the transition period be used by states that had pass-through payments in their MCO, PIHP, or PAHP contracts when we finalized that rule. These are the states for which we were concerned, based on the comments to the June 1, 2015 proposed rule, that an abrupt end to pass-through payments could be disruptive to their health care delivery system and safety-net providers. We believe that limiting the use of the transition period to states that had pass-through payments in effect as of the effective date of the May 6, 2016 final rule provides for the achievement of the policy goal of eliminating these types of payments. We did not intend for the May 6, 2016 final rule to incentivize or encourage states to add new pass-through payments, as we believe that these payments are inconsistent with actuarially sound rates.

Under proposed paragraph (d)(1)(ii), we would not approve a retroactive adjustment or amendment, notwithstanding the adjustments to the base amount permitted in §438.6(d)(2), to managed care contract(s) and rate certification(s) to add new pass-through payments or increase existing pass-through payments defined in §438.6(a). We clarify that we would not permit a pass-through payment amount to exceed the lesser of the amounts calculated pursuant to paragraph (d)(3) of this proposed rule. We are proposing paragraph (d)(1)(ii) to prevent states from undermining our policy goal to limit the use of the transition period to states that had pass-through payments in effect as of the effective date of the May 6, 2016 final rule. This proposed change also supports the policy rationale under the May 6, 2016 final rule and the July 29, 2016

CMCS Informational Bulletin (CIB) by prohibiting new or increased pass-through payments in Medicaid managed care contract(s), notwithstanding the adjustments to the base amount described above. As stated in the final rule and CIB, we believe that pass-through payments are not consistent with the statutory requirements in section 1903(m) of the Act and regulations for actuarially sound capitation rates because pass-through payments do not tie provider payments with the provision of services. The proposed change also addresses our concern that new or increased pass-through payments substantially complicate the required transition of pass-through payments to permissible provider payment models, as such additions or increases by states will further delay the development of permissible, stronger payment approaches that are based on the utilization or delivery of services to enrollees covered under the contract, or the quality and outcomes of services.

As an alternative to proposed paragraphs (d)(1)(i) and (ii), we considered linking eligibility for the transition period to those states with pass-through payments for hospitals, physicians, or nursing facilities that were in approved (not just submitted for our review and approval) managed care contract(s) and rate certification(s) only for the rating period covering July 5, 2016. However, we believe that such an approach is not administratively feasible for states or CMS because it does not recognize the nuances of the timing and approval processes; we believe our proposed approach provides the appropriate parameters and conditions for pass-through payments in managed care contract(s) and rate certification(s) during the transition period. We request comment on our proposed approach.

In proposed paragraph (d)(3), we propose to amend the cap on the amount of pass-through payments to hospitals that may be incorporated into managed care contract(s) and rate certification(s) during the transition period for hospital payments, which will apply to rating periods for contract(s) beginning on or after July 1, 2017. Specifically, we propose to revise

§438.6(d)(3) to require that the limit on pass-through payments each year of the transition period be the lesser of: (A) the sum of the results of paragraphs (d)(2)(i) and (ii)[2], as modified under the schedule in this paragraph (d)(3); or (B) the total dollar amount of pass-through payments to hospitals identified by the state in the managed care contract(s) and rate certification(s) used to meet the requirement in paragraph (d)(1)(i). This proposed language would limit the amount of pass-through payments each contract year to the lesser of the calculation adopted in the May 6, 2016 final rule (the "base amount"), as decreased each successive year under the schedule in this paragraph (d)(3), or the total dollar amount of pass-through payments to hospitals identified by the state in managed care contract(s) and rate certification(s) described in paragraph (d)(1)(i). For example, if a state had $10 million in pass-through payments to hospitals in the contract and rate certification used to meet the requirement in paragraph (d)(1)(i), that $10 million figure would be compared each year to the base amount as reduced on the schedule described in this paragraph (d)(3); the lower number would be used to limit the total amount of pass-through payments to hospitals allowed for that specific contract year.

