DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438 and 457

[CMS–2408–P]

RIN 0938–AT40

Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care

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

ACTION: Proposed rule.

SUMMARY: This proposed rule advances CMS' efforts to streamline the Medicaid and Children's Health Insurance Plan (CHIP) managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. These proposed revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 14, 2019.

ADDRESSES: In commenting, please refer to file code CMS–2408–P. 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–2408–P, P.O. Box 8016, Baltimore, MD 21244–8013.

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–2408–P, 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:

John Giles, (410) 786–1255, for Medicaid Managed Care Operations.

Jennifer Sheer, (410) 786–1769, for the Medicaid Managed Care Quality provisions.

Melissa Williams, (410) 786–4435, for the CHIP provisions.

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.

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. Medicaid Managed Care

A. Background

States may implement a managed care delivery system using four types of federal authorities—sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act); each is described briefly below.

Under section 1915(a) of the Act, states can implement a voluntary managed care program by executing a contract with organizations that the state has procured using a competitive procurement process. To require beneficiaries to enroll in a managed care program to receive services, a state must obtain approval from CMS under two primary authorities:

- Through a state plan amendment that meets standards set forth in section 1932(a) of the Act, states can implement a mandatory managed care delivery system. This authority does not allow states to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible), American Indians/Alaska Natives (except as permitted in section 1932(a)(2)(C) of the Act), or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the state.
- We may grant a waiver under section 1915(b) of the Act, permitting a state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a state may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2- (or 5-) year period.

We may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that include waivers permitting the state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, states may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such flexibility is approvable only if the objectives of the Medicaid statute are likely to be met, and the demonstration is subject to evaluation.

These authorities may permit states to operate their programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- *Statewideness* [section 1902(a)(1) of the Act]: States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole state;
- *Comparability of Services* [section 1902(a)(10) of the Act]: States may provide different benefits to people enrolled in a managed care delivery system; and
- *Freedom of Choice* [section 1902(a)(23)(A) of the Act]: States may generally require people to receive their Medicaid services only from a managed care plan's network of providers or primary care provider.

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 (hereinafter referred to as ''the 2016 final rule'') that modernized the Medicaid and CHIP managed care regulations to reflect changes in the use of managed care delivery systems. The 2016 final rule aligned many of the rules governing Medicaid and CHIP managed care with those of other major sources of coverage; implemented applicable statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of managed care program rates; strengthened efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries; and enhanced policies related to program integrity.

In the January 18, 2017 **Federal Register** (82 FR 5415), we published the ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' final rule (the 2017 pass-through payments final rule) that made changes 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). That final rule prevented 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.

Since publication of the 2016 final rule, the landscape for healthcare delivery continues to change, and states are continuing to work toward reforming healthcare delivery systems to address the unique challenges and needs of their local citizens. To that end, the Department of Health and Human Services (HHS) and CMS issued a letter [1] to the nation's Governors on March 14, 2017, affirming the continued HHS and CMS commitment to partnership with states in the administration of the Medicaid program, and noting key areas where we would improve collaboration with states and move toward more effective program management. In that letter, we committed to a thorough review of the managed care regulations to prioritize beneficiary outcomes and state priorities.

Since our issuance of that letter, stakeholders have expressed that the current federal regulations are overly prescriptive and add costs and administrative burden to state Medicaid programs with little improvements in outcomes for beneficiaries. As part of the agency's broader efforts to reduce administrative burden, we undertook a review to analyze the current managed care regulations to ascertain if there were ways to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule is the result of that review and seeks to streamline the managed care regulations by reducing unnecessary and duplicative administrative burden and further reducing federal regulatory barriers to help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

B. Provisions of the Proposed Rule

This preamble discusses our proposed changes in the context of the current law. Throughout this document, the term ''PAHP'' is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it would be specifically addressed as a ''Non-Emergency Medical Transportation (NEMT) PAHP.''

1. Standard Contract Requirements (§ 438.3)

In the 2016 final rule, we added a new provision at 42 CFR 438.3(t) requiring that contracts with a managed care organization (MCO), prepaid inpatient health plan (PIHP), or PAHP that cover Medicare-Medicaid dually eligible enrollees provide that the MCO, PIHP, or PAHP sign a Coordination of Benefits Agreement (COBA) and participate in the automated crossover claim process administered by Medicare. The purpose of this provision was to promote efficiencies for providers by allowing providers to bill once, rather than sending separate claims to Medicare and the Medicaid MCO, PIHP, or PAHP.

Since publication of the 2016 final rule, we have heard from a number of states that, prior to the rule, had effective processes in place to identify and send appropriate crossover claims to their managed care plans from the crossover file the states received from us. Medicaid beneficiaries can be enrolled in multiple managed care plans and/or the state's fee-for-service (FFS) program. For example, a beneficiary may have medical care covered by an MCO, dental care covered by a PAHP, and behavioral health care covered by the state's FFS program. However, when a managed care plan enters into a crossover agreement with Medicare, as required in § 438.3(t), we then send crossover claims for Medicaid managed care enrollees of that plan to the managed care plans, as well as to the state Medicaid agency. When this occurs, the managed care plan(s) may receive claims for services that are not the contractual responsibility of the managed care plan. Additionally, states noted that having all claims sent to the managed care plan(s) can result in some claims being sent to the wrong plan when beneficiaries change plans. These states have expressed that to discontinue existing effective processes for routing crossover claims to their managed care plans to comply with this provision adds unnecessary costs and burden to the state and plans, creates confusion for payers and providers, and delays provider payments.

To address these concerns, we propose to revise § 438.3(t) to remove the requirement that managed care plans must enter into a COBA directly and instead would require contracts with managed care plans to specify the methodology by which the state would ensure that the managed care plans receive all appropriate crossover claims for which they are responsible. Under this proposal, states would be able to determine the method that best meets the needs of their program, whether by requiring the managed care plans to enter into a COBA and participate in the automated claims crossover process directly or by using an alternative method by which the state forwards appropriate crossover claims it receives from Medicare to each MCO, PIHP, or PAHP. Additionally, we propose to include a requirement that, if the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

2. Actuarial Soundness Standards (§ 438.4)

a. Option To Develop and Certify a Rate Range (§ 438.4(c))

As noted in the 2016 final rule, before the 2016 final rule was published, we

[1] Letter to the nation's Governors on March 14, 2017: *https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf*.

considered any capitation rate paid to a managed care plan that fell anywhere within the certified rate range to be actuarially sound (81 FR 27567). However, to make the rate setting and the rate approval process more transparent, we changed that process in the 2016 final rule at § 438.4 to require that states develop and certify as actuarially sound each individual rate paid per rate cell to each MCO, PIHP, or PAHP with enough detail to understand the specific data, assumptions, and methodologies behind that rate (81 FR 27567). We noted that states could continue to use rate ranges to gauge an appropriate range of payments on which to base negotiations with an MCO, PIHP, or PAHP, but would have to ultimately provide certification to CMS of a specific rate for each rate cell, rather than a rate range (81 FR 27567). We believed that this change would enhance the integrity of the Medicaid rate-setting process and align Medicaid policy more closely with actuarial practices used in setting rates for non-Medicaid plans (81 FR 27568).

Since publication of the 2016 final rule, we have heard from stakeholders that the requirement to certify a capitation rate per rate cell, rather than to certify a rate range, has the potential to diminish states' ability to obtain the best rates when contracts are procured through competitive bidding. For example, we heard from one state that historically competitively bid the administrative component of the capitation rate that the requirement to certify a capitation rate per rate cell would not permit the state, and therefore, the federal government, to realize a lower rate that could have been available through the state's previous procurement process. States that negotiate dozens of managed care plans' rates annually have also cited the potential burden associated with losing the flexibility to certify rate ranges. Our 2016 Medicaid Managed Care Enrollment Report shows that 15 states submitted rate certifications on 20 plans or more, and one state (California) submitted rate certifications for 130 plans.[2] States have claimed that the elimination of rate ranges could potentially increase administrative costs and burden to submit separate rate certifications and justifications for each capitation rate paid per rate cell.

To address states' concerns while ensuring that rates are actuarially sound and federal resources are spent appropriately, we propose to add § 438.4(c) to provide an option for states to develop and certify a rate range per rate cell within specified parameters. We have designed our proposal to address our previously articulated concerns over the lack of transparency when large rate ranges were used by states to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change. The proposed rate range option at new paragraph (c) would allow states to certify a rate range per rate cell subject to specific limits and would require the submission of a rate recertification if the state determines that changes are needed within the rate range during the rate year. Under our proposal, an actuary must certify the upper and lower bounds of the proposed rate range as actuarially sound.

Specifically in § 438.4(c)(1), we propose the specific parameters for the use of rate ranges: (1) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range; (2) the upper and lower bounds of the rate range are certified as actuarially sound consistent with the requirements of part 438; (3) the upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05; (4) the rate certification documents the state's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range; and (5) compliance with specified limits on the state's ability to pay managed care plans at different points within the rate range. States using this option would be prohibited from paying MCOs, PIHPs, and PAHPs at different points within the certified rate range based on the willingness or agreement of the MCOs, PIHPs, or PAHPs to enter into, or adhere to, intergovernmental transfer (IGT) agreements, or the amount of funding the MCOs, PIHPs, or PAHPs provide through IGTs. We are proposing these specific conditions and limitations on the use of rate ranges to address our concerns noted above; that is, that rates are actuarially sound and ensure appropriate stewardship of federal resources, while also permitting limited state flexibility to use certified rate ranges. We believe that the conditions and limitations on the use of rate ranges as set forth in this proposed rule strike the appropriate balance between prudent fiscal and program integrity and state flexibility. We invite comment on these specific proposals and whether additional conditions should be considered to ensure that rates are actuarially sound. Finally, we would like to emphasize that this proposal would require states to demonstrate in their rate certification how the upper and lower bounds of the rate range are actuarially sound.

Under proposed § 438.4(c)(2)(i), states certifying a rate range would be required to document the capitation rates, prior to the start of the rating period for the applicable MCO, PIHP, and PAHP, at points within the certified rate range consistent with the state's criteria in proposed paragraph (c)(1)(iv). States electing to use a rate range would have to submit rate certifications to CMS prior to the start of the rating period and they must comply with all other regulatory requirements including § 438.4, except § 438.4(b)(4) as specified. During the contract year, states using the rate range option in § 438.4(c)(1) would not be able to modify capitation rates within the plus or minus 1.5 percent range allowed under § 438.7(c)(3); we propose to codify this as § 438.4(c)(2)(ii). This proposed provision would enable CMS to give states the flexibility and administrative simplification to use certified rate ranges. While the use of rate ranges is not standard practice in rate development, this proposed change aligns with standard rate development practices by requiring recertification when states elect to modify capitation rates within a rate range during the rating year. States wishing to modify the capitation rates within a rate range during the rating year would be required, in proposed § 438.4(c)(2)(iii), to provide a revised rate certification demonstrating that the criteria for initially setting the rate within the range, as described in the initial rate certification, were not applied accurately; that there was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or that other adjustments are appropriate and reasonable to account for programmatic changes.

We acknowledge that our proposal has the potential to reintroduce some of the risks that were identified in the 2016 final rule related to the use of rate ranges in the Medicaid program. In the 2016 final rule, we generally prohibited the use of rate ranges, including changes limited to a de minimis plus or minus 1.5 percent range permitted under § 438.7(c)(3) that was finalized in the rule to provide some administrative relief to states with respect to small changes in the capitation rates, to eliminate any potential ambiguity in

[2] *See* 2016 Medicaid Managed Care Enrollment Report, Table 5 Enrollment by Program and Plan as of 2016, pages 24–84, *available at https://www.medicaid.gov/medicaid/managed-care/enrollment/index.html.*

rate setting and to be consistent with our goal to make the rate setting and rate approval processes more transparent. We specifically noted in the 2016 final rule that states have used rate ranges to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change or certification that the change was based on actual experience incurred by the MCOs, PIHPs, or PAHPs that differed in a material way from the actuarial assumptions and methodologies initially used to develop the capitation rates (81 FR 27567–27568).

We further noted in the 2016 final rule that the prohibition on rate ranges was meant to enhance the integrity and transparency of the rate setting process in the Medicaid program, and to align Medicaid policy more closely with the actuarial practices used in setting rates for non-Medicaid health plans. We noted that the use of rate ranges was unique to Medicaid managed care and that other health insurance products that are subject to rate review submit and justify a specific premium rate. We stated in the 2016 final rule our belief that once a managed care plan has entered into a contract with the state, any increase in funding for the contract should correspond with something of value in exchange for the increased capitation payments. We also provided additional context that our policy on rate ranges was based on the concern that some states have used rate ranges to increase capitation rates paid to managed care plans without changing any obligations within the contract or certifying that the increase was based on managed care plans' actual expenses during the contract period. In the 2016 final rule, we reiterated that the prohibition on rate ranges was consistent with the contracting process where managed care plans are agreeing to meet obligations under the contract for a fixed payment amount (81 FR 27567–27568).

The specific risks described above are still concerns for CMS, as such we have proposed specific conditions and limitations on the use of rate ranges in this proposed rule to address our concerns. Our rate range proposal is intended to prevent states from using rate ranges to shift costs to the federal government. There are some states that currently make significant retroactive changes to the contracted rates at or after the end of the rating period. As we noted in the 2016 final rule, we do not believe that these changes are made to reflect changes in the underlying assumptions used to develop the rates (for example, the utilization of services, the prices of services, or the health status of the enrollee), but rather we are concerned that these changes are used to provide additional reimbursements to the plans or to some providers (81 FR 27834). Additionally, we believe the rate ranges compliant with our proposal will be actuarially sound, unlike the rate ranges that were permissible prior to the 2016 final rule. As noted in the 2016 final rule, 14 states used rate ranges with a width of 10 percent or smaller (that is, the low end and the high end of the range were within 5 percent of the midpoint of the range), but in some states, the ranges were as wide as 30 percent (81 FR 27834). We believe that our proposal would limit excessive ranges because proposed § 438.4(c)(1)(i) and (ii) would require the upper and lower bounds of the rate range to be certified as actuarially sound and that the rate certification would identify and justify the assumptions, data, and methodologies used to set the bounds. While we believe that this proposal would strike the right balance between state flexibility and our statutory responsibility to ensure that managed care capitation rates are actuarially sound, we also understand that our proposed approach may reintroduce undue risk in Medicaid rate-setting.

Therefore, we are requesting public comments on our proposal in general and on our proposed approach. We request public comment on the value of the additional state flexibility described in this proposal relative to the potential for the identified risks described here and in the 2016 final rule, including other unintended consequences that could arise from this proposal that we have not yet identified or described. We request public comment on whether additional conditions or limitations on the use of rate ranges would be appropriate to help mitigate the risks we have identified. We also request public comment from states on the utility of state flexibility in this area—specifically, we are asking states to provide specific comments about their policy needs and clear explanations describing how utilizing rate ranges effectively meets these needs or whether current regulatory requirements on rate ranges are sufficiently flexible to meet their needs. We are also asking states to provide quantitative data to help CMS quantify the benefits and risks associated with this proposal. We also encourage states and other stakeholders to comment on the need, benefits, risks, and proposed risk mitigations described in this proposed revision.

b. Capitation Rate Development Practices That Increase Federal Costs and Vary With the Rate of Federal Financial Participation (FFP) (§ 438.4(b)(1) and (d))

In the 2016 final rule, at § 438.4(b), we set forth the standards that capitation rates must meet to be approved as actuarially sound capitation rates eligible for FFP under section 1903(m) of the Act. Section 438.4(b)(1) requires that capitation rates be developed in accordance with generally accepted actuarial principles and practices and meet the standards described in § 438.5 dedicated to rate development standards. In the 2016 final rule (81 FR 27566), we acknowledged that states may desire to establish minimum provider payment rates in the contract with the managed care plan. We also explained that because actuarially sound capitation rates must be based on the reasonable, appropriate, and attainable costs under the contract, minimum provider payment expectations included in the contract would necessarily be built into the relevant service components of the rate. However, we finalized in the regulation at § 438.4(b)(1) a prohibition on different capitation rates based on the FFP associated with a particular population as part of the standards for capitation rates to be actuarially sound. We explained in the 2015 proposed rule (80 FR 31120) that different capitation rates based on the FFP associated with a particular population represented cost-shifting from the state to the federal government and were not based on generally accepted actuarial principles and practices.

In the 2016 final rule (81 FR 27566), we adopted § 438.4(b)(1) largely as proposed and provided additional guidance and clarification in response to public comments. We stated that the practice intended to be prohibited in § 438.4(b)(1) was variance in capitation rates per rate cell that was due to the different rates of FFP associated with the covered populations. We also provided an example in the 2016 final rule. In the example, we explained that we have seen rate certifications that set minimum provider payment requirements or established risk margins for the managed care plans only for covered populations eligible for higher percentages of FFP. We provided in the final rule that such practices, when not supported by the application of valid rate development standards, were not permissible. We further explained that the regulation would not prohibit the state from having different capitation rates per rate cell based on differences

in the projected risk of populations under the contract or based on different payment rates to providers that were required by federal law (for example, section 1932(h) of the Act). In the 2016 final rule, we stated that, as finalized, § 438.4(b)(1) provided that any differences among capitation rates according to covered populations must be based on valid rate development standards and not on network provider reimbursement requirements that apply only to covered populations eligible for higher percentages of FFP (81 FR 27566).

Since publication of the 2016 final rule, we have continued to hear from stakeholders that more guidance is needed regarding the regulatory standards finalized in § 438.4(b)(1). At least one state has indicated that if arrangements that vary provider reimbursement pre-date the differences in FFP for different covered populations, the regulation should not be read to prohibit the resulting capitation rates. While we believe that the existing text of § 438.4(b)(1) is sufficiently clear, we also want to be responsive to the comments from stakeholders and to eliminate any potential loophole in the regulation. Therefore, we are proposing to revise § 438.4(b)(1) and to add a new paragraph § 438.4(d) to clearly specify our standards for actuarial soundness. First and foremost, we are not changing the existing regulatory standard or text in § 438.4(b)(1) that capitation rates must have been developed in accordance with the standards specified in § 438.5 and generally accepted actuarial principles and practices. We are proposing to revise the remainder of § 438.4(b)(1).

We are proposing that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Further, we are proposing that any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of FFP associated with the covered populations in a manner that increases federal costs consistent with proposed § 438.4(d) described below. This proposal is intended to eliminate any ambiguity in the regulation and clearly specify our intent that variation in the assumptions, methodologies, and factors used to develop rates must be tied to actual cost differences and not to any differences that increase federal costs and vary with the rate of FFP. We intend the phrase ''assumptions, methodologies, and factors'' to cover the methods and data used to develop the actuarially sound capitation rates.

In conjunction with our proposed revisions to § 438.4(b)(1), we are also proposing a new paragraph (d) in this section to provide specificity regarding the rate development practices that increase federal costs and vary with the rate of FFP. We are proposing in § 438.4(d) a regulatory requirement that requires an evaluation of any differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs that increase federal costs and vary with the rate of FFP associated with the covered populations. This evaluation must be conducted for the entire managed care program and include all managed care contracts for all covered populations. We are proposing to require this evaluation across the entire managed care program and all managed care contracts for all covered populations to protect against state managed care contracting practices that may cost-shift to the federal government. Specifically, this would entail comparisons of each managed care contract to others in the state's managed care program to ensure that variation among contracts does not include rate setting methods or policies that would be prohibited under this proposal.

Additionally, we are proposing at § 438.4(d)(1) regulation text to clearly list certain rate development practices that increase federal costs and are prohibited under our proposal for § 438.4(b)(1) and (d): (1) A state may not use higher profit margin, operating margin, or risk margin when developing capitation rates for any covered population, or contract, than the profit margin, operating margin, or risk margin used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; (2) a state may not factor into the development of capitation rates the additional cost of contractually required provider fee schedules, or minimum levels of provider reimbursement, above the cost of similar provider fee schedules, or minimum levels of provider reimbursement, used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; and (3) a state may not use a lower remittance threshold for a medical loss ratio for any covered population, or contract, than the remittance threshold used for the covered population, or contract, with the lowest average rate of FFP. We are proposing § 438.4(d)(1) to be explicitly clear about certain rate development practices that increase federal costs and vary with the rate of FFP. We note that this proposal would explicitly prohibit these specific rate development practices under any and all scenarios, and under this proposal, we would find these rate development practices to be in violation of our regulatory standards for actuarially sound capitation rates; we also note that the rate development practices proposed under § 438.4(d)(1) are not intended to represent an exhaustive list of practices that increase federal costs and vary with the rate of FFP, as we recognize that there may be additional capitation rate development practices that have the same effect and would also be prohibited under this proposed rule. We believe that this proposal will ensure that our regulatory standards for actuarial soundness are consistent with our intent, and that cost-shifting from the state to the federal government does not occur.

Finally, in proposed § 438.4(d)(2), we are proposing to specify that CMS may require a state to provide written documentation and justification, during our review of a state's capitation rates, that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts, not otherwise referenced in proposed (d)(1), represent actual cost differences based on the characteristics and mix of the covered services or the covered populations. This proposal is consistent with our proposal at § 438.7(c)(3), to add regulatory text to specify that the adjustments to capitation rates would also be subject to the requirements at § 438.4(b)(1), and to require a state to provide documentation for adjustments permitted under proposed § 438.7(c)(3) to ensure that modifications to a final certified capitation rate comply with our proposed regulatory requirements. We are specifically requesting public comments on these proposed revisions to § 438.4(b)(1) and new proposed § 438.4(d), including on whether these proposed changes are sufficiently clear regarding the rate development practices that are prohibited in § 438.4(b)(1).

3. Rate Development Standards: Technical Correction (§ 438.5(c)(3)(ii))

In the 2016 final rule, we finalized at § 438.5(c)(3) an exception to the base data standard at § 438.5(c)(2) in recognition of circumstances where states may not be able to meet the standard at (c)(2). We explained in the 2016 final rule preamble (81 FR 27574) that states requesting the exception under § 438.5(c)(3) must submit a description of why the exception is

needed and a corrective action plan detailing how the state would bring their base data into compliance no more than 2 years after the rating period in which the deficiency was discovered.

Regrettably, the regulation text regarding the corrective action timeline at § 438.5(c)(3)(ii) was not as consistent with the preamble or as clear as we intended. The regulation text finalized in 2016 provides that the state must adopt a corrective action plan to come into compliance ''no later than 2 years from the rating period for which the deficiency was identified.'' The preamble text described the required corrective action plan as detailing how the problems ''would be resolved in no more than 2 years after the rating period in which the deficiency was discovered.'' This discrepancy resulted in ambiguity that confused some stakeholders as to when the corrective action plan must be completed and their base data must be in compliance. To remove this ambiguity, we propose to replace the word ''from'' at § 438.5(c)(3)(ii) with the phrase ''after the last day of.'' We also note that the preamble used the term ''discovered'', while the regulatory text used the term ''identified.'' We propose to retain the term ''identified'' in the regulatory text since we believe this term is more appropriate in this context. We believe that this proposed change would clarify the corrective action plan timeline for states to achieve compliance with the base data standard; that is, states would have the rating year for which the corrective action period request is made, plus 2 years following that rating year to develop rates using the required base data. For example, if the state's rate development for calendar year 2018 does not comply with the base data requirements, the state would have 2 calendar years after the last day of the 2018 rating period to come into compliance. This means that the state's rate development for calendar year 2021 would need to use base data that is compliant with § 438.5(c)(2).

We solicit comment on our proposal and whether any additional clarification is necessary.

4. Special Contract Provisions Related to Payment (§ 438.6)

a. Risk-Sharing Mechanism Basic Requirements (§ 438.6(b))

In 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 (the 2015 proposed rule) (80 FR 31098, June 1, 2015), we proposed to redesignate the basic requirements for risk contracts previously in § 438.6(c)(2) as § 438.6(b). In § 438.6(b)(1), we proposed a non-exhaustive list of risk-sharing mechanisms (for example, reinsurance, risk corridors, and stop-loss limits) and required that all such mechanisms be specified in the contract. In the preamble, we stated our intent to interpret and apply § 438.6(b)(1) to any mechanism or arrangement that has the effect of sharing risk between the MCO, PIHP, or PAHP, and the state (80 FR 31122). We did not receive comments on paragraph (b)(1) and finalized the paragraph as proposed in the 2016 final rule (81 FR 27578) with one modification.

In the 2016 final rule, we included at § 438.6(c)(5)(i) the standard from the then-current rule (adopted in 2002 in the ''Medicaid Program; Medicaid Managed Care: New Provisions'' final rule (67 FR 40989, June 14, 2002) (hereinafter referred to as the ''2002 final rule'')) that risk-sharing mechanisms must be computed on an actuarially sound basis. That element of the 2016 final rule was inadvertently omitted in the 2015 proposed rule. As managed care contracts are risk-based contracts, mechanisms that share or distribute risk between the state and the managed care plan are inherently part of the capitation rates paid to plans for bearing the risk. Therefore, the risk-sharing mechanisms should be developed in conjunction with the capitation rates and using the same actuarially sound principles and practices.

Risk-sharing mechanisms are intended to address the uncertainty inherent in setting capitation rates prospectively. As such, we expected states to identify and apply risk-sharing requirements prior to the start of the rating period. Because we believed that the final rule was clear on the prospective nature of risk-sharing and our expectations around the use of risk-sharing mechanisms, we did not specifically prohibit retroactive use. However, since publication of the 2016 final rule, we have found that some states have applied new or modified risk-sharing mechanisms retrospectively; for example, some states have sought approval to change rates after the claims experience for a rating period became known to the state and the managed care plan. We acknowledge the challenges in setting prospective capitation rates and encourage the use of appropriate risk-sharing mechanisms. In selecting and designing risk-sharing mechanisms, states and their actuaries are required to only use permissible strategies, use appropriate utilization and price data, and establish reasonable risk-sharing assumptions.

Despite a state's best efforts to set accurate and appropriate capitation rates, unexpected events can occur during a rating period that necessitate a retroactive adjustment to the previously paid rates. When this occurs, § 438.7(c)(2) provides the requirements for making a retroactive rate adjustment. Section 438.7(c)(2) clarifies that the retroactive adjustment must be supported by an appropriate rationale and that sufficient data, assumptions, and methodologies used in the development of the adjustment must be described in sufficient detail and submitted in a new rate certification along with the contract amendment.

To address the practice of adopting or amending risk-sharing mechanisms retroactively, we propose to amend § 438.6(b)(1) to require that risk-sharing mechanisms be documented in the contract and rate certification documents prior to the start of the rating period. As described in the 2017 Medicaid Managed Care Rate Development Guide,[3] we believe it is important to include a description in the rate certification, especially if the development of risk-sharing mechanisms has any implications for the Medical Loss Ratio (MLR) and items that factor into the assumptions for certification of the final capitation rate for each risk contract. To ensure clarity, we are also proposing to amend the regulation at § 438.6(b)(1) to explicitly prohibit retroactively adding or modifying risk-sharing mechanisms described in the contract or rate certification documents after the start of the rating period.

We acknowledge that our proposed requirement that risk-sharing mechanisms be documented in a state's contract and rate certification documents prior to the start of the rating period means, as a practical matter, that states electing to use risk-sharing mechanisms would have to submit contracts and rate certifications to CMS prior to the start of the rating period. We note here that section 1903(m)(2)(A)(iii) of the Act, as well as implementing regulations at § 438.806, require that the Secretary must provide prior approval for MCO contracts that meet certain value thresholds before states can claim FFP. This longstanding requirement is

[3] Centers for Medicare & Medicaid Services. 2017 Medicaid Managed Care Rate Development Guide. *https://www.medicaid.gov/medicaid/managed-care/downloads/2017-medicaid-managed-care-rate-development-guide.pdf.*

implemented in the regulation at § 438.806(c), which provides that FFP is not available for an MCO contract that does not have prior approval from CMS. CMS has, since the early 1990s, interpreted and applied this requirement by not awarding FFP until the contract has been approved and permitting FFP back to the initial date of a contract approved after the start of the rating period if an approvable contract were in place between the state and the managed care plan. This practice is reflected in the State Medicaid Manual, § 2087.

Lastly, the proposed change would make § 438.6(b)(1) more consistent with § 438.7(b)(5), which requires the rate certification to describe all risk-adjustment methodologies. While risk mitigation methodologies (which address which parties bear the risk of financial loss under the contract) are not risk-adjustment methodologies (which address compensation based on the health status of enrollees), we believe they have a similar impact on payment to the managed care plan and that the same rules about being described in the rate certification should apply. The current regulation text in § 438.6(b)(1) is not explicit that risk mitigation methodologies be in the rate certification and our proposal would revise the regulation to explicitly include this requirement.

We solicit comments on these proposed changes.

b. Delivery System and Provider Payment Initiatives Under MCO, PIHP, or PAHP Contracts (§ 438.6(a) and (c))

As finalized in the 2016 final rule, § 438.6(c)(1) permits states to, under the circumstances enumerated in § 438.6(c)(1)(i) through (iii), direct the managed care plan's expenditures under the contract. Among other criteria, such directed payment arrangements require prior approval by CMS, per § 438.6(c)(2); our approval is based on meeting the standards listed in § 438.6(c)(2), including that the state expects the directed payment to advance at least one of the goals and objectives in the state's quality strategy for its Medicaid managed care program. We have been reviewing and approving directed payment arrangements submitted by states since the 2016 final rule, and we have observed that a significant number of them require managed care plans to adopt minimum rates, and that most commonly, these minimum rates are those specified under an approved methodology in the Medicaid state plan. Additionally, most of these types of directed payment arrangements seek to accomplish the same goal in the state's quality strategy—to ensure adequate access to providers.

Due to the frequency and similarities of these types of directed payment arrangements, we believe that they should be specifically addressed in § 438.6(c)(1)(iii). Therefore, at § 438.6(a), we propose to add a definition for ''state plan approved rates'' to mean amounts calculated as a per unit price of services described under CMS approved rate methodologies in the state plan. We also propose to revise § 438.6(c)(1)(iii)(A) to specifically reference a directed payment arrangement that is based on an approved state plan rate methodology. As with all directed payment arrangements under § 438.6(c), a directed payment arrangement established under proposed paragraph (c)(1)(iii)(A) would have to be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

We note here that supplemental payments contained in a state plan are not, and do not constitute, state plan approved rates as proposed in § 438.6(a); we propose to include a statement to this effect under proposed paragraph (c)(1)(iii)(A). For the purposes of this proposed rule, a rate described in the approved rate methodology section of the state plan would reflect only the per unit price of particular services. Supplemental payments are not calculated or paid based on the number of services rendered, and therefore, are separate and distinct from state plan approved rates under this proposed rule. We also propose to define supplemental payments in § 438.6(a) as amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the state plan or under a waiver and are in addition to the amounts calculated through an approved state plan rate methodology.

Further, we propose to redesignate current paragraph § 438.6(c)(1)(iii)(A) as (c)(1)(iii)(B) and to include a revision to distinguish a minimum fee schedule for network providers that provide a particular service from use of the state plan approved rates. Proposed paragraphs (c)(1)(iii)(A) and (B) would now recognize two distinct minimum fee schedule directed payment arrangements. To accommodate our proposal, we also propose to redesignate current paragraphs (c)(1)(iii)(B) and (C) as paragraphs (c)(1)(iii)(C) and (D), respectively.

As we have reviewed and approved directed payment arrangements submitted by states since publication of the 2016 final rule, we have observed that our regulation does not explicitly address some types of potential directed payments that states are seeking to implement. For example, some states are experimenting with payment models that use a cost-based reimbursement, a Medicare equivalent reimbursement, an average commercial rate reimbursement, or reimbursement based on another market-based standard. To encourage states to continue developing payment models that produce optimal results for their local markets and to clarify how the regulatory standards apply in such cases, we are also proposing to add a new paragraph § 438.6(c)(1)(iii)(E) that would allow states to require managed care plans to adopt a cost-based rate, a Medicare equivalent rate, a commercial rate, or other market-based rate for network providers that provide a particular service under the contract. We believe that authorizing these additional types of payment models for states to implement would eliminate any need for states to modify their payment models as only minimum or maximum fee schedules to fit neatly into the construct of the current rule. In addition, adopting regulation text specific to these other methodologies for specific fee schedules is consistent with our policy to provide flexibility to the state where possible.

Along with the proposed changes in § 438.6(c)(1)(iii)(A), we are also proposing a corresponding change to the approval requirements in § 438.6(c)(2). In the 2016 final rule, we established an approval process that requires states to demonstrate in writing that payment arrangements adopted under § 438.6(c)(1)(i) through (iii) meet the criteria specified in § 438.6(c)(2) prior to implementation. Since implementing this provision of the 2016 final rule, states have noted that the approval process for contract arrangements that include only minimum rate methodologies that are already approved by CMS and included in the Medicaid state plan are substantially the same as the approval requirements under the Medicaid state plan. Some states have stated that the written approval process in § 438.6(c)(2) is unnecessary given that a state would have already justified the rate methodology associated with particular services in the Medicaid state plan (or a state plan amendment) to receive approval by CMS that the rates are efficient, economical, and assure quality of care under section 1902(a)(30)(A) of the Act.

Therefore, to avoid unnecessary and duplicative federal approval processes, we propose to eliminate the prior

approval requirement for payment arrangements that are based on state plan approved rates. To do so, we propose to redesignate existing paragraph (c)(2)(ii) as (c)(2)(iii), add a new paragraph (c)(2)(ii), and to redesignate paragraphs § 438.6(c)(2)(i)(A) through (F) as (c)(2)(ii)(A) through (F), respectively. We also propose to revise the remaining paragraph at § 438.6(c)(2)(i) to require, as in the current regulation, that all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices; we propose to delete the remaining regulatory text from current paragraph (c)(1)(i).

In proposed new paragraph (c)(2)(ii), we would specify prior approval requirements for payment arrangements under paragraphs (c)(1)(i), (ii), and (iii)(B) through (E). For reasons discussed above, the amended paragraph (c)(2)(ii) would also explicitly provide that payment arrangements under paragraph (c)(1)(iii)(A) do not require prior approval from CMS; although, we propose to retain the requirement that such payment arrangements continue to meet the criteria in paragraphs (c)(2)(ii)(A) through (F). We believe that this proposed revision would reduce administrative burden for many states by eliminating the need to obtain written approval prior to implementation of this specific directed payment arrangement that utilizes previously approved rates in the state plan. With the redesignation of paragraph (c)(2)(ii)(A) through (F), we propose to keep in place the existing requirements for CMS approval to be granted.