This proposed language would prevent increases of aggregate pass-through payments for hospitals during the transition period beyond what was already in place when the pass-through payment limits and transition periods were finalized in the May 6, 2016 final rule. As an alternative to our proposal here, we considered stepping down both the base amount (as provided in paragraph (d)(3)) and the total dollar amount of pass-through payments to hospitals identified by the state in managed care contract(s) and rate certification(s) described in paragraph (d)(1)(i), as part of the lesser of calculation. The lower stepped-down amount would be used as the cap

[2] The portion of the base amount calculated in §438.6(d)(2)(i) is analogous to performing UPL calculations under a FFS delivery system, using payments from managed care plans for Medicaid managed care hospital services in place of the state's payments for FFS hospital services under the state plan. The portion of the base amount calculated in §438.6(d)(2)(ii) takes into account hospital services and populations included in managed care during the rating period that includes pass-through payments which were in FFS two years prior.

each year of the transition period. However, we believe such an approach would require a state to phase down their pass-through payments more quickly than originally intended under the May 6, 2016 final rule. Our proposal here is not intended to speed up the rate of a state's phase down of pass-through payments; rather, we are intending to prevent increases in pass-through payments and the addition of new pass-through payments beyond what was already in place when the pass-through payment limits and transition periods were finalized given that this was the final rule's intent. We request comment on our proposed approach.

In addition, we are proposing to amend paragraph (d)(3) to provide that states must meet the requirements in paragraph (d)(1)(i) to continue pass-through payments for hospitals during the transition period. We believe this additional text is necessary to be consistent with our intent, explained above, for the proposed revisions to paragraph (d)(1). As in the May 6, 2016 final rule, pass-through payments to hospitals must be phased out no longer than on the 10-year schedule, beginning with rating periods for contracts that start on or after July 1, 2017. We added the phrase "rating periods" to be consistent with our terminology in the final rule; we made this clarifying edit throughout proposed paragraphs (d)(3) and (d)(5). We request comment on our proposed amendments to paragraph (d)(3).

Finally, we are proposing to revise §438.6(d)(5) to be consistent with the proposed revisions in §438.6(d)(1)(i) and to limit the total dollar amount of pass-through payments that is available each contract year for physicians and nursing facilities. We are not proposing to implement a phase-down for pass-through payments to physicians or nursing facilities. We propose that for states that meet the requirements in paragraph (d)(1)(i), rating periods for contracts beginning on or after July 1, 2017 through rating periods for contracts beginning on or after July 1, 2021, may continue to require pass-through payments to physicians or nursing facilities under the MCO, PIHP, or PAHP contract; such pass-through payments may be no more

than the total dollar amount of pass-through payments for each category identified in the managed care contracts and rate certifications used to meet the requirement in paragraph (d)(1)(i). We added the phrase "rating periods" to be consistent with our terminology in the final rule; we made this clarifying edit throughout proposed paragraphs (d)(3) and (d)(5). This approach is consistent with the general goal of not increasing pass-through payments beyond what was included as of the effective date of the final rule when the pass-through payment limits and transition periods were finalized and creating a consistent standard in alignment with the proposed changes in §438.6(d)(3) to limit increasing pass-through payments made to hospitals, physicians, and nursing facilities under Medicaid managed care contracts. We request comment on our proposal as a whole and the specific proposed regulation text.

III. Collection of Information Requirements

This rule would not impose any new or revised information collection, reporting, recordkeeping, or third-party disclosure requirements or burden. Our proposed revision of §438.6(d) would not impose any new or revised IT system requirements or burden because the existing regulation at §438.7 requires the rate certification to document special contract provisions under §438.6. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

IV. Regulatory Impact Analysis

A. Statement of Need

As discussed throughout this proposed rule, we have significant concerns that pass-through payments have negative consequences for the delivery of services in the Medicaid program. The existence of pass-through payments may affect the amount that a managed care plan is willing or able to pay for the delivery of services through its base rates or fee schedule.

In addition, pass-through payments make it more difficult to implement quality initiatives or to direct beneficiaries' utilization of services to higher quality providers because a portion of the capitation rate under the contract is independent of the services delivered and outside of the managed care plan's control. Put another way, when the fee schedule for services is set below the normal market, or negotiated rate, to account for pass-through payments, moving utilization to higher quality providers can be difficult because there may not be adequate funding available to incentivize the provider to accept the increased utilization. When pass-through payments guarantee a portion of a provider's payment and divorce the payment from service delivery, it is more challenging for managed care plans to negotiate provider contracts with incentives focused on outcomes and managing individuals' overall care.