In the 2016 final rule, we specified at paragraph § 438.6(c)(2)(ii)(C) that contract arrangements which direct expenditures made by the MCO, PIHP, or PAHP under paragraphs (c)(1)(i) or (c)(1)(ii) for delivery system or provider payment initiatives may not direct the amount or frequency of expenditures by managed care plans. We believed that this requirement was necessary to deter states from requiring managed care plans to reimburse particular providers specified amounts with specified frequencies. However, based on our experience in reviewing and approving directed payment arrangements since the 2016 final rule, we now recognize that this provision may have created unintended barriers to states pursuing innovative payment models. Some states have adopted or are pursuing payment models, such as global payment initiatives, which are designed to move away from a volume-driven system to a system focused on value and population health. Moreover, some of these payment models attempt to build on existing pay for performance or integrated care programs, or align with programs implemented by other payers at the state level. These innovative payment models can require that the state direct the amount or frequency of expenditures by the managed care plan to achieve the state's goals for improvements in quality, care, and outcomes under the payment model.

We believe that these innovative payment models necessitate acknowledging the complexity and variation in local market forces and that states need more flexible parameters to effectively negotiate these complex payment arrangements and achieve a more comprehensive transition from volume to value. Therefore, we propose to delete existing § 438.6(c)(2)(ii)(C) which would permit states to direct the amount or frequency of expenditures made by managed care plans under paragraphs (c)(1)(i) or (c)(1)(ii). As a conforming change, we would redesignate existing § 438.6(c)(2)(ii)(D) as § 438.6(c)(2)(iii)(C).

In the 2016 final rule at existing § 438.6(c)(2)(i)(F) (redesignated to paragraph § 438.6(c)(2)(ii)(F) in this proposed rule), we established that a contract arrangement directing a managed care plan's expenditures may not be renewed automatically. While § 438.6(c)(2)(i)(F) does not permit for the automatic renewal of a contract arrangement described in paragraph (c)(1), it does not prohibit states from including payment arrangements in a contract for more than one rating period. We have received numerous payment arrangement proposals from states requesting a multi-year approval of their payment arrangement to align with their delivery system reform efforts or contract requirements.

To provide additional guidance to states on the submission and approval process for directed payments, on November 2, 2017, we issued a CMCS Informational Bulletin (CIB) entitled ''Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts'' (available at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf*). The CIB explained that based on our experience with implementation of § 438.6(c)(2), we recognize that some states are specifically pursuing multi-year payment arrangements to transform their health care delivery systems. The CIB also described that states can develop payment arrangements under § 438.6(c)(1)(i) and (ii), which are intended to pursue delivery system reform, over a period of time that is longer than one year so long as the state explicitly identifies and describes how the payment arrangement would vary or change over the term of the arrangement.

We understand that some payment arrangements, particularly value-based purchasing arrangements or those tied to larger delivery system reform efforts, can be more complex and may take longer for a state to implement. Setting the payment arrangement for longer than a one-year term would provide a state with more time to implement and evaluate whether the arrangement meets the state's goals and objectives to advance its quality strategy under § 438.340. As stated in the CIB, we interpret the regulatory requirements under § 438.6(c) to permit multi-year payment arrangements when certain criteria are met. We set out the criteria in the CIB for multi-year approvals of certain directed payment arrangements, and we now propose to codify those criteria in a new § 438.6(c)(3).

Specifically, we propose in new paragraph (c)(3)(i) that we would condition a multi-year approval for a payment arrangement under paragraphs (c)(1)(i) and (ii) on the following criteria: (1) The state has explicitly identified and described the payment arrangement in the contract as a multi-year payment arrangement, including a description of the payment arrangement by year, if the payment arrangement varies by year; (2) the state has developed and described its plan for implementing a multi-year payment arrangement, including the state's plan for multi-year evaluation, and the impact of a multi-year payment arrangement on the state's goal(s) and objective(s) in the state's quality strategy in § 438.340; and (3) the state has affirmed that it will not make any changes to the payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year payment arrangement without CMS prior approval. If the state determines that changes to the payment methodology, or magnitude of the payment, are necessary, the state must obtain prior approval of such changes using the process in paragraph (c)(2). We note that in addition to codifying criteria for the approval of multi-year payment arrangements, the proposed new paragraph (c)(3)(i) addresses any potential ambiguity in the 2016 final rule regarding the permissibility of states to enter into multi-year payment arrangements with managed care plans. However, the proposed paragraph

(c)(3)(i) would not change the requirement that a payment arrangement that directs a managed care plan's expenditures must meet all of the approval requirements in § 438.6(c)(2), including that the payment arrangement must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

Finally, in alignment with our guidance in the November CIB, we propose to specify at paragraph (c)(3)(ii) that the approval of a payment arrangement under paragraph (c)(1)(iii) of this section would be for one rating period. As explained above, while we understand and acknowledge that value-based purchasing payment arrangements or those tied to larger delivery system reform efforts can be more complex and may take longer for a state to implement, we believe that more traditional payment arrangements and fee schedules under paragraph (c)(1)(iii) should continue to be reviewed and evaluated on an annual basis by both states and CMS. We believe that it is important to continue ensuring that such payment arrangements under paragraph (c)(1)(iii) continue to be consistent with states' and our goals and objectives for directed payments under Medicaid managed care contracts.

We solicit comments on these proposals.

c. Pass-Through Payments Under MCO, PIHP, and PAHP Contracts (§ 438.6(d))

In the 2016 final rule, and the 2017 pass-through payment final rule (82 FR 5415), we finalized a policy to limit state direction of payments, including pass-through payments, at § 438.6(c) and (d). We defined pass-through payments at § 438.6(a) as any amount required by the state, and considered in calculating the actuarially sound capitation rate, to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to 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; graduate medical education (GME) payments; or federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. We noted in our 2017 pass-through payment final rule that a distinguishing characteristic of a pass-through payment is that a managed care plan is contractually required by the state to pay providers an amount that is disconnected from the amount, quality, or outcomes of services delivered to enrollees under the contract during the rating period of the contract (82 FR 5416).[4] When managed care plans only serve as a conduit for passing payments to providers independent of delivered services, such payments reduce managed care plans' ability to control expenditures, effectively use value-based purchasing strategies, implement provider-based quality initiatives, and generally use the full capitation payment to manage the care of enrollees.

In the 2016 final rule, we also noted that section 1903(m)(2)(A) of the Act requires that capitation payments to managed care plans be actuarially sound and clarified our interpretation of that standard as meaning that payments under the managed care contract must align with the provision of services to beneficiaries covered under the contract. We clarified the statutory and regulatory differences between payments made on a FFS basis and on a managed care basis (81 FR 27588). We provided an analysis and comparison of section 1902(a)(30)(A) of the Act regarding FFS payments and implementing regulations that impose aggregate upper payment limits (UPL) on rates for certain types of services or provider types to section 1903(m)(2)(A) regarding the requirement that capitation payments in managed care contracts be actuarially sound and implementing regulations that require payments to align with covered services delivered to eligible populations. Based on that analysis, we concluded that pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services. Despite this conclusion, we acknowledged in the 2016 final rule that, for many states, pass-through payments have been approved in the past as part of Medicaid managed care contracts and served as a critical source of support for safety-net providers caring for Medicaid beneficiaries (81 FR 27589). We therefore adopted a transition period for states that had already transitioned services or eligible populations into managed care and had pass-through payments in their managed care contracts as part of the regulations that generally prohibit the use of pass-through payments in actuarially sound capitation rates. Although § 438.6(d) is not explicitly limited to pass-through payments in the context of an established managed care program, the use of pass-through payments in place as of the 2016 final rule as an upper limit on permitted pass-through payments during the transition periods described in § 438.6(d) effectively precludes new managed care programs from adopting pass-through payments.

We used the 2016 final rule to identify the pass-through payments in managed care contract(s) and rate certification(s) that are eligible for the pass-through payment transition period. We provided a detailed description of the policy rationale (81 FR 27587 through 27592) for why we established pass-through payment transition periods and limited pass-through payments to hospitals, nursing facilities, and physicians, and this policy rationale has not changed. We focused on the three provider types identified in § 438.6(d) because these are the most common provider types to which states make supplemental payments within federal UPLs under state plan authority.

Since implementation of the 2016 and 2017 final rules, we have worked with many states that have not transitioned some or all services or eligible populations from their FFS delivery system into a managed care program. Data from the CMS Medicaid Managed Care Data Collection System (MMCDCS) show that a large and growing majority of states contract with MCOs and that states are also rapidly expanding their use of MCOs to reach larger geographic areas, serve more medically complex beneficiaries, and deliver long-term services and supports (LTSS). Nationally, two-thirds (68.1 percent) of all Medicaid beneficiaries were enrolled in comprehensive MCOs in 2016, up from 65.5 percent in 2015. According to MMCDCS data, as of July 2016, 37 states have 50 percent or more of their Medicaid populations enrolled in a comprehensive MCO, up from 34 states in 2015; while 26 states have 20 percent or more of their Medicaid populations in FFS, and three of those states have 100 percent (Alaska and Connecticut) or almost 100 percent (Wyoming) of their Medicaid populations in FFS.[5]

Some states would like to begin to transition some services or eligible

[4] Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems, Final Rule, (82 FR 5415–5429, January 18, 2017).

[5] Medicaid Managed Care Enrollment and Program Characteristics, 2016; Updated Spring 2018. Available at *https://www.medicaid.gov/medicaid/managed-care/downloads/enrollment/2016-medicaid-managed-care-enrollment-report.pdf.*

populations from FFS to managed care, but would also like to continue to make supplemental payments to hospitals, physicians, or nursing facilities. We recognize the challenges associated with transitioning supplemental payments into payments based on the delivery of services or value-based payment structures. The transition from one payment structure to another requires robust provider and stakeholder engagement, broad agreement on approaches to care delivery and payment, establishing systems for measuring outcomes and quality, planning, and evaluating the potential impact of change on Medicaid financing mechanisms. We also recognize that implementing value-based payment structures or other, delivery system reform initiatives, and addressing 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.

To address states' requests to continue making supplemental payments for certain services and assist states with transitioning some or all services or eligible populations from a FFS delivery system into a managed care delivery system, we propose to add a new § 438.6(d)(6) that would allow states to make pass-through payments under new managed care contracts during a specified transition period if certain criteria are met. Here and in the regulation text proposed at § 438.6(d)(6), we refer to transitioning services from FFS Medicaid to Medicaid managed care plan(s); this phrasing refers both to when a state expands the scope of its managed care program in terms of services (for example, offering behavioral health services in Medicaid managed care that were previously provided under Medicaid FFS for populations that are already enrolled in managed care) and populations (that is, adding new populations to Medicaid managed care when previously those populations received all Medicaid services through FFS).

Specifically, we propose in § 438.6(d)(6)(i) through (iii) that states may require managed care plans to make pass-through payments, as defined in § 438.6(a), to network providers that are hospitals, nursing facilities, or physicians, when Medicaid populations or services are initially transitioning or moving from a Medicaid FFS delivery system to a Medicaid managed care delivery system, provided the following requirements are met: (1) The services will be covered for the first time under a Medicaid managed care contract and were previously provided in a Medicaid FFS delivery system prior to the first rating period, as defined in § 438.2, of the specified pass-through payment transition period; (2) the state made supplemental payments, as defined in § 438.6(a), to hospitals, nursing facilities, or physicians for those specific services that will be covered for the first time under a Medicaid managed care contract during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period (this 12-month period is the same standard that is currently codified in existing pass-through payment regulations at § 438.6(d)(2) in relation to the calculation of the base amount for hospital pass-through payments under § 438.6(d)(3)); and (3) the aggregate amount of the pass-through payments that the state requires the managed care plan to make is less than or equal to the amounts calculated in proposed paragraphs (d)(6)(iii)(A), (B), or (C) for the relevant provider type for each rating period of the pass-through payment transition period—this requirement means that the aggregate amount of the pass-through payments for each rating period of the specified pass-through payment transition period that the state requires the managed care plan to make must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period for each applicable provider type.

We also propose at § 438.6(d)(6)(iv) that the state may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

We propose paragraphs (d)(6)(iii)(A), (B) and (C) to address the maximum aggregate pass-through payment amounts to hospitals, nursing facilities, and physicians for each rating period of the specified 3-year pass-through payment transition period; that is, we propose three paragraphs to determine the maximum aggregate amount of the pass-through payments for each rating period of the 3-year pass-through payment transition period that the state can require the managed care plan to make to ensure that pass-through payments under proposed § 438.6(d)(6) are less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments to hospitals, nursing facilities, or physicians, respectively, during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period for each applicable provider type. This means that the aggregate pass-through payments under the new 3-year pass-through payment transition period must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments in Medicaid FFS.

To include pass-through payments in the managed care contract(s) and capitation rates(s) under proposed new paragraph (d)(6), the state would have to calculate and demonstrate that the aggregate amount of the pass-through payments for each rating period of the pass-through payment transition period is less than or equal to the amounts calculated in proposed paragraphs (d)(6)(iii)(A), (B), or (C) for the relevant provider type. In § 438.6(d)(6)(iii), we propose that for determining the amount of each component for the calculations contained in proposed paragraphs (d)(6)(iii)(A), (B), and (C), the state must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period. As a practical matter, the proposed calculation would require the state to use Medicaid Management Information System (MMIS) adjudicated claims data from the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period. This timeframe and use of 2-year old data was chosen so that the state has complete utilization data for the service type that would be subject to the pass-through payments. The proposed calculation would also require the state to restrict the amount used in each component of the calculation to the amount actually paid through a supplemental payment for each applicable provider type. We note that our proposal would generally refer to the same provider types as Medicaid FFS specified under 42 CFR part 447. The calculation process under these proposed paragraphs would involve 4 basic steps:

- *Step 1:* For each applicable provider type, identify the actual payment amounts that were attributed to and actually paid as FFS supplemental payments during the 12-month period

immediately 2 years prior to the first rating period of the pass-through payment transition period.

- *Step 2:* Divide (a) the payment amounts paid through payment rates for the services that are being transitioned from payment in FFS to the managed care contract for each applicable provider type by (b) the total payment amounts paid through payment rates for services provided in FFS for each applicable provider type to determine the ratio. In determining these amounts, the state must use the amounts paid for each provider type during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period.
- *Step 3:* Multiply the amount in Step 1 by the ratio produced by Step 2.
- *Step 4:* The aggregate amount of pass-through payments that the state may require the MCO, PIHP, or PAHP to make for each rating period of the 3-year pass-through payment transition period must be demonstrated to be less than or equal to the result achieved in Step 3.

Following the above steps, we offer the following formula to help illustrate the aggregate amount of pass-through payments for each rating period of the pass-through payment transition period for each applicable provider type:

$$\textit{Permissible Aggregate Payment Amounts}$$

$$= (\textit{Medicaid FFS Supplemental Payments Paid to Provider Type X})$$

$$\times \left(\frac{\textit{Amounts Paid in Medicaid FFS to Provider Type X through Medicaid for Transitioning Services}}{\textit{Total Amounts Paid in Medicaid FFS to Provider Type X for All Services}}\right)$$

To demonstrate how the calculation is performed, we provide the following example in which we assume that a state Medicaid program paid $60 million in claims in FFS for inpatient hospital services in CY 2016. To acknowledge the Medicaid FFS UPL, we assume that those same services would have been reimbursed at $100 million using Medicare payment principles. The difference between the amount that Medicare would have paid and the amount Medicaid actually paid in claims is $40 million. For Step 1, of the $40 million difference, the state actually paid $20 million in supplemental payments to inpatient hospitals in CY 2016. For this example, we assume that CY 2016 is the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period in which inpatient hospital services will be transitioned to a managed care contract; therefore, we assume the pass-through payments are for CY 2018. This transition to managed care could be either by moving Medicaid beneficiaries from FFS to coverage under managed care contracts that cover inpatient hospital services or by moving inpatient hospital services into coverage under managed care contracts.

Next, in Step 2, the state determines the ratio of the payment amounts paid in FFS for inpatient hospital services that will be transitioned from payment in a FFS delivery system to the managed care contract within the specific provider category and requisite period in relation to the total payment amounts paid in FFS for all inpatient hospital services within the same provider category during the same period. For example, if the state paid $36 million in FFS for inpatient hospital services for a specific population out of the $60 million in total claims paid in FFS for inpatient hospital services during 2016, and the state wants to transition the population associated with the $36 million in paid claims to the managed care contract, then the ratio is $36 million divided by $60 million, or 60 percent.

In Step 3, the state would multiply the $20 million in actual supplemental payments paid by 60 percent, resulting in $12 million, which is the amount described in Step 4 as the total amount that the state would be permitted to require the managed care plans to make in pass-through payments to inpatient hospitals for each rating period during the pass-through payment transition period described in proposed paragraph (d)(6)(iv).

In an effort to provide network providers, states, and managed care plans with adequate time to design and implement payment systems that link provider reimbursement with services, we also propose, in new paragraph (d)(6)(iv), to allow states a transition period for up to 3 years to transition FFS supplemental payments into payments linked to services and utilization under the managed care contract. We are proposing the 3-year pass-through payment transition period to provide states with time to integrate pass-through payment arrangements into allowable payment structures under actuarially sound capitation rates, including value-based purchasing, enhanced fee schedules, Medicaid-specific delivery system reform, or the other approaches consistent with § 438.6(c). A state may elect to use a shorter transition period but would be permitted a maximum of 3 years to phase out the pass-through payments. We believe that the proposed 3-year pass-through payment transition period in paragraph (d)(6)(iv) is appropriate because states have not yet transitioned these services (and corresponding supplemental payments) into managed care contracts; therefore, states should be in a better position to design payment structures that appropriately account for these payments during the transition to managed care (unlike the current pass-through payments rules, which only provide transition periods for pass-through payments that were already incorporated into managed care contracts and rates prior to the adoption of specific limits on the state direction of payments made by managed care plans). We specifically invite comment on whether the 3-year pass-through payment transition period is the appropriate transition time.

Unlike the 2016 final rule, this proposal would not set a specific calendar date by which states must end pass-through payments; rather, our proposal would provide a transition period for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP. By providing states, network providers, and managed care plans time and flexibility to integrate current pass-through payment arrangements into permissible managed care payment structures, states would be able to avoid disruption to safety-net provider systems that they have developed in their Medicaid programs.

We solicit comments on our proposals.

d. Payments to MCOs and PIHPs for Enrollees That Are a Patient in an Institution for Mental Disease (IMD) (§ 438.6(e))

Under the policies we adopted in the 2016 final rule at § 438.6(e), we permitted FFP for a full monthly capitation payment to an MCO or PIHP for an enrollee aged 21 to 64 who received inpatient treatment in an institution for mental disease (IMD) for part of the month when certain requirements are met, including a requirement that the stay in the IMD be for no more than 15 days in the month for which the capitation payment is made (81 FR 27563). Since publication of the 2016 final rule, we have heard from states and other stakeholders that FFP should be provided for capitation payments made for months that include stays longer than 15 days, especially on behalf of Medicaid enrollees who may require substance use disorder (SUD) treatment as a result of the ongoing opioid crisis.

We considered proposing changes to the regulation at § 438.6(e); however, after careful review, we still believe that the underlying legal analysis regarding the transfer of risk that underpinned the policy in the 2016 final rule is appropriate. We have also conducted a literature and data review since publication of the rule but could not identify any new data sources other than those we relied upon in the 2016 final rule that supported 15 days (81 FR 27560). We request public comment on additional data sources that we should review. We also have concerns about the potential for cost-shifting to the federal government. Therefore, to address concerns expressed by Medicaid directors regarding the 15-day limit in the context of SUD treatment and the ongoing opioid crisis, we encourage states to apply for a section 1115(a) SUD demonstration to enable states to receive FFP for longer lengths of stay in IMDs. In November 2017, we developed the current section 1115(a) SUD demonstration initiative [6] that greatly simplified the application and approval process, offered more streamlined and flexible components, and included enhanced monitoring and evaluation features. We have already approved several states and are actively working with additional states that have indicated an interest in applying.

[6] SMD #17–003: Strategies to Address the Opioid Epidemic: *https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.*

5. Rate Certification Submission (§ 438.7)

Section 438.7(c)(3) gives states flexibility to make *de minimis* rate adjustments during the contract year by enabling states to increase or decrease the capitation rate certified per rate cell by 1.5 percent (resulting in an overall 3 percent range) without submitting a revised rate certification. We stated in the 2016 final rule that the fluctuation of plus or minus 1.5 percent does not change the actuarial soundness of a capitation rate as that percentage is generally not more than the risk margin incorporated into most states' rate development process and reasoned that the resulting rate would remain actuarially sound (81 FR 27568). By giving states the flexibility to make small adjustments around the certified rate, we intended to ease the administrative burden of rate review on states while meeting our goals of transparency and integrity in the rate-setting process.

Since the publication of the 2016 final rule, some stakeholders have expressed a desire for CMS to clearly express that once a state has certified the final capitation rate paid per rate cell under each risk contract, the state can adjust the certified rate plus or minus 1.5 percent at any time within the rating period without submitting justification to CMS. We clarify here that when states are adjusting a final certified rate within the contract year within the range of 1.5 percent up or down from the final certified rate, states do not need to submit a revised rate certification or justification to CMS, unless documentation is specifically requested by CMS in accordance with our proposed revisions in paragraph (c)(3). Proposed § 438.7(c)(3) would include the existing text authorizing the state to increase or decrease the capitation rate per rate cell up to 1.5 percent without submitting a revised rate certification. Proposed paragraph (c)(3) would also retain the remaining text in current § 438.7(c)(3) that such adjustments to the final certified rate must be consistent with a modification of the contract as required in § 438.3(c) and adds new proposed text to specify that the adjustments would also be subject to the requirements at § 438.4(b)(1), and that we would be able to require a state to provide documentation for adjustments permitted under § 438.7(c)(3) to ensure that modifications to a final certified capitation rate comply with the requirements in §§ 438.3(c) and (e), and 438.4(b)(1).

In the 2016 final rule, we highlighted our concerns that different capitation rates based on the FFP associated with a particular population could be indicative of cost shifting from the state to the federal government and were not consistent with generally accepted actuarial principles (81 FR 27566). The rate development standards we instituted with the final rule sought to eliminate such practices. The +/− 1.5 percent rate changes permitted in § 438.7(c)(3) are not intended to be used by states to shift costs to the federal government. To ensure against cost shifting, we are explicitly requiring that any changes of the capitation rate within the permissible 1.5 percent are subject to the requirement in § 438.4(b)(1), which prohibits differing capitation rates based on FFP and requires that any proposed differences among capitation rates according to covered populations be based on valid rate development standards and not based on the rate of FFP associated with the covered populations. In addition, § 438.4(b)(1) requires that rates be developed in accordance with § 438.5 and generally accepted actuarial principles and practices; using this cross-reference to regulate mid-year changes of capitation rates within the +/− 1.5 percent range ensures that these changes are not arbitrary or designed to shift costs to the federal government. The proposed regulation permits CMS to require documentation as to how the adjusted rate is consistent with that requirement and other criteria related to the actuarial soundness of rates.

Nationally, states are expanding their managed care programs to include more Medicaid beneficiaries, and both plans and states have requested additional guidance regarding our rate review and approval process. We believe that additional guidance can serve to enhance the efficiency of the review and approval process for states and CMS alike, particularly for states that are new to Medicaid managed care. When states first transition from a FFS delivery system to a managed care delivery system, they often need extra assistance to enable them to be more efficient in developing procurement processes and to increase their likelihood of setting actuarially sound capitation rates. Additionally, competitive procurement processes can be costly and time consuming when considering the scope and number of stakeholders involved in the process. Rate setting can be particularly challenging when it is part of the competitive bidding process. As such, we believe that additional guidance from CMS may benefit those

states and us in the rate review and approval process.

To respond to these needs, we propose to add § 438.7(e) to commit CMS to, at least annually, issuing guidance that describes: (1) The federal standards for capitation rate development; (2) the documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of a contract; (3) the documentation required to determine that the capitation rates have been developed in accordance part 438; (4) any updates or developments in the rate review process to reduce state burden and facilitate prompt actuarial reviews; and (5) the documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistently with the requirements of § 438.4 through § 438.8. We note here that CMS would not adopt new requirements in this guidance; such guidance would only interpret the regulations and specify procedural rules for complying with the requirements in the rule, such as the information provided in rate certifications. This guidance will be published as part of the annual rate guide for Medicaid managed care under the PRA package, CMS–10398 #37, OMB control number 0938–1148.

Although we have published rate review guidance every year since 2014, particularly for those areas described in proposed § 438.7(e)(1) through (3), we propose to codify this practice in § 438.7(e) to demonstrate our commitment to efficient review and approval processes. Although the current rate review guidance has not previously addressed those areas described in proposed § 438.7(e)(4) and (5), we propose that annual guidance include these because states have specifically requested guidance in these areas. We will continue to work with states to ensure greater transparency regarding the rate review process and ensure that states are optimally informed to prepare and submit rate certifications for our review and approval.

We solicit comments on our proposals and whether additional areas of guidance would be helpful to states.

6. Medical Loss Ratio (MLR) Standards: Technical Correction (§ 438.8)

In the 2015 proposed rule (80 FR 31109), we proposed at § 438.8(e)(4) that expenditures related to fraud prevention activities, as set forth in § 438.608(a)(1) through (5), (7), (8) and (b), may be attributed to the numerator but would be limited to 0.5 percent of MCO's, PIHP's, or PAHP's premium revenues. The MLR numerator is defined in § 438.8(e); the numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims; the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality; and fraud prevention activities. This proposal was never finalized and does not align with the MLR requirements for Medicare or the private market. We proposed a corresponding requirement, at paragraph (k)(1)(iii), for submission by each managed care plan of data showing the expenditures for activities described in § 438.608(a)(1) through (5), (7), (8) and (b). In the 2016 final rule (81 FR 27530), we did not finalize § 438.8(e)(4) as proposed, and instead finalized § 438.8(e)(4) to provide that MCO, PIHP, or PAHP expenditures on activities related to fraud prevention, as adopted for the private market at 45 CFR part 158, would be incorporated into the Medicaid MLR calculation in the event the private market MLR regulations were amended. However, we erroneously finalized § 438.8(k)(1)(iii) as proposed instead of referencing the updated finalized regulatory language in § 438.8(e)(4). Therefore, we are proposing in this rule to revise § 438.8(k)(1)(iii) to replace ''expenditures related to activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b)'' with ''fraud prevention activities as defined in § 438.8(e)(4)'' to be consistent with our changes to § 438.8(e)(4) in the previous final rule. We are also proposing to correct a technical error in paragraph (e)(4) by removing the phrase ''fraud prevention as adopted'' and adding in its place the phrase ''fraud prevention consistent with regulations adopted'' to clarify the regulatory text.

7. Non-Emergency Medical Transportation PAHPs (§ 438.9)

In the 2016 final rule, at § 438.9(b)(2), we inadvertently failed to exempt NEMT PAHPs from complying with § 438.4(b)(9). Section 438.9(b) generally exempts NEMT PAHPs from complying with regulations in part 438 unless the requirement is listed. Under the regulation, NEMT PAHPs are not required to comply with the MLR standards. Therefore, we believe that the inclusion of all of § 438.4 in § 438.9(b)(2) causes a conflict because § 438.4(b)(9) specifically addresses states' responsibility to develop capitation rates to achieve a medical loss ratio of at least 85 percent. To eliminate that conflict, we propose to revise § 438.9(b)(2) by adding ''except § 438.4(b)(9).''

8. Information Requirements (§ 438.10)

a. Language and Format (§ 438.10(d))

In the 2016 final rule, we finalized provisions at § 438.10(d)(2), (d)(3), and (d)(6)(iv), requiring that states and managed care plans include taglines in prevalent non-English languages and in large print in all written materials for potential enrollees and enrollees. Based on print document guidelines from the American Printing House for the Blind, Inc., we defined large print to mean no smaller than 18-point font (81 FR 27724).[7] Taglines required to be large print are those that explain the availability of written translation or oral interpretation, how to request auxiliary aids and services for individuals who have limited English proficiency or a disability, and the toll-free phone number of the entity providing choice counseling services.

Our goal remains to ensure that materials for enrollees and potential enrollees are accessible for individuals who are vision-impaired. However, since the publication of the final rule, states and plans have found that requiring taglines in 18-point font size sometimes increases overall document length, thereby decreasing the ease of use by enrollees and eliminating the use of certain effective formats such as postcards and trifold brochures.

To address these issues, we propose to replace the requirement to include taglines on ''all written materials'' with a requirement for taglines only on materials for potential enrollees that ''are critical to obtaining services'' in § 438.10(d)(2). This proposed change aligns the documents that require taglines with the documents that must be translated into prevalent non-English languages and facilitates the use of smaller, more user-friendly documents. We note that states have the ability to require taglines on any additional materials that they choose, as including taglines only on documents that are critical to obtaining services is a minimum standard.

Additionally, we propose to revise § 438.10(d)(2) by deleting the definition of large print as ''no smaller than 18-point'' and adopting the ''conspicuously visible'' standard for taglines that is codified at 45 CFR 92.8(f)(1), a regulation implementing section 1557 of the Patient Protection and Affordable Care Act of 2010 (PPACA) (Pub. L. 111–148, enacted March 23, 2010 as

[7] American Printing House for the Blind, Inc. Print Document Guidelines. *http://www.aph.org/research/design-guidelines/.*

amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010)).[8] Section 1557 of the PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs, including Medicaid. We believe that adopting a more flexible requirement would encourage states to use effective forms of written communication and avoid unnecessarily long documents. For example, taglines in a font size smaller than 18-point would permit states to more easily use postcards and tri-fold brochures, which may be more effective for relaying certain information since they are shorter and offer more design options for visual appeal. We note again that states would retain the ability to create additional requirements for greater specificity of font size for taglines for written materials subject to § 438.10 as long as they meet the standard of conspicuously-visible and comply with all other federal non-discrimination standards, including providing auxiliary aids and services to ensure effective communications for individuals with disabilities.

In § 438.10(d)(3), we propose to make the same substantive changes proposed for § 438.10(d)(2) above, as well as to reorganize the paragraph for clarity. We believe that combining the requirements for the provision of alternative formats, taglines, and inclusion of the managed care plan's member/customer service unit telephone number into one sentence in paragraph (d)(3), would improve readability and clarity.

Section 438.10(d)(6) addresses requirements for all written materials provided by states and MCOs, PIHPs, PAHPs, primary care case management (PCCM) and PCCM entities to enrollees and potential enrollees. As we are proposing to limit the tagline requirement to materials that are critical to obtaining services, we propose to delete § 438.10(d)(6)(iv).

b. Information for All Enrollees of MCOs, PIHPs. PAHPs, and PCCM Entities: General Requirements (§ 438.10(f))

In the comprehensive revision to federal regulations governing Medicaid managed care in 2002, we required notice to enrollees of a provider's termination within 15 days of a covered plan's receipt or issuance of the termination notice (67 FR 41015). For purposes of this provision, an affected enrollee is one who received his or her primary care from, or was seen on a regular basis by, the terminated provider. We established the 15-day time-period following receipt of notice because we wanted to ensure that enrollees received notice of the provider terminations in advance given the reality that providers often give little notice of their plans to terminate participation in a network (67 FR 41015). Section 438.10(f)(1) requires that a managed care plan must make a good-faith effort to provide notice of the termination of a contracted in-network provider to each affected enrollee within 15 days of receipt or issuance of the termination notice. However, there can be circumstances when plans or providers send a termination notice to meet their contractual obligations but continue negotiating in an effort to resolve the issue(s) that triggered the decision to commence termination procedures. If the issue(s) can be amicably resolved, then the termination notice is sometimes rescinded and the provider remains in the network. In these situations, the issuance of notices by a state to enrollees before resolution efforts have been attempted, can cause alarm and confusion for enrollees who believe that they need to locate a new provider.

In an effort to prevent unnecessary notices from being sent to enrollees, proposed § 438.10(f)(1) would change the requirement that managed care plans issue notices within 15 calendar days after receipt or issuance of the termination notice to the later of 30 calendar days prior to the effective date of the termination or 15 calendar days after the receipt or issuance of the notice. For example, if the plan receives a termination notice from a provider on March 1 for a termination that is effective on May 1, the proposed regulation would contemplate written notice to enrollees be provided by April 1 (30 days prior to effective date) or by March 16 (within 15 days of receipt of the termination notice), whichever is later. In this example, the managed care plan would have to issue a notice to the enrollees by April 1, since it is later.

c. Information for All Enrollees of MCOs, PIHPs. PAHPs and PCCM Entities: Enrollee Handbooks (§ 438.10(g))

In the 2016 final rule, an erroneous reference was included in § 438.10(g)(2)(ii)(B) to ''. . . paragraph (g)(2)(i)(A). . . .'' Because there is no such paragraph as § 438.10(g)(2)(i)(A), we propose in this rule to correct the reference to ''. . . paragraph (g)(2)(ii)(A). . . .''

d. Information for All Enrollees of MCOs, PIHPs. PAHPs and PCCM Entities: Provider Directories (§ 438.10(h))

In the 2016 final rule, we added the requirement at § 438.10(h)(1)(vii) that managed care plans include information in their provider directories on whether the provider has completed cultural competence training. We added this requirement to the final rule in recognition of the linguistic and cultural diversity of Medicaid beneficiaries (81 FR 27724). After the final rule was published, the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) (the Cures Act) amended section 1902 of the Act,[9] to add requirements for publication of a FFS provider directory.[10] Now that the Congress has established new standards for provider directories in FFS Medicaid, we believe that it is beneficial to Medicaid managed care enrollees to align the requirements for Medicaid managed care with the FFS directories, especially since many managed care enrollees also receive some services on a FFS basis. The proposed amendment would require that the information in the directory include the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the skilled medical interpreter providing interpretation services at the physician's or provider's office. The statute does not require information on whether the provider has completed cultural competence training. Therefore, we propose to amend § 438.410(h)(1)(vii) to eliminate the phrase ''and whether the provider has completed cultural competence training.''

In the 2016 final rule, we finalized at § 438.10(h)(3) requirements that information in a paper directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days of receiving updated provider information. In paragraph (h)(1), we clarified that paper provider directories need only be provided upon request, and we encouraged plans to find efficient ways to provide accurate directories within the required timeframes (81 FR 27729).