We realize that some pass-through payments have served as a critical source of support for safety-net providers who provide care to Medicaid beneficiaries. Several commenters raised this issue in response to the June 1, 2015 proposed rule[3]. Therefore, in response to some commenters' request for a delayed implementation of the limitation on directed payments and to address concerns that an abrupt end to these payments could create significant disruptions for some safety-net providers who serve Medicaid managed care enrollees, we included in the May 6, 2016 final rule a delay in the compliance date and a transition period for existing pass-through payments to hospitals, physicians, and nursing facilities. These transition periods begin with the compliance date, and were designed and finalized to enable affected providers, states, and managed care plans to transition away from existing pass-through payments. Such payments could be transitioned into payments tied to covered services, value-based payment structures, or delivery system reform initiatives without undermining access for the beneficiaries; alternatively, states could step down such payments and devise other methods to support safety-net providers

[3] Available at: https://www.gpo.gov/fdsys/pkg/FR-2015-06-01/pdf/2015-12965.pdf

to come into compliance with §438.6(c) and (d).

However, as noted previously, the transition period and delayed enforcement date caused some confusion regarding increased and new pass-through payments. The May 6, 2016 final rule created a strong incentive for states to move swiftly to put pass-through payments into place in order to take advantage of the pass-through payment transition periods established in the May 6, 2016 final rule. Contrary to our discussion in the May 6, 2016 final rule regarding the statutory requirements in section 1903(m) of the Act and regulations for actuarially sound capitation rates, some states expressed interest in developing new and increased pass-through payments for their respective Medicaid managed care programs as a result of the May 6, 2016 final rule. In response to this interest, we published the July 29, 2016 CMCS Informational Bulletin (CIB) to quickly address questions regarding the ability of states to increase or add new pass-through payments under Medicaid managed care plan contracts and capitation rates, and to describe our plan for monitoring the transition of pass-through payments to approaches for provider payment under Medicaid managed care programs that are based on the delivery of services, utilization, and the outcomes and quality of the delivered services.

We noted in the CIB that the transition from one payment structure to another requires robust provider and stakeholder engagement, agreement on approaches to care delivery and payment, establishing systems for measuring outcomes and quality, planning efforts to implement changes, and evaluating the potential impact of change on Medicaid financing mechanisms. Whether implementing value-based payment structures, implementing other delivery system reform initiatives, or eliminating pass-through payments, there will be transition issues for states coming into compliance; adequately working through transition issues, including ensuring adequate base rates, is central to both delivery system reform and to strengthening access, quality, and efficiency in the Medicaid program. We stressed that the purpose and

intention of the transition periods is to acknowledge that pass-through payments existed prior to the final rule and to provide states, network providers, and managed care plans time and flexibility to integrate existing pass-through payment arrangements into permissible payment structures.

As we noted in the CIB and throughout this proposed rule, we believe that adding new or increased pass-through payments for hospitals, physicians, or nursing facilities, beyond what was included as of July 5, 2016, into Medicaid managed care contracts exacerbates a problematic practice that is inconsistent with our interpretation of statutory and regulatory requirements, complicates the required transition of these pass-through payments to stronger payment approaches that are based on the utilization or delivery of services to enrollees covered under the contract, or the quality and outcomes of such services, and reduces managed care plans' ability to effectively use value-based purchasing strategies and implement provider-based quality initiatives. In the CIB, we signaled the possible need, and our intent, to further address this policy in future rulemaking and link pass-through payments through the transition period to the amounts of pass-through payments in place at the time the Medicaid managed care rule was effective on July 5, 2016.

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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of

available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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). We estimate that this rule is "economically significant" as measured by the $100 million threshold, and hence a major rule under the Congressional Review Act.

The May 6, 2016 final rule included a RIA (81 FR 27830). During that analysis, we did not project a significant fiscal impact for §438.6(d). When we reviewed and analyzed the May 6, 2016 final rule, we concluded that states would have other mechanisms to build in the amounts currently provided through pass-through payments in approvable ways, such as approaches consistent with §438.6(c)(1)(i) through (iii). If a state was currently building in $10 million in pass-through payments to hospitals under their current managed care contracts, we assumed that the state would incorporate the $10 million into their managed care rates in permissible ways rather than spending less in Medicaid managed care. While it is possible that

this would be more difficult for states with relatively larger amounts of pass-through payments, the long transition period provided under the May 6, 2016 final rule to phase out pass-through payments should help states to integrate existing pass-through payments into actuarially sound capitation rates through permissible Medicaid financing structures, including enhanced fee schedules or the other approaches consistent with §438.6(c)(1)(i) through (iii).