Since the publication of the 2016 final rule, states and managed care plans have raised concerns about the cost of reprinting the entire directory monthly. While the final rule did not require that the directory be reprinted in its entirety monthly, many managed care plans

[8] Nondiscrimination in Health Programs and Activities final rule (81 FR 31375).

[9] Section 1902(a)(83)(A)(ii)(II) of the Act.

[10] Section 5006 of the Cures Act added paragraph (83)(A)(ii)(II) to section 1902(a) of the Act.

were forced to do so to recognize savings from printing in large quantities. To address this inefficiency, as well as to provide managed care plans with another option for reducing the number of paper directories requested by enrollees due to the lack of access to a computer, we propose to modify the requirements for updating the paper provider directory that would permit less than monthly updates to paper directories if the managed care plan offers a mobile-enabled, electronic directory.

Research has shown that 64 percent of U.S. adults living in households with incomes less than $30,000 a year owned smartphones in 2016.[11] Further, lower-income adults are more likely to rely on a smartphone for access to the internet, because they are less likely to have an internet connection at home.[12] Recent studies show that the majority of Americans have used their smartphones to access information about their health,[13] and consider online access to health information important.[14] We believe that providing mobile-enabled access to online provider directories may provide additional value to enrollees by allowing them to access the information anytime, anywhere which is not feasible with a paper directory. Mobile applications for beneficiaries are increasingly available in programs serving older adults and individuals with disabilities and include access to Medicare marketing materials [15] and medical claims on Blue Button [16] to empower enrollees to better manage and coordinate their healthcare. For enrollees that request a paper directory, we believe the quarterly updates will not significantly disadvantage them as other avenues for obtaining provider information are readily available, such as the managed care plan's customer service or the state's beneficiary support system.

To reflect this change and modify the requirements for updating the paper provider directory to permit less than monthly updates if the managed care plan offers a mobile-enabled directory, we propose several revisions to § 438.10(h)(3). First, we propose to add paragraphs (i) and (ii) to § 438.10(h)(3) which would delineate requirements for paper directories from those for electronic directories. Second, we propose to add paragraphs (i)(A) and (B) which would reflect, respectively, that monthly updates are required if a plan does not offer a mobile enabled directory and that only quarterly updates are required for plans that do offer a mobile enabled directory. Lastly, we propose to make ''directories'' singular (''directory'') at § 438.10(h)(3)(ii) which would avoid implying that a managed care plan must have more than one directory of providers.

We remind managed care plans that some individuals with disabilities, who are unable to access web applications or require the use of assistive technology to access the internet, may require auxiliary aids and services to access the provider directory. In keeping with the requirement that managed care plans must provide auxiliary aids and services to ensure effective communication for individuals with disabilities consistent with section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, enacted on September 26, 1973) and section 1557 of the PPACA, these individuals should, upon request, be given the most current provider directories in the same accessible format (paper or electronic) that they receive other materials.

We encourage managed care plans to perform direct outreach to providers on a regular basis to improve the accuracy of their provider data and to ensure that all forms of direct enrollee assistance (such as telephone assistance, live web chat, and nurse help lines) are effective, easily accessible, and widely publicized.

9. Disenrollment: Requirements and Limitations (§ 438.56)

We inadvertently included PCCMs and PCCM entities in paragraph § 438.56(d)(5) related to grievance procedures. Because PCCMs and PCCM entities are not required by § 438.228, which does impose such a requirement on MCOs, PIHPs and PAHPs, to have an appeals and grievance process, we propose to revise § 438.56(d)(5) to delete references to PCCMs and PCCM entities. We note that states may impose additional requirements on their managed care plans but believe that our regulations should be internally consistent on this point.

10. Network Adequacy Standards (§ 438.68)

As discussed in the 2015 proposed rule (80 FR 31144 through 31146), we proposed a new § 438.68 to stipulate that a state must establish network adequacy standards for specified provider types. We proposed in § 438.68(b)(1) that states develop and enforce time and distance standards for specified provider types (if covered under the contract). In that proposed rule, we explained that states were encouraged to use other measures in addition to time and distance. In response to comments on the 2015 proposed rule, we declined to set other national requirements or specific benchmarks for time and distance (for example, 30 miles or 30 minutes) in the 2016 final rule (81 FR 27661). Instead, we noted that we believed it best not to be overly prescriptive and give states the flexibility to build upon the required time and distance standards as they deem appropriate and meaningful for their programs and populations. (81 FR 27661).

In the 2015 proposed rule discussion of the requirement now codified at § 438.68(b)(2), we requested comment on network adequacy standards for LTSS. As noted in the final rule, commenters recommended that we adopt some form of network adequacy standards for LTSS, but the comments were few in number and lacked consensus regarding specific standards that have been used or that have proven adequate to assure network adequacy. For these reasons, we stated that the best strategy was for states to develop their own time and distance standards for LTSS provider types to which a beneficiary travels. Similarly, we did not require any specific type of minimum network adequacy standard for LTSS provider types that travel to the beneficiary, and instead deferred such an analysis to the states (81 FR 27665).

As states have worked to comply with the final rule, they have alerted us to increasing concerns about the appropriateness of uniformly applying time and distance standards. In some situations, time and distance may not be the most effective type of standard for determining network adequacy and some states have found that time and distance analysis produces results that do not accurately reflect provider availability. For example, a state that has a heavy reliance on telehealth in certain areas of the state may find that a provider to enrollee ratio is more useful in measuring meaningful access, as the enrollee could be well beyond a normal time and distance standard but can still easily access many different providers on a virtual basis. A 2017 Brookings/Schaefer Center report notes that in some clinical areas, telemedicine

[11] *http://www.pewinternet.org/fact-sheet/mobile/.*

[12] *Id.*

[13] *http://www.pewresearch.org/fact-tank/2015/04/30/racial-and-ethnic-differences-in-how-people-use-mobile-technology/.*

[14] *https://www.ncbi.nlm.nih.gov/pubmed/27413120.*

[15] 2016 Medicare Marketing Guideline 100.6. *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf.*

[16] *http://bluebuttonconnector.healthit.gov/.*

could make proximity measures obsolete, or counterproductive.[17]

To address states' concerns and ensure that states use the most effective and accurate standards for their programs, we propose to revise § 438.68(b)(1) and (b)(2) by deleting the requirements for states to set time and distance standards and adding a more flexible requirement that states set a quantitative minimum access standard for specified health care providers and LTSS providers. We believe that this change would enable states to choose from a variety of quantitative network adequacy standards that meet the needs of their respective Medicaid programs in more meaningful and effective ways. Quantitative standards that states may elect to use include, but are not limited to, minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We believe it is particularly important that states have flexibility for the standards for LTSS programs given the often very limited supply of providers and the potential functional limitations of the LTSS population. We encourage states to solicit stakeholder input in the development of their network standards. By proposing these changes, the requirements for network adequacy standards would be consistent for all provider types. As such, we propose to remove paragraphs § 438.68(b)(2)(i) and (b)(2)(ii), and reflect all LTSS network adequacy requirements in § 438.68(b)(2).

We propose to use the broader standard of ''a quantitative network adequacy standard'' rather than ''time and distance,'' because each type of standard addresses a different issue. For example, a time and distance standard addresses how long or far an enrollee may have to travel for care, whereas ''wait-times for an appointment'' address the availability or capacity of providers in the network to serve enrollees in a timely manner. We encourage states to use the quantitative standards in combination—not separately—to ensure that there are not gaps in access to and availability of services for enrollees.

[17] Hall, Mark, A. and Ginsburg, Paul, B. A Better Approach to Regulating Provider Network Adequacy (September 2017). Available at *https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf.*

Section 438.68(b)(1) specifies the provider types for which states are required to establish network adequacy standards. Section 438.68(b)(1)(iv) requires states to establish time and distance standards for ''specialist, adult and pediatric.'' As noted in the final rule, we believe that states should set network adequacy standards that are appropriate at the state level and are best suited to define the number and types of providers that fall into the ''specialist'' category based on differences under managed care contracts, as well as state Medicaid programs. Therefore, we believe it would be inappropriate for us to define ''specialist'' at the federal level (81 FR 27661). Since the publication of the 2016 final rule, we have received numerous questions from states and other stakeholders about who should define the types of providers to be included as specialists. We are clarifying with this proposal that states have the authority under the final rule to define ''specialist'' in whatever way they deem most appropriate for their programs. To make this authority clear, we propose to revise § 438.68(b)(1)(iv) to add ''(as designated by the state)'' after ''specialist.'' This proposed change would eliminate potential uncertainty regarding who has responsibility to select the provider types included in this category for the purposes of network adequacy. In addition, the proposed modification to § 438.68(b)(1)(iv) would reduce the burden on a state by eliminating the need to set a standard for every possible specialist, as a few states interpreted the text of the final rule.

In § 438.68(b)(1)(viii), we require states to establish time and distance standards for ''additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.'' In the 2016 final rule, we finalized the language in § 438.68(b)(1)(viii) because it provided the flexibility to address future national provider workforce shortages and future network adequacy standards (81 FR 27660). Additionally, we noted that if we ever elected to utilize this provision to identify additional provider types, we would only do so after soliciting public input (81 FR 27660). Since the 2016 final rule was published, states have expressed concern that if we rely on this authority and its flexibility of identifying ''additional provider types,'' managed care plans may have to assess network adequacy and possibly build network capacity without sufficient time. Based on these comments, we propose to remove § 438.68(b)(1)(viii) to eliminate any uncertainty states may have regarding this requirement.

11. Adoption of Practice Guidelines (§ 438.236)

In the 2016 final rule, we attempted to remove the terminology ''contracting health care professionals'' throughout the rule because it is not defined in any regulation or statute and we believed that use of ''network provider'' as defined in § 438.2 was more accurate. We inadvertently missed removing the term at § 438.236(b)(3). To correct this, we propose to remove the words ''contracting health care professionals'' and insert ''network providers'' in § 438.236(b)(3).

12. Enrollee Encounter Data (§ 438.242(c))

In § 438.242(b)(3) of the final rule, we required that all contracts between a state and an MCO, PIHP, or PAHP provide for the submission of all enrollee encounter data that the state is required to submit to CMS under § 438.818. Since the final rule, some states and managed care plans have expressed concern about, and been hesitant to submit, certain financial data—namely, the allowed amount and the paid amount. Managed care plans consider this information to be proprietary and inappropriate for public disclosure. We understand this concern but emphasize the importance of these data for proper monitoring and administration of the Medicaid program, particularly for capitation rate setting and review, financial management, and encounter data analysis. Additionally, the allowed and paid amounts of claims are routinely included on explanation of benefits provided to enrollees; thus making this information already publicly available. To clarify the existing requirement and reflect the importance of this data, we propose to revise § 438.242(c)(3) to explicitly include ''allowed amount and paid amount.'' We note that the proposed change to § 438.242(c)(3) would in no way change the rights of federal or state entities using encounter data for program integrity purposes to access needed data. Nor would it change the disclosure requirements for explanation of benefits notices or other disclosures to enrollees about their coverage.

The health insurance industry has consistently asserted that the contractual payment terms between managed care plans and providers is confidential and trade secret information and that the disclosure of this information could cause harm to

the competitive position of the managed care plan or provider. We recognize the significance of managed care plans' concerns and commit to treating this data as trade secret when the requirements for such a classification are met. CMS recognizes the significance of the volume of data collected in the Transformed Medicaid Statistical Information System (T–MSIS) and takes its obligations seriously to protect from disclosure information that is protected under federal law. Our goal in proposing to explicitly name allowed and paid amount in § 438.242(b)(3) is to ensure that the scope of the collection of encounter data is clear. We affirm our commitment to safeguarding data protected by federal law from inappropriate use and disclosure.

13. Medicaid Managed Care Quality Rating System (QRS) (§ 438.334)

In the 2016 final rule (81 FR 27686), we established at § 438.334 the authority to require states to operate a Medicaid managed care quality rating system (QRS) and incorporated this provision in its entirety into CHIP at § 457.1240(d). The regulation provides that CMS, in consultation with states and other stakeholders, develop a QRS framework, including the identification of performance measures and methodologies, which states could adopt. States have the option to use the CMS-developed framework or establish a state-specific QRS producing substantially comparable information about plan performance subject to CMS approval of the alternative system.

Several policy objectives are supported by the QRS requirement. First, implementation of a QRS provides a vehicle to hold states and plans accountable for the care provided to Medicaid and CHIP beneficiaries. Second, a QRS empowers beneficiaries by providing them with information about the plans in their state, enabling them to be more informed health care consumers. Third, a QRS provides an important tool for states to drive improvements in plan performance and the quality of care provided by their programs.

Since publication of the 2016 final rule, we have begun the early stages of a stakeholder engagement process needed for the CMS-developed framework. We have conducted interactive listening sessions with various stakeholders, including state and health plan stakeholder groups directors, and interviewed several beneficiaries. We also have convened a diverse technical expert panel (TEP) to meet periodically to advise CMS on the framework, objectives, measures, and methodologies for the CMS-developed QRS. The TEP includes representatives from state Medicaid and CHIP agencies, plans, beneficiary advocates, and quality measurement experts. We expect that this robust engagement of states and other stakeholders would continue through the publication of the notice of a proposed QRS framework called for in the current regulations at § 438.334(b).

The requirement in the current regulations that all Medicaid and CHIP QRS yield substantially comparable information serves to enable comparison of plans performance across states. States and beneficiary advocates have expressed strong support for this goal. In addition, the standardization of measures and methodologies necessary to generate comparable information would reduce burden on plans with products in multiple states. During our early stakeholder engagement sessions, however, the technical and methodological complexities of producing substantially comparable information to enable meaningful comparisons between plans across states, was raised—challenges which are heightened by the heterogeneous nature of states' Medicaid and CHIP programs. Some states expressed concern that the 2016 final rule may not have struck the optimal balance between the interests of standardization and state flexibility. We agree, and therefore, are proposing to make several revisions to the QRS regulations at § 438.334 (note that we propose no changes to § 457.1240(d), therefore all proposed changes would apply equally to both a state's Medicaid and CHIP programs). These revisions are intended to better balance the goal of facilitating inter-state comparisons of plan performance and reducing plan burden with the need for state flexibility and the practical challenges inherent in producing comparable ratings across states.

Specifically, we propose to revise the requirement in § 438.334(c)(1)(i) (redesignated as paragraph (c)(1)(ii) in this proposed rule) that an alternative state QRS produce substantially comparable information to that yielded by the CMS-developed QRS to require that the information yielded be substantially comparable to the extent feasible to enable meaningful comparison across states, taking into account differences in state programs that complicate achieving comparability. We also propose to add a new paragraph (c)(4) to explicitly provide that we would engage with states and other stakeholders in developing subregulatory guidance on what it means for an alternative QRS to yield substantially comparable information, and how a state would demonstrate it meets the standard. We also propose revisions to paragraph (b) to provide that, in developing the CMS-developed QRS framework in consultation with states and other stakeholders and using public notice and an opportunity to comment, we would identify a set of mandatory performance measures. We propose to redesignate § 438.334(c)(1)(i) and (c)(1)(ii) as paragraphs (c)(1)(ii) and (c)(1)(iii), respectively, and add new paragraph (c)(1)(i) which would provide that a state alternative QRS must include the mandatory measures identified in the framework. Recognizing the challenges that exist in achieving comparable ratings across states, we believe that identifying a uniform set of mandatory measures which are key to high-quality Medicaid and CHIP programs in any state would be critical. The QRS is subject to the Paperwork Reduction Act approval process, including notice and comment under the PRA, and is included in CMS–10553, OMB Control Number 0938–1281. States would retain flexibility to include additional measures important to serving their quality goals and meeting the needs of their beneficiaries and stakeholder communities. We note that Medicaid and CHIP QRS and our recently-launched Scorecard Initiative serve related goals, and we expect to coordinate the measures selected for the Scorecard initiative and those selected for the CMS-developed QRS.

The current regulation provides that the CMS-developed QRS would ''align with the summary indicators'' used by the QRS developed for the qualified health plans (QHP) in the Federally-Facilitated Exchange (FFE) (hereinafter referred to as the ''QHP QRS''). In the QRS listening sessions and TEP meetings held to date, states and other stakeholders have raised that, because the populations served by the QHPs, Medicaid and CHIP are different (with both Medicaid and CHIP serving a significantly higher proportion of children and Medicaid serving a significantly greater proportion of older adults and individuals with disabilities), complete alignment with the QHP QRS may not make sense for Medicaid and CHIP. Therefore, we propose to revise § 438.334(b) to provide that the CMS-developed QRS would align with the QHP QRS where appropriate. Some stakeholders also have suggested that the Medicaid and CHIP QRS also should align, where appropriate, with the Medicare Advantage 5-Star Rating System and the

Medicare-Medicaid Plan (MMP) Financial Alignment Initiative integrated Star Rating strategy (currently in development) in order to reduce reporting burden on plans that operate in the other markets, as well as offering Medicaid and CHIP managed care plans. We agree that aligning the Medicaid and CHIP QRS with these other rating systems, to the extent appropriate given the different populations served by each program and benefit variations between programs, would reduce burden and confusion for plan issuers, which may offer products in more than one program. Therefore, we propose revisions at § 438.334(b) that the CMS-developed QRS also align, where appropriate, to other CMS approaches to rating managed care plans. Alignment will be determined as part of the ongoing development of the proposed measures and methodologies and will be addressed in the QRS-specific rulemaking.