A number of states have integrated some form of pass-through payments into their managed care contracts for hospitals, nursing facilities, and physicians. In general, the size and number of the pass-through payments for hospitals has been more significant than for nursing facilities and physicians. We noted in the final rule (81 FR 27589) a number of reasons provided by states for using pass-through payments in their managed care contracts. As of the effective date of the final rule, we estimate that at least eight states have implemented approximately $105 million in pass-through payments for physicians annually; we estimate that at least three states have implemented approximately $50 million in pass-through payments for nursing facilities annually; and we estimate that at least 16 states have implemented approximately $3.3 billion in pass-through payments for hospitals annually. These estimates are somewhat uncertain, as before the final rule, we did not have regulatory requirements for states to document and describe pass-through payments in their managed care contracts or rate certifications. The amount of pass-through payments often represents a significant portion of the overall capitation rate under a managed care contract. We have seen pass-through payments that have represented 25 percent, or more, of the overall managed care contract and 50 percent of individual rate cells. The rationale for these pass-through payments in the development of the capitation rates is often not transparent, and it is not clear what the relationship of these pass-through payments is to the provision of services or the requirement for actuarially sound rates.

Since the publication of the final rule, we received a formal proposal from one state

regarding $250 – 275 million in pass-through payments to hospitals; we have been working with the state to identify permissible implementation options for their proposal, including under §438.6(c), and tie such payments to the utilization and delivery of services (as well as the outcomes of delivered services). We heard informally that two additional states are working to develop pass-through payment mechanisms to increase total payments to hospitals by approximately $10 billion cumulatively. We also heard informally from one state regarding a $200 million proposal for pass-through payments to physicians. We also continue to receive inquiries from states, provider associations, and consultants who are developing formal proposals to add new pass-through payments, or increase existing pass-through payments, and incorporate such payments into Medicaid managed care rates. While it is difficult for us to conduct a detailed quantitative analysis given this considerable uncertainty and lack of data, we believe that without this proposed (and a subsequent final) rulemaking, states would continue to ramp-up pass-through payments in ways that are not consistent with the pass-through payment transition periods established in the final rule.

Since we cannot produce a detailed quantitative analysis, we have developed a qualitative discussion for this RIA. We believe there are many benefits with this regulation, including consistency with the statutory requirements in section 1903(m) of the Act and regulations for actuarially sound capitation rates, improved transparency in rate development processes, stronger payment approaches that are based on the utilization or delivery of services to enrollees covered under the contract, or the quality and outcomes of such services, and improved support for delivery system reform that is focused on improved care and quality for Medicaid beneficiaries. We believe that the costs of this regulation to state and federal governments will not be significant; CMS currently reviews and works with states on managed care contracts and rates, and because pass-through payments exist today, any additional costs to state or federal

governments should be negligible.

Relative to the current baseline, this rule is likely to prevent increases in or the development of new pass-through payments, which would reduce state and federal government transfers to hospitals, physicians, and nursing facilities. Because we lack sufficient information to forecast the eventual overall impact of the May 6, 2016 final rule on state pass-through payments, we provide only a qualitative discussion of the impact of this rule on avoided transfers. Given these avoided transfers, we believe this rule is economically significant as defined by Executive Order 12866.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Small entities are those entities, such as health care providers, having revenues between $7.5 million and $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We do not believe that this proposed rule would have a significant economic impact on a substantial number of small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that 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 a Metropolitan Statistical Area and has fewer than 100 beds. We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on small rural hospitals. We are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities or a significant impact on

the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

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 2016, that is approximately $146 million. This proposed rule does not mandate any costs (beyond this threshold) resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirements or costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

D. Alternatives Considered

During the development of this proposed rule, we assessed all regulatory alternatives and discussed in the preamble a few alternatives that we considered. First, in discussing our proposed revisions to paragraphs (d)(1)(i) and (ii) in this proposed rule, we considered linking eligibility for the transition period to those states with pass-through payments for hospitals, physicians, or nursing facilities that were in approved (not just submitted for CMS review and approval) managed care contract(s) and rate certification(s) only for the rating period covering July 5, 2016. However, we believe that such an approach is not administratively feasible for states or CMS because it does not recognize the nuances of the timing and approval processes;

we believe our proposed approach provides the appropriate parameters and conditions for pass-through payments in managed care contract(s) and rate certification(s) during the transition period.