Currently, § 438.334 requires states to obtain our approval prior to implementing an alternative QRS. Pre-approval enables us to determine if an alternative QRS complies with the regulation and meets the ''substantially comparable'' standard before a state invests resources into QRS implementation. However, some states have expressed concern about having enough time to implement a QRS if prior approval from CMS is required. To reduce the upfront administrative burden on states and speed time for implementation, we propose to revise the current introductory language in § 438.334(c)(1) and (c)(1)(ii) to eliminate the requirement that states obtain prior approval before implementing an alternative QRS. In addition, the use of mandatory measures in addition to state-selected measures provides some assurance about the comparability of the alternative QRS developed by the state. Instead of prior CMS approval, we propose at § 438.334(c)(3) that states would, upon CMS request, submit their alternative QRS framework, including the performance measures and methodology to be used in generating plan ratings; documentation of the public comment process described in § 438.334(c)(2)(i) and (ii) including issues raised by the Medical Care Advisory Committee and the public, any policy revisions or modifications made in response to the comments, and rationale for comments not accepted; and other information specified by CMS to demonstrate compliance with § 438.334(c). As part of our general oversight responsibilities, we would still review states' alternative QRS and work with states on any identified deficiencies. This approach is similar to the oversight process CMS uses for states' eligibility verification plans (§ 435.945(j), incorporated into the CHIP requirements by reference at § 457.380(i)), which requires states to submit eligibility verification plans to CMS for finalization upon request, in a manner and format prescribed by CMS.

We solicit comments on these proposals.

14. Managed Care State Quality Strategy (§ 438.340)

Current § 438.340 sets forth the minimum elements of a managed care state quality strategy and the requirements for development, evaluation, revision and public display of the quality strategy. Each state contracting with an MCO, PIHP, or PAHP as defined in § 438.2 or with a risk-bearing PCCM entity, as described in § 438.310(c)(2), must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP, or PCCM entity. Section 438.340(b) sets forth the minimum elements of a managed care state quality strategy.

In the 2016 final rule, we expanded the previous state managed care quality strategy requirements, which applied to states contracting with MCOs and PIHPs, to also apply to states contracting with PAHPs or PCCM entities described in § 438.310(c)(2). As part of that revision, and to conform to other changes in this part, we added paragraph (b)(8), which requires a description of how the state would assess the performance and quality outcomes achieved by each PCCM entity described in § 438.310(c)(2). This paragraph was intended to capture the application of all relevant areas of the state's quality strategy to risk-bearing PCCM entities, in conformance with the inclusion of PCCM entities at § 438.340(a). We intended that states which contract with PCCM entities described in § 438.310(c)(2) would design and describe all of the quality strategy elements to include PCCM entities as appropriate; for example, within the state's goals and objectives for continuous quality improvement in paragraph (b)(2). We similarly intended that other aspects of the managed care quality strategy would apply equally to these PCCM entities, including § 438.340(b)(3)(i) (relating to quality metrics and performance targets); § 438.340(b)(6) (relating to the state's plan to identify, evaluate and reduce health disparities and to provide demographic information to managed care plans); and § 438.340(c)(1)(ii) (regarding Tribal consultation for states who enroll Indians in PCCM entities). However, current § 438.340(b)(2), (b)(3)(i), (b)(6) and (c)(1)(ii) do not explicitly reference PCCM entities, resulting in possible confusion about the application of these quality strategy elements to states which contract with PCCM entities. Our intention in the 2016 final rule was to apply these provisions equally to PCCM entities. Therefore, we propose to add PCCM entities described in § 438.310(c)(2) to the list of managed care plans identified in § 438.340(b)(2), (b)(3)(i), (b)(6) and (c)(1)(ii). We also propose for greater clarity to delete § 438.340(b)(8) and to redesignate paragraphs (b)(9), (b)(10), and (b)(11) as paragraphs (b)(8), (b)(9), and (b)(10), respectively.

We do not propose to add a reference to PCCM entities described in § 438.310(c)(2) to § 438.340(b)(1) because the regulations cross-referenced in paragraph (b)(1)—that is, § 438.68 (relating to state-defined network adequacy), § 438.206 (relating to availability of service standards), and § 438.236 (relating to clinical practice guidelines)—do not apply to PCCM entities. Similarly, we do not propose to add PCCM entities to the list of managed care entities in § 438.340(b)(3)(ii) (related to performance improvement projects (PIPs)) because states are not required under § 438.330(d) to require that PCCM entities conduct PIPs. However, since states have the option to require PIPs for PCCM entities, we encourage states that choose to have their PCCM entities conduct PIPs to describe these PIPs in their managed care quality strategy.

Section 438.340(b)(6) of the current regulations requires that states include, as an element of the managed care quality strategy, their plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on six demographic factors (age, race, ethnicity, sex, primary language, and disability status). It also requires states to transmit this demographic information for each Medicaid enrollee to the enrollee's managed care plan at the time of enrollment into the plan. Section 438.340(b)(6) currently provides that ''disability status,'' for the purposes of this paragraph, means whether the individual qualified for Medicaid on the basis of a disability.

We are concerned that this definition of ''disability status'' may be unintentionally narrow. For example, some individuals with disabilities may not be eligible for Medicaid on the basis of disability, or their disability status may change over time. Others may not

be disabled under the definition used by the Medicaid program, but may be considered disabled under other state or federal laws or regulations (for example, the Americans with Disabilities Act). We believe states should provide a managed care plan with the most accurate, complete, and current demographic information about an enrollee available to the state, regardless of whether this information is from an enrollee's Medicaid eligibility application or from another source. We recognize that the most common source of information about an individual's disability status will be that obtained during the application process, and states are not required to actively seek out sources of information not readily available to the state. However, if states have other or more current sources of information for these six demographic factors, states would be expected to use and transmit that more current information.

Therefore, we propose to remove the sentence defining disability status from § 438.340(b)(6) in addition to adding the reference to PCCM entities described in § 438.310(c)(2). Under the proposed revised regulation, qualifying for Medicaid on the basis of disability would be one source of information to determine a beneficiary's disability status, but not necessarily the only source of this information. We note that this requirement for states to provide demographic information for each Medicaid enrollee to the managed care plan at the time of enrollment is a minimum standard; we encourage states to send updated demographic information to an enrollee's managed care plan whenever updated demographic information is available to the state.

We solicit comments on these proposals.

15. Activities Related to External Quality Review (§ 438.358)

Section 438.358(b)(1) sets forth the mandatory external quality review (EQR)-related activities states must require for their MCOs, PIHPs, and PAHPs. Section 438.358(b)(1)(iii) requires a review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with certain managed care standards. In the 2016 final rule, the cross-citation in § 438.358(b)(1)(iii) to standards at § 438.204(g) was replaced with a streamlined cross-reference to part 438 subpart D (81 FR 27706). We noted that the streamlining of the cross-reference did not propose a significant change from what comprises the current compliance review activity. Subpart D previously had contained cross-references to all of the applicable standards for access to care and structure and operations that are contained in subparts A, B, C, and F. However, several of those cross-references within subpart D were removed in the 2016 final rule, specifically references to § 438.56 (Disenrollment requirements and limitations), § 438.100 (Enrollee rights), and § 438.114 (Emergency and post-stabilization services). The removal of these cross-references from subpart D inadvertently dropped reference citations for these critical standards from the EQR compliance review. This was not our intention, as these sections have been included in the EQR protocol for the compliance review activity since the initial release of the protocols in 2003 and in all subsequent revisions of the protocols. Therefore, we propose a technical correction to add directly to § 438.358(b)(1)(iii) the three cross-references to §§ 438.56, 438.100 and 438.114.

We solicit comments on these proposals.

16. Exemption From External Quality Review (§ 438.362)

Section 438.362 implements section 1932(c)(2)(C) of the Act, which provides that a state may exempt an MCO from undergoing an EQR when certain conditions are met. First, the MCO must have a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, as well as the current Medicaid contract under section 1903(m) of the Act. Second, the two contracts must cover all or part of the same geographic area within the state. Third, the Medicaid contract must have been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years, the MCO has been found to be performing acceptable for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries. Neither the statute nor § 438.362 requires states to exempt plans from EQR; this is provided only as an option for states. States have discretion to require all their managed care plans to undergo EQR, even those that appear eligible for an exemption under this section.

In the 2016 final rule (81 FR 27713), we received comments regarding limiting the use of exemption which also raised transparency concerns. Since the issues raised in the comments were outside the scope of that rulemaking, we encouraged, but did not require, states to make public which Medicaid health plans have been exempted from EQR under § 438.362 and for how long. We indicated we would consider proposing in future rulemaking, a requirement that states post this information publicly. Therefore, we propose to add § 438.362(c) to require that states annually identify on their website, in the same location where EQR technical reports are posted, the names of the MCOs it has exempted from EQR, and when the current exemption period began. We believe that posting this information on the state's website would not present a burden to states since states already make exemption determinations, inform their EQRO of which plans are exempted from EQR, and maintain EQR information on their website, activities which are already accounted for in the associated information collections.

As an alternative, we are considering revising § 438.364(a) (External Quality Review Results-Information that must be produced) to require that states identify the exempted plans and the beginning date of the current exemption period in the annual EQR technical report. This identification could be in addition to or as an alternative to posting this information directly on the state's website. We could revise paragraph (a)(i) to add a sentence incorporating the same information we propose to add to § 438.362.

We solicit comments on this proposal. We also welcome information about how states are currently using the exemption provision and how states currently make that information publicly available.

17. External Quality Review Results (§ 438.364)

On page 27886 of 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 (81 FR 27498, May 6, 2018), we made a technical error in the regulation text of § 438.364(d) (Safeguarding patient identity). In this paragraph, we inadvertently referenced paragraph (b) of this section (Revision) instead of referencing paragraph (c) of this section (Availability of Information). Accordingly, we propose to revise § 438.364(d) to reflect the correct reference.

18. Grievance and Appeal System: Statutory Basis and Definitions (§ 438.400)

In the 2016 final rule, we finalized at § 438.400(b)(3) the definition of an ''adverse benefit determination'' including denials in whole or in part of payment for service. The term adverse

benefit determination was proposed and finalized in the 2016 final rule as a replacement for the term ''action,'' which had been defined with the same definition in the 2002 rule. Under § 438.404(a), managed care plans are required to give enrollees timely notice of an adverse benefit determination in writing and consistent with the requirements in § 438.10 generally. Given the broad meaning of the term ''denial of a payment,'' some managed care plans may be generating a notice to each enrollee for every denied claim, even those that are denied for purely administrative reasons (such as missing the National Provider Identifier, missing the enrollee's sex, or because the claim is a duplicate) and which generate no financial liability for the enrollee. Issuing notices of such adverse benefit determinations for which the enrollee has no financial liability nor interest in appealing simply to comply with § 438.404(a) may create administrative and economic burdens for plans, and unnecessary confusion and anxiety for enrollees who frequently misunderstand the notices as statements of financial liability.

To alleviate unnecessary burden on the managed care plans and enrollees, we propose to add language in § 438.400(b)(3), that would indicate that a denial, in whole or in part, of a payment for a service because the claim does not meet the definition of a clean claim at § 447.45(b) [18] is not an adverse benefit determination. As such, the notice requirements in § 438.404 would not be triggered. We believe this proposed modification would eliminate burden on plans to send unnecessary notices and avoid anxiety for enrollees receiving such notices. This proposed change is not expected to expose enrollees to financial liability without notice, or jeopardize their access to care or rights to an appeal.

While notices to enrollees for claims that do not comply with the clean claim definition in § 447.45(b) would not be required under our proposed amendment to § 438.400(b)(3), the notice requirements for all future claims (including resubmission of the same claim) would have to be independently determined. For example, if a provider resubmits a clean claim after the initial one was not processed because it did not comply with the requirements in § 447.45(b), and the managed care plan subsequently issues an adverse benefit determination, the managed care plan would still be required to issue a timely notice under § 438.404(a) for the second claim. Whether an adverse benefit determination notice is required would have to be determined for each claim, regardless of whether notices were required for previously submitted claims.

We solicit comments on our proposal.

19. Grievance and Appeal System: General Requirements (§§ 438.402 and 438.406)

In the 2016 final rule, we adopted the requirement that an oral appeal must be followed by a written, signed appeal at § 438.402(c)(3)(ii).[19] This requirement was also included at § 438.406(b)(3), regarding handling of grievances and appeals, where managed care plans must treat oral inquiries seeking to appeal an adverse benefit determination as appeals and that such oral inquiries must be confirmed in writing. We received comments to the proposed rule that stated that the written, signed requirements added an unnecessary barrier to enrollees filing an appeal with the managed care plan. At that time, we believed that this requirement was necessary to ensure appropriate and accurate documentation of enrollees' appeals. While the resolution timeframe for an oral appeal begins on the date of the oral appeal, managed care plans cannot issue a resolution until the enrollee submits the written, signed appeal (81 FR 27511). Managed care plans have found that some enrollees may take too long to submit the written, signed appeal, while others fail to submit the written appeal at all. This creates problems for managed care plans who must invest resources to encourage enrollees to submit the documentation, as well as uncertainty for managed care plans as to how to comply with § 438.406 (Handling Grievances and Appeals) in cases when the enrollee does not submit the written, signed appeal.

After the opportunity to hear from states regarding their experience with this requirement, we propose to eliminate the requirement for enrollees to submit a written, signed appeal after an oral appeal is submitted. We believe the removal of the requirement would reduce barriers for enrollees who would not have to write, sign, and submit the appeal, decrease the economic and administrative burden on plans, and would expedite the appeals process. This proposed change would also harmonize the managed care appeal process with the state fair hearing process.[20]

We considered retaining the written, signed appeal requirement, but permitting the managed care plan to proceed with the process in the absence of it, if the managed care plan demonstrates that a good faith effort was made to obtain the written, signed appeal. However, we believed that demonstrating a good faith effort increased burden on the states and plans with no additional benefit for the enrollee. Therefore, we are proposing the elimination of the written, signed appeal requirement in §§ 438.402(c)(3)(ii) and 438.406(b)(3), as we believe the elimination of the written requirement benefits all parties involved. Although we are proposing to eliminate the requirement that an oral appeal must be followed by a written, signed appeal, as we noted in the 2016 final rule, we continue to expect managed care plans to treat oral appeals in the same manner as written appeals (81 FR 27511). We are proposing to retain the current regulatory language in § 438.406(b)(3) that specifies that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

20. Resolution and Notification: Grievances and Appeals (§ 438.408)

In the 2016 final rule, we revised the timeframe for enrollees to request a state fair hearing to 120 calendar days at § 438.408(f)(2). We adopted this timeframe because we believed it would give enrollees more time to gather the necessary information, seek assistance for the state fair hearing process, and make the request for a state fair hearing (81 FR 27516). However, we have heard from stakeholders that the 120-calendar day requirement has created an inconsistency in filing timeframes between Medicaid FFS and managed care, creating administrative burdens for states and confusion for enrollees. The FFS rule limits the timeframe beneficiaries have to request a hearing to no more than 90 days (§ 431.221(d)).[21] It was not our intent to burden states with additional tracking of the fair hearing process in multiple systems, on multiple timeframes. Nor do

[18] Under § 447.5(b), a clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a States claim system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

[19] Redesignated from § 438.402(b)(3)(ii) in the 2002 final rule (67 FR 41110).

[20] Section 431.221(a)(1)(i) requires state Medicaid agencies to permit an individual or authorized representative of the individual to submit state hearing requests via different modalities—including telephone—without requiring a subsequent written, signed appeal.

[21] 42 CFR 431.221(d) states that the agency must allow the applicant or beneficiary a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearing.

we want to confuse enrollees in states where some services are provided through FFS and others through managed care.

Therefore, we propose to revise § 438.408(f)(2) to stipulate that the timeframe for enrollees to request a state fair hearing would be no less than 90 calendar days and no greater than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution. We believe the proposed revision would allow states that wish to align managed care with the FFS filing timeframe to do so while not jeopardizing the enrollee's ability to gather information and prepare for a state hearing. This proposal would also allow states that have already implemented the 120-calendar day timeframe to maintain that timeframe without the need for additional changes.

We solicit comments on our proposal.

II. Children's Health Insurance Program (CHIP) Managed Care

A. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, enacted February 17, 2009), the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted on February 4, 2009), and the PPACA made applicable to CHIP several Medicaid managed care provisions in section 1932 of the Act, including section 1932(a)(4), Process for Enrollment and Termination and Change of Enrollment; section 1932(a)(5), Provision of Information; section 1932(b), Beneficiary Protections; 1932(c), Quality Assurance Standards; section 1932(d), Protections Against Fraud and Abuse; and section 1932(e), Sanctions for Noncompliance. In addition, the PPACA applied to CHIP sections 1902(a)(77) and 1902(kk) of the Act related to provider and supplier screening, oversight, and reporting. Our 2016 final rule implemented these statutory provisions and built on initial guidance provided in State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively. The provisions in the 2016 final rule both reflected and superseded this earlier guidance.

Since the publication of the 2016 final rule, and subsequent technical corrections to the rule in a correction notice published on January 3, 2017 (82 FR 37) (the 2017 correction notice), we have observed the need for additional minor technical or clarifying changes to the CHIP managed care provisions, primarily to clarify that certain Medicaid requirements do not apply to CHIP. These changes are described in more detail below.

B. Updates to CHIP Managed Care

1. Compliance Dates for Part 457 Managed Care Provisions

The compliance section of the preamble to the 2016 final rule states that unless otherwise noted, states would not be held out of compliance with new requirements in part 457 of this final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as they comply with the previously applicable regulations (that is, the regulations in place before the 2016 final rule). (81 FR 27499). Some stakeholders have expressed that the compliance section as drafted is not clear about when states need to comply with the CHIP managed care regulations. We clarify here that, except as otherwise noted, compliance with the revisions to the CHIP managed care regulations in part 457 under the 2016 final rule is required as of the first day of the state fiscal year beginning on or after July 1, 2018, regardless of whether or not the managed care contract in effect is a multi-year contract entered into a previous fiscal year or is a new contract effective for the first state fiscal year beginning on or after that date.

2. Information Requirements (§ 457.1207)

Section 457.1207 sets forth the CHIP requirements for providing enrollment notices, informational materials, and instructional materials for enrollees and potential enrollees of managed care entities by adopting the Medicaid requirements in § 438.10 by cross-reference. We inadvertently failed to exclude three cross references that should not apply to CHIP.

Section 438.10(c)(2) requires states to utilize the state's beneficiary support system as specified in § 438.71. CHIP does not adopt the beneficiary support system requirements; therefore, we did not intend that states would be required to use these systems for CHIP enrollees and we propose to modify the language in § 457.1207 to reflect this technical correction.

Section 438.10(g)(2)(xi)(E) requires that enrollee handbook notify enrollees that, when requested, benefits will continue when the enrollee files an appeal or state fair hearing (also known as ''aid paid pending''). CHIP does not adopt the Medicaid appeals process known as ''aid paid pending'' and we intended to exclude the requirement to notify CHIP enrollees of this requirement from the handbook, as the option does not exist in CHIP (we explicitly exclude this provision in § 457.1260). We propose to modify the language in § 457.1207 to reflect this technical correction.

Additionally, § 438.10(g)(2)(xii) requires that the enrollee handbooks for MCOs, PIHPs, PAHPs, and PCCM entities must provide information on how to exercise an advance directive, as set forth in § 438.3(j). CHIP does not adopt advanced directive requirements, and therefore, we did not intend that plans would be required to notify CHIP enrollees on how to exercise advanced directives and we propose to modify the language in § 457.1207 to reflect this technical correction.

We solicit comments on these proposals.

3. Structure and Operations Standards (§ 457.1233)

In the 2016 final rule, at § 457.1233(b), we adopted the provisions in § 438.230 related to MCO, PIHP, PAHP and PCCM entity requirements for contracting with subcontractors. However, in § 457.1233(b) we inadvertently included PCCMs instead of PCCM entities. We propose to revise § 457.1233 in this rulemaking to conform to the requirement that § 438.230 applies to PCCM entities.

Also, at § 457.1233(d), we adopted the provisions in § 438.242 that require states operating a separate CHIP to collect enrollee encounter data from managed care plans. In finalizing § 438.242, we also intended to apply to CHIP the requirements of § 438.818, which is cross-referenced in § 438.242 and requires the submission of enrollee encounter data to CMS. We propose to revise § 457.1233 in this rulemaking to make explicit our intention to apply the terms of § 438.818 to CHIP.

Finally, in the 2016 final rule at § 457.1233(d) we made a technical error regarding the CHIP applicability date. Our cross-reference to § 438.242 inadvertently applied the Medicaid applicability date of July 1, 2017 for the health information system requirements instead of the later compliance date generally applicable to CHIP (which is as of the first day of the state fiscal year beginning on or after July 1, 2018) that was specified in the 2016 final rule (''Except as otherwise noted, states will not be held out of compliance with new requirements in part 457 of this final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as they comply with the corresponding standard(s) in *part 457* contained in the parts 430 through 481, edition revised

as of October 1, 2015.'') and discussed in detail in section II.B.1 of this proposed rule. Therefore, we also propose to revise § 457.1233(d) to address this technical correction.

We solicit comments on our proposals.

4. Quality Measurement and Improvement (§ 457.1240)

In the 2016 final rule, we aligned CHIP quality measurement and improvement standards (with minor exceptions) for CHIP MCOs, PIHPs and PAHPs with the Medicaid standards at §§ 438.330, 438.332, 438.334, and 438.340 by adopting references to those sections in § 457.1240(b). Where appropriate, § 457.1240 of the 2016 final rule also applied these Medicaid standards to PCCM entities. However, we inadvertently missed a cross-reference to one of the Medicaid standards—§ 438.330(b)(2), relating to the collection and submission of quality performance measurement data—which we intended to apply to PCCM entities. We propose revisions to § 457.1240(b) to correct this omission and reflect application of § 438.330(b)(2) to PCCM entities in CHIP. The proposed changes in § 438.340, as discussed in the preamble at section I.B.13 of this proposed rule, are addressed with regard to CHIP in section II.B.8. of this proposed rule.

Additionally, we inadvertently failed to exclude references to consultation with the state's Medical Care Advisory Committee when drafting or revising the state's quality strategy in § 438.330(c)(1)(i) and if the state chooses to use an alternative managed care QRS in § 438.334(c)(2)(i) and (c)(3). Consultation with the Medical Care Advisory Committee is required for Medicaid under § 431.12. However, CHIP is not subject to § 431.12, and therefore, the consultation requirements in § 438.330(c)(1)(i) and § 438.334(c)(2)(i) and (c)(3) are not applicable to CHIP. We propose to revise § 457.1240 to correct these errors.

We solicit comments on our proposal.

5. Grievance System (§ 457.1260)

In the 2016 final rule, we aligned CHIP with the Medicaid grievance and appeals provisions in subpart F of part 438, by incorporating those subpart F, part 438 provisions into § 457.1260, with two substantive exceptions. First, § 457.1260 provides that references to ''state fair hearings'' in the part 438 provisions should be read as referring to part 457, subpart K (which imposes certain CHIP applicant and enrollee protections). Second, § 457.1260 excludes the applicability date in § 438.400(c) from applying in the CHIP context. Since that 2016 final rule, we have become aware of a number of issues related to how § 457.1260 currently incorporates the requirements applicable to Medicaid managed care plans and we are proposing here to amend § 457.1260 to address those concerns.

To avoid a lengthy list of excluded provisions from a general incorporation of subpart F of part 438, we are proposing new regulation text that incorporates specific provisions from subpart F of part 438, does not incorporate the specific paragraphs and provisions that have raised the issues detailed below, and fills in the blanks of how MCEs in state CHIPs must establish and operate their grievance and appeals system. No revisions are proposed to CHIP's current incorporation of § 438.406, § 438.410, § 438.412 or § 438.416. CHIP did not adopt § 438.420 in the 2016 final rule. The proposed revisions address the following items in § 438.400, § 438.402, § 438.404, § 438.408, and § 438.424:

- *Definition of adverse benefit determination (§ 438.400):* We inadvertently failed to exclude a reference to paragraph (6) of the definition of adverse benefit determination in § 438.400. This paragraph includes in the definition of adverse benefit determination the denial of enrollee's request to exercise his or her choice to obtain services outside the network under § 438.52. We did not adopt § 438.52 in CHIP, and therefore, this should not have been included in the definition of adverse benefit determination for CHIP. Our proposed regulation text at § 457.1260(a)(2) incorporates the definitions adopted in § 438.400 excluding this one provision in the definition of adverse benefit determination.
- *External medical reviews (§ 438.402):* At § 457.1120(a), CHIP already provides states with two options to conduct an external review of a health services matter and we inadvertently applied to CHIP an additional, optional external medical review in the Medicaid rule at § 438.402(c)(1)(i)(B). We now realize that this additional external medical review has been incorporated under our current regulation text. Therefore, within § 457.1260(b) which corresponds to § 438.402, we do not include the Medicaid external medical review provisions (§ 438.402(c)(1)(B)) from the list of appeal and grievance provisions that we are proposing to incorporate in proposed § 457.1260. In addition, proposed § 457.1260(b)(2) through (4) replace § 438.402(c)(1)(i)(A), (c)(1)(ii), and (c)(2), respectively, by substituting references to ''state fair hearings'' from the Medicaid rules for references to part 457, subpart K (which imposes certain CHIP applicant and enrollee protections, including the external review). This approach is substantively consistent with the current rule. Our proposed regulation text, at § 457.1260(b), continues to incorporate Medicaid grievance and appeals system establishment and operation rules in § 438.402(a), (b), (c)(2) and (3).
- *Timing of notice of adverse benefit determinations (§ 438.404):* We have realized that there may have been some confusion about whether states should follow the timing of notice of adverse benefit determination requirements described in § 438.404(c)(1) or § 457.1180. We propose to clarify that we did not intend to incorporate the requirements of 42 CFR part 431, subpart E into CHIP from § 438.404(c)(1) and that states may continue, under proposed § 457.1260(c)(3), to provide timely written notice for termination, suspension, or reduction of previously authorized CHIP-covered services, which mirrors the timing of notice requirements in § 457.1180. We propose that for denials and limitations of services, the timing of notices would continue to follow § 438.404(c)(3). In addition, proposed § 457.1260(c)(2) replaces § 438.404(b)(3) by substituting the reference to ''state fair hearings'' with the reference to part 457, subpart K. However, our proposed regulation text, at § 457.1260(c), continues to incorporate the notice requirements of Medicaid adverse benefit determination rules in § 438.404(a), (b)(1), (2), and (4) through (6), and (c)(2) through (6).
- *Resolution and notification (§ 438.408):* Proposed § 457.1260(e)(2) mirrors the language of § 438.408(a) but we have proposed a restatement of the text within § 457.1260 so that the use of ''this section'' in the text now refers to the language in § 457.1260 in lieu of § 438.408. In addition, proposed § 457.1260(e)(3) through (7) replace § 438.408(b)(3), (e)(2), (f)(1), (f)(1)(i), and (f)(2), respectively, by substituting references to ''state fair hearings'' for references to part 457, subpart K. For the reasons discussed above, we do not include the Medicaid external medical review provisions (§ 438.408(f)(1)(ii)) from the list of appeal and grievance provisions that we are proposing to incorporate in proposed § 457.1260. However, our proposed regulation text, at § 457.1260(e), continues to incorporate the resolution and notification requirements of Medicaid grievance and appeals rules in

§ 438.408(b), (c)(1) and (2), (d), (e)(1), and (f)(3).

• *Services not furnished (§ 438.424):* The current regulation inadvertently incorporates and applies the Medicaid standard at § 438.424(b), which requires a state to pay for disputed services furnished while an appeal is pending—which we did not intend to apply to CHIP. The Medicaid rule at § 438.420, regarding the continuation of benefits while an appeal is pending is not a policy that we wish to incorporate into CHIP. Therefore, the CHIP regulation at § 457.1260 should not include either § 438.420 or § 438.424(b), which provides that a state must pay for those disputed services furnished while the appeal is pending if the decision to deny authorization of the services is reversed. Therefore, in proposed § 457.1260, we do not incorporate § 438.420 or § 438.424(b). However, proposed § 457.1260(h) mirrors § 438.424(a) except for substituting the reference to ''state fair hearings'' with the reference to part 457, subpart K.

Accordingly, we propose to revise § 457.1260 to better reflect CMS policy for CHIP. We solicit comment on whether our more detailed regulation text, which incorporates specific provisions of subpart F of part 438, is sufficiently clear and detailed for the appropriate administration of grievances and appeals in the CHIP context.

We solicit comments on our proposal.

6. Sanctions (§ 457.1270)

In the 2016 final rule, CHIP adopted the Medicaid requirements related to sanctions in part 438 subpart I at § 457.1270. We inadvertently did not include a provision in § 457.1270 that states may choose to establish sanctions for PCCMs and PCCM entities as specified in § 438.700(a). In addition, we did not indicate that references in § 438.706(a)(1) and (b) should be read to refer to the requirements of subpart L of part 457, rather than references to sections 1903(m) and 1932 of the Act. We are revising the language of § 457.1270 to reflect these technical changes.

We solicit comments on our proposal.

7. Program Integrity Safeguards (§ 457.1285)

Section 457.1285 sets forth the CHIP requirements for providing enrollment notices, informational materials, and instructional materials for enrollees and potential enrollees of managed care entities by adopting the Medicaid requirements in subpart H of part 438, except for the terms of § 438.604(a)(2), by cross-reference. We inadvertently failed to exclude one cross reference that should not apply to CHIP. CHIP does not adopt the Medicaid actuarial soundness requirements, therefore, states do not need to use the specified plan information collected in § 438.608(d)(1) and (3) for setting actuarially sound capitation rates as required by Medicaid in § 438.608(d)(4) and we are seeking to modify the language of § 457.1285 to reflect this technical correction.

We solicit comments on our proposal.

8. CHIP Conforming Changes To Reflect Medicaid Managed Care Proposals

In the 2016 final rule, CHIP adopted many of the Medicaid regulations via cross-reference. We are proposing in this rulemaking to revise some of these Medicaid regulations. While we are not revising the cross-references to these regulations, we wanted to highlight that the changes proposed to the following Medicaid regulations in this rulemaking also would apply, by existing cross-reference, to CHIP. We welcome comments on the proposed changes as they apply to CHIP:

• *MLR standards (§ 438.8(k)):* As discussed in section I.B.6. of this proposed rule, we proposed revisions to § 438.8(k)(1)(iii) and (e)(4). Section 438.8(k) is incorporated into the CHIP regulations in § 457.1203(e) and (f).

• *Information requirements (§ 438.10):* As discussed in section I.B.8 of this proposed rule, we proposed several revisions to § 438.10. Section 438.10 is incorporated into the CHIP regulations at §§ 457.1206(b)(2) (via cross-reference to § 457.1207), 457.1207, and 457.1210(c)(5) (via cross-reference to § 457.1207).

• *Disenrollment: Requirements and limitations (§ 438.56):* As discussed in section I.B.9. of this proposed rule, we proposed revisions to § 438.56(d)(5) by deleting ''PCCMs or PCCM entities.'' Section 438.56 is adopted in CHIP at § 457.1212.

• *Network adequacy standards (§ 438.68):* As discussed in section I.B.10. of this proposed rule, we are proposing revisions to the provider-specific network adequacy standards in § 438.68(b). The Medicaid network adequacy standards are applied to CHIP per § 457.1218.

• *Practice guideline (§ 438.236):* As discussed in the preamble at section I.B.11. of this proposed rule, we proposed revisions to § 438.236(b)(3) by deleting contracting health care professionals and replacing it with network providers. Section 438.236 is incorporated into the CHIP regulations at § 457.1233(c).

• *Health information systems (§ 438.242):* As discussed in section I. B.12. of this proposed rule, we are proposing revisions to the health information systems requirements in § 438.242. Section 438.242 is adopted in CHIP at § 457.1233(d).

• *Medicaid managed care QRS (§ 438.334):* As discussed in the section I.B.13. of this proposed rule, we proposed revisions to § 438.334(b), (c)(1), and (c)(1)(ii), redesignating current paragraphs (c)(1)(i) and (c)(1)(ii) as (c)(1)(ii) and (c)(1)(iii), respectively, and adding new paragraph (c)(1)(i). We also proposed revisions to redesignated paragraph (c)(1)(ii) and adding new paragraph (c)(4). Section 438.334 is adopted in CHIP at § 457.1240(d).

• *Managed care State quality strategy (§ 438.340):* As discussed in the preamble at section I.B.14. of this proposed rule, we proposed revisions to § 438.340(b)(2), (b)(3)(i), (b)(6), and (c)(1)(ii).We also proposed removing § 438.340(b)(8), and redesignating paragraphs (b)(9), (b)(10), and (b)(11) as paragraphs (b)(8), (b)(9) and (b)(10), respectively. Section 438.340 is incorporated into the CHIP regulations at § 457.1240(e).

• *Activities related to EQR (§ 438.358):* As discussed in section I.B.15. of this proposed rule, we proposed revisions to § 438.358(b)(1)(iii). Section 438.358 is incorporated into the CHIP regulations at § 457.1250(a).

• *EQR Results (§ 438.364(d)):* As discussed in section I.B.17 of this proposed rule, we proposed revisions to § 438.364(d). Section 438.364 is incorporated into CHIP regulations at § 457.1250(a).

• *Statutory basis, definitions, and applicability (§ 438.400):* As discussed in section I.B.18. of this proposed rule, we proposed revisions to § 438.400(b)(3). Section 438.400 is incorporated into the CHIP regulations at § 457.1260.

• *General requirements (§§ 438.402 and 438.406):* As discussed in section I.B.19. of this proposed rule, we proposed revisions to §§ 438.402(c)(3)(ii) and 438.406(b)(3). Sections 438.402 and 438.406 are incorporated in CHIP in § 457.1260.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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.

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

A. Background

The burden associated with the requirements under part 438 is the time and effort it would take each of the state Medicaid programs to comply with this proposed rule. This proposed rule would revise certain Medicaid managed care regulations based on state and consumer experience with the requirements adopted in the 2016 final rule (81 FR 27497) in order to reflect a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care.