Second, in discussing our proposed revisions to paragraphs (d)(3) and (d)(5) in this proposed rule, we described that the aggregate amounts of pass-through payments in each provider category would be used to set applicable limits for the provider type during the transition period, without regard to the specific provider(s) that receive a pass-through payment. As an alternative, we considered whether the state should be limited by amount and recipient during the transition period; however, we believe this narrower policy would be more limiting than originally intended under the May 6, 2016 final rule when the pass-through payment transition periods were finalized.

E. Accounting Statement

As discussed in this RIA, the benefits, costs, and transfers of this regulation are identified in table 1 as qualitative impacts only.

TABLE 1: Accounting Statement

				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Non-Quantified	Benefits include: consistency with the statutory requirements in section 1903(m) of the Act and regulations for actuarially sound capitation rates; improved transparency in rate development processes; stronger payment approaches that are based on the utilization or delivery of services to enrollees covered under the contract, or the quality and outcomes of such services; and improved support for delivery system reform that is focused on improved care and quality for Medicaid beneficiaries.						
Costs							
Non-Quantified	Costs to state or federal governments should be negligible.						
Transfers							
Non-Quantified	Relative to the current baseline, this rule is likely to prevent increases in or the development of new pass-through payments, which would reduce state and federal government transfers to hospitals, physicians, and nursing facilities. Given these avoided transfers, we believe this rule is economically significant as defined by Executive Order 12866.						

List of Subjects in 42 CFR Part 438

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

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

PART 438—MANAGED CARE

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

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

2. Section 438.6 is amended by revising paragraphs (d)(1), (3), and (5) to read as follows:

§438.6 Special contract provisions related to payment.

* * * * *

(d) * * * (1) General rule. States may continue to require MCOs, PIHPs, and PAHPs to make pass-through payments (as defined in paragraph (a) of this section) to network providers that are hospitals, physicians, or nursing facilities under the contract, provided the requirements of this paragraph (d) are met. States may not require MCOs, PIHPs, and PAHPs to make pass-through payments other than those permitted under this paragraph (d).

(i) In order to use a transition period described in this paragraph (d), a State must demonstrate that it had pass-through payments for hospitals, physicians, or nursing facilities in:

(A) Managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016, and were submitted for CMS review and approval on or before July 5, 2016; or

(B) If the managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016 had not been submitted to CMS on or before July 5, 2016, the managed care contract(s) and rate certification(s) for a rating period before July 5, 2016 that had been most recently submitted for CMS review and approval as of July 5, 2016.

(ii) CMS will not approve a retroactive adjustment or amendment, notwithstanding the

adjustments to the base amount permitted in paragraph (d)(2) of this section, to managed care contract(s) and rate certification(s) to add new pass-through payments or increase existing pass-through payments defined in paragraph (a) of this section.

* * * * *

(3) Schedule for the reduction of the base amount of pass-through payments for hospitals under the MCO, PIHP, or PAHP contract and maximum amount of permitted pass-through payments for each year of the transition period. For States that meet the requirement in paragraph (d)(1)(i) of this section, pass-through payments for hospitals may continue to be required under the contract but must be phased out no longer than on the 10-year schedule, beginning with rating periods for contract(s) that start on or after July 1, 2017. For rating periods for contract(s) beginning on or after July 1, 2027, the State cannot require pass-through payments for hospitals under a MCO, PIHP, or PAHP contract. Until July 1, 2027, the total dollar amount of pass-through payments to hospitals may not exceed the lesser of:

(i) A percentage of the base amount, beginning with 100 percent for rating periods for contract(s) beginning on or after July 1, 2017, and decreasing by 10 percentage points each successive year; or

(ii) The total dollar amount of pass-through payments to hospitals identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section.

* * * * *

(5) Pass-through payments to physicians or nursing facilities. For States that meet the requirement in paragraph (d)(1)(i) of this section, rating periods for contract(s) beginning on or after July 1, 2017 through rating periods for contract(s) beginning on or after July 1, 2021, may continue to require pass-through payments to physicians or nursing facilities under the MCO,

PIHP, or PAHP contract of no more than the total dollar amount of pass-through payments to physicians or nursing facilities, respectively, identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section. For rating periods for contract(s) beginning on or after July 1, 2022, the State cannot require pass-through payments for physicians or nursing facilities under a MCO, PIHP, or PAHP contract.

* * * * *

CMS-2402-P

Dated: November 10, 2016.

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare &

Medicaid Services.

Dated: November 10, 2016.

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Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

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