To estimate the burden for these proposals in part 438, we utilized state submitted data for enrollment in managed care plans for CY 2016. The enrollment data reflected 54,588,095 enrollees in MCOs, 17,941,681 enrollees in PIHPs or PAHPs, and 5,399,640 enrollees in PCCMs, for a total of 80,184,501 managed care enrollees. This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 42 states that contract with 519 MCOs, 14 states that contract with 134 PIHPs or PAHPs, 19 states that contract with 21 non-emergency transportation PAHPs, 18 states with 26 PCCM or PCCM entities, and 20 states that contract with one or more managed care plans for managed LTSS) Many states contract with more than one entity; however, we de-duplicated the counts to determine that 40 states contract with MCOs, PIHPs, or PAHPs; and 47 states contract with MCOs, PIHPs, PAHPs, or PCCMs. To estimate the burden for these proposals in part 457, we utilized state submitted data for enrollment in managed care plans for CY 2016. The enrollment data reflected 9,013,687 managed care enrollees. This data also showed that 32 states use managed care entities for CHIP enrollment.

B. 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 Direct Health and Medical Insurance Carriers (NAICS 524114) (*https://www.bls.gov/oes/current/naics5_524114.htm*). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—OCCUPATION TITLES AND WAGE RATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Actuary	15–2011	$49.81	$49.81	$99.62
Business Operations Specialist	13–1000	34.11	34.11	68.22
Computer Programmer	15–1131	43.42	43.42	86.84
General Operations Mgr	11–1021	72.51	72.51	145.02
Office and Administrative Support Worker	43–9000	19.02	19.04	38.08

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

C. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Standard Contract Requirements (§ 438.3)

Proposed amendments to § 438.3(t) would permit states to choose between requiring their MCOs, PIHPs, and PAHPs to sign a COBA with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. If the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration. We estimate it would take 1 hour for a programmer to implement the message on the remittance advice. If 10 states elect to pursue an alternative method, we estimate an aggregate one-time state burden of 10 hrs (10 states × 1 hour) and $860.84 (10 hrs × $86.84 for a computer programmer). As this would be a one-time expense, we annualize this amount to 3.33 hrs and $286.95.

Additionally, for states that elect to require an alternative method, the proposed amendments to § 438.3(t) would also alleviate managed care plans in those states of the burden of obtaining a COBA. We estimate 6 states with 25 plans may elect this option and save 4 hours per plan by a Business Operations Specialist −100 hrs (25 plans × 4 hrs) and −$6,822 (100 hrs × $68.22/hr). As this would be a one-time savings, we annualize this amount to −1.33 hrs and −$2,274.

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

Proposed amendments to § 438.6(c) would remove the requirement for states to obtain prior approval for directed payment arrangements that utilize a state approved FFS fee schedule. To obtain prior approval, states submit a preprint (OMB control #0938–1148 (CMS–10398 #52)) to CMS. We estimate that 20 states may elect annually to request approval for 40 directed payments that utilize a state approved FFS fee schedule. By eliminating the requirement that states submit a preprint for each arrangement, we estimate that a state could save 1 hour per directed payment arrangement for a Business Operations Specialist at $68.22/hr. We estimate an annual savings of −40 hours (20 states × 2 preprints each × 1 hour per preprint) and −$2,728.80 (40 hours × $68.22/hr).

3. ICRs Regarding Information Requirements (§ 438.10)

Proposed amendments to § 438.10(d)(2) and (d)(3) would no longer require states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$12,009,380.89 ((−$272,940.47 = $.005 × 54,588,095) + (−$272,940.47 = 0.005 × 54,588,095) + (−$11,463,499.95 = $.21 × 54,588,095)). These estimates are based on commonly available prices for bulk paper and toner purchases.

4. ICRs Regarding Network Adequacy Standards (§ 438.68)

Proposed amendments to § 438.68(a) would eliminate a requirement that states develop time and distance standards for provider types set forth in § 438.68(b)(1) and for LTSS providers if covered in the MCO, PIHP, or PAHP contract; the proposal would replace the requirement to adopt time and distance standards with a requirement to adopt a quantitative standard to evaluate network adequacy. We previously estimated in the 2016 final rule that states would spend 10 hr in the first year developing the network adequacy standards for the provider types specified in § 438.68(b)(1) and did not estimate additional burden for states after the first year (81 FR 27777). We further estimated a one-time state burden of 10 additional hrs at $64.46/hr for a business operations specialist to develop LTSS standards. We propose to eliminate the time and distance requirement and replace it with a more flexible requirement that states develop any quantitative network adequacy standard for the same provider types. Since time and distance is a quantitative network adequacy standard, for states that used time and distance prior to the 2016 final rule or for those that have adopted time and distance in order to comply with the 2016 final rule, discontinuing the use of time and distance is merely an option that they may elect. Additionally, as clarified in the 2016 final rule (81 FR 27661), states have always had the ability to have network adequacy standards in addition to time and distance if they choose. We believe the proposed change increases flexibility for states without affecting burden on states.

5. ICRs for Grievance and Appeal System: Statutory Basis, Definitions, and Applicability

Proposed amendments to § 438.400(b) would revise the definition of an ''adverse benefit determination'' to exclude claims that do not meet the definition of ''clean claim'' at § 447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$10,644,678.32 ((−$136,470.23 = $.005 × 27,294,047) + (−$136,470.23 = 0.005 × 27,294,047) + (−$10,371,737.86 = $.38 × 27,294,047)). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates.

6. ICRs Regarding Grievance and Appeal System: General Requirements (§ 438.402)

Proposed amendments to §§ 438.402(c)(3)(ii) and 438.406(b)(3) would no longer require enrollees to follow up an oral appeal with a written appeal. This change would alleviate the burden on plans to follow up with enrollees that do not submit the written appeal. We estimate that plans may have an Office and Administrative Support Worker spend up to 2 hours per appeal calling or sending letters to enrollees in an effort to receive the written appeal. We estimate that 300 plans in 20 states have an average of 200 oral appeals that are not followed up with a written appeal. We estimate an aggregate annual private sector burden reduction of −120,000 hours (300 plans × 200 appeals × 2 hrs) and −$4,569,600 (− 120,000 hrs × $38.08/hour).

7. ICRs Regarding Information Requirements (§ 457.1207)

Section 438.10(d)(2) and (d)(3) are adopted by cross-;reference in the CHIP regulations at § 457.1207. As discussed above, proposed amendments to § 438.10(d)(2) and (d)(3) would remove requirements for states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. As discussed above, while we have no data indicating how many states experienced increased document length and/or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$1,983,013.15 ((−$45,068.44 = $.005 × 9,013,687) + (−$45,068.44 = $.005 × 9,013,687) + (−$1,892,876.27 = $.21 × 9,013,687)). These estimates are based on commonly available prices for bulk paper and toner purchases.

8. ICRs for Grievance and Appeal System: Definitions (§ 457.1260)

Section 438.400(b) is adopted by cross-reference in the CHIP regulations at § 457.1260. As discussed above, proposed amendments to § 438.400(b) would revise the definition of an ''adverse benefit determination'' to exclude claims that do not meet the definition of ''clean claim'' at § 447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. As also discussed above, while we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$1,757,669.16 ((−$22,534.22 = $.005 × 4,506,844) + (−$22,534.22 = $.005 × 4,506,844) + (−$1,712,600.72 = $.38 × 4,506,844)). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates.

D. Summary of Proposed Burden and Burden Reduction Estimates

Tables 2 and 3 set out our proposed annual burden and burden reduction estimates. While the annual burden estimates are unchanged over the 3-year approval period, the one-time estimates have been annualized by 3 to account

for OMB's 3-year approval period. The burden and burden reduction associated with this proposed rule would be included in revised PRA packages. PRA package CMS–10108 would continue to contain all of part 438 except for those related to subpart E. Provisions related to quality measurement and improvement (§§ 438.310, 438.320, 438.330, 438.332, 438.334, and 438.340) would remain in the separate CMS–10553. Provisions related to EQR (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370) would remain in the separate CMS–R–305 and are unchanged by this proposed rule. The proposed CHIP managed care regulation burden would remain in PRA package CMS–10554.

TABLE 2—SUMMARY OF ANNUAL PROPOSED PRA-RELATED REQUIREMENT AND BURDEN UNDER 42 CFR PART 438

CFR section	Number of respondents	Number of responses	Burden per response (hours)	Total annual hours	Labor rate $/hr	Cost ($) per response	Total cost ($)	Frequency	Annualized hours	Annualized costs ($)
§ 438.3(t)	10	10	1	10	$86.84	$86.84	$860.84	Once	0.333	$286.95
§ 438.3(t)	6	25	−4	−100	68.22	−272.88	−6,822	Once	−1.333	−2,274
§ 438.6(c)	20	2	−1	−40	68.22	−68.22	−2,728.80	Annual	−40	−2,728.80
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.005	−272,940.47	Annual	n/a	−272,940.47
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.005	−272,940.47	Annual	n/a	−272,940.47
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.21	−11,463,499.95	Annual	n/a	−11,463,499.95
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.005	−136,470.23	Annual	n/a	−136,470.23
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.005	−136,470.23	Annual	n/a	−136,470.23
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.38	−10,371,738	Annual	n/a	−10,371,738
§ 438.402(c)(3)(i)	300	60,000	−2	−120,000	38.08	−76.16	−4,569,600	Annual	−120,000	−4,569,600
Total				−120,130		−329.81	−27,232,349.31			−27,228,375.20

TABLE 3—SUMMARY OF ANNUAL PROPOSED PRA-RELATED REQUIREMENT AND BURDEN UNDER 42 CFR PART 457

CFR section	Number of respondents	Number of responses	Burden per response (hours)	Total annual hours	Labor rate $/hr	Cost ($) per response	Total cost ($)	Frequency	Annualized hours	Annualized costs ($)
§ 457.1207	32	9,013,687	n/a	n/a	n/a	$0.005	−$45,068.44	Annual	n/a	−$45,068.44
§ 457.1207	32	9,013,687	n/a	n/a	n/a	0.005	−45,068.44	Annual	n/a	−45,068.44
§ 457.1207	32	9,013,687	n/a	n/a	n/a	0.21	−1,892,876.27	Annual	n/a	−1,892,876.27
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.005	−22,534.22	Annual	n/a	−22,534.22
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.005	−22,534.22	Annual	n/a	−22,534.22
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.38	−1,712,600.72	Annual	n/a	−1,712,600.72
Total										−3,740,682.31

E. Exempt ICRs

1. Fewer Than 10 Respondents

While the requirements under §§ 438.7, 438.10(h)(3), and 438.408(f)(2) are subject to the PRA, in each instance we estimate fewer than 10 respondents would engage in the optional activities to take advantage of the flexibility proposed in this proposed rule in connection with the proposed amendments to these regulation sections. Consequently, the information collection requirements are exempt (5 CFR 1320.3(c)) from the PRA requirements (44 U.S.C. 3501 *et seq.*).

Proposed amendments to § 438.7 would require states that make modifications to the capitation rate within the permissible 1.5 percent range to submit documentation if requested by CMS. We do not expect to have reason to request documentation for more than 5 certifications from 1–5 states per year.

Proposed amendments to § 438.10(h)(3) would allow states to only update paper directories quarterly if they have a mobile-enable provider directory. Given the costs of developing a mobile-enabled provider directory, and the modest cost reduction associated with updating monthly versus quarterly, as well as the cost savings associated with printing on demand, we estimate that fewer than 10 states would opt to require their plans to utilize this provision.

Proposed amendments to § 438.408(f)(2) would change the timeframe in which an enrollee must request a state fair hearing from 120 calendar days to no fewer than 90 calendar days and no greater than 120 calendar days. As most states have already implemented the 120-calendar day timeframe for managed care, and the proposed change imposes no requirement for states to change their filing timeframe, we believe that fewer than 10 respondents would elect to change the timeframe for enrollees to request a state fair hearing.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, we request that you please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. However, all comments received within the 60-day comment period provided for by the PRA will be reviewed and considered.

Comments must be received on/by January 14, 2019.

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 would 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 would respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

As described in detail in section I.B. of this proposed rule, many of the revisions to part 438 outlined in this proposed rule are part of the agency's broader efforts to reduce administrative burden and to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule seeks to streamline the managed care regulations by reducing unnecessary and duplicative administrative burden and further reducing federal regulatory barriers to

help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

B. Overall Impact

We have examined the impact 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), 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). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). Based on our analysis, this rule does not reach the economic threshold, and thus, is not considered a major rule.

We have examined the proposed provisions in this rule and determined that most of the proposed revisions to part 438 outlined in this proposed rule are expected to reduce administrative burden as we noted in the COI (see section IV. of this proposed rule). Aside from our analysis on burden reduction in the COI, we believe that the only provision in this proposed rule that we should specifically analyze in this regulatory impact analysis is the proposed revision to managed care pass-through payments because of the general magnitude associated with managed care payments and our previous efforts to analyze financial impacts associated with managed care pass-through payments.

The May 6, 2016 final rule (81 FR 27830) and the January 18, 2017 pass-through payment final rule (82 FR 5425) both contained regulatory impact analyses that discussed the financial and economic effects of pass-through payments. In the May 6, 2016 final rule, 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). 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. We expected that the long pass-through payment transition periods provided under the May 6, 2016 final rule would help states to integrate existing pass-through payments into actuarially sound capitation rates or permissible Medicaid financing structures, including enhanced fee schedules or the other approaches consistent with § 438.6(c) that tie managed care payments to services and utilization covered under the contract.

In the January 18, 2017 pass-through payment final rule, we noted that a number of states had integrated some form of pass-through payments into their managed care contracts for hospitals, nursing facilities, and physicians. We also noted that as of the effective date of the May 6, 2016 final rule, we estimated that at least eight states had implemented approximately $105 million in pass-through payments for physicians annually; we estimated that at least three states had implemented approximately $50 million in pass-through payments for nursing facilities annually; and we estimated that at least 16 states had implemented approximately $3.3 billion in pass-through payments for hospitals annually. We noted that the amount of pass-through payments often represented a significant portion of the overall capitation rate under a managed care contract, and that we had seen pass-through payments that had represented 25 percent, or more, of the overall managed care contract and 50 percent of individual rate cells. In our analysis of that final rule, we concluded that while it was difficult for CMS to conduct a detailed quantitative analysis given considerable uncertainty and lack of data, we believed that without the pass-through payment final rule, which prohibited new and increased pass-through payments that were not in place as of the effective date of the May 6, 2016 final rule, states would continue to increase pass-through payments in ways that were not consistent with the pass-through payment transition periods established in the May 6, 2016 final rule.

Since there is still considerable uncertainty regarding accurate and reliable pass-through payment data, we are only including a qualitative discussion for the proposed revisions in this RIA. Under proposed § 438.6(d)(6), we are proposing to assist states with transitioning some or all services or eligible populations from a Medicaid FFS delivery system into a Medicaid managed care delivery system by allowing states to make pass-through payments under new managed care contracts during a specified transition period if certain criteria in the proposed rule are met. One of the proposed requirements in the rule is that the aggregate amount of the pass-through payments for each rating period of the transition period that the state requires the managed care plan to make must be less than or equal to the payment amounts attributed to and actually paid as Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians in Medicaid FFS. This means that under this new pass-through payment transition period, the aggregate payments added to Medicaid managed care contracts as pass-through payments must be budget neutral to the aggregate payments transitioned from Medicaid FFS. We also note that under the new pass-through payment transition period, states would only have 3 years to include these payments as pass-through payments before needing to transition the payments into allowable payment structures under actuarially sound capitation rates.

We acknowledge that relative to the current pass-through payment baseline, this proposed rule permits states to incorporate new pass-through payments under a new transition period when states are transitioning some or all services or eligible populations from a Medicaid FFS delivery system into a Medicaid managed care delivery system; however, the net financial impact to state and federal governments, and the Medicaid program, must be zero given the proposed requirements in this rule that aggregate pass-through payments under the new transition period must be less than or equal to the payment amounts attributed to and actually paid as Medicaid FFS supplemental payments in Medicaid FFS. Since this proposal only permits payment amounts attributed to Medicaid FFS to be made under Medicaid managed care contracts, this is not an increase in Medicaid payments; rather, these payments only represent a movement of funding across Medicaid delivery systems for a limited and targeted amount of time when

Medicaid populations or services are initially transitioning from a Medicaid FFS delivery system to a Medicaid managed care delivery system. Without this proposed transition period, we believe that existing federal pass-through payment requirements could incentivize states to retain some Medicaid populations and/or Medicaid services in their Medicaid FFS programs. We also believe that some states may choose to delay implementation of Medicaid managed care programs, especially if states have not already been working with stakeholders regarding existing Medicaid FFS supplemental payments. As we noted in our proposal, we want to ensure that federal pass-through payment rules do not unintentionally incent states to keep populations or services in Medicaid FFS, and we do not want federal rules to unintentionally create barriers that prevent states from moving populations or services into Medicaid managed care. As noted in the 2016 final rule (81 FR 27852), potential benefits to the changes in the Medicaid managed care rule include improved health outcomes for Medicaid enrollees through improved care coordination and case management, as well as improved access to care. We believe that this limited and targeted transition period will help states further these goals.

Finally, as noted throughout this rule, this limited and targeted transition period is only available if the state actually made Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first rating period of the transition period, and the aggregate amount of the pass-through payments that the state requires the managed care plan to make must be less than or equal to the amounts paid under Medicaid FFS. As noted in our proposal, states would be required to calculate and demonstrate that the aggregate amount of the pass-through payments for each rating period of the transition period is less than or equal to the amounts attributed to and actually paid as Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians. As a practical matter, states would be required to use MMIS-adjudicated claims data from the 12-month period immediately 2 years prior to the first rating period of the transition period for the purposes of these calculations, and we would verify that the pass-through payment amounts are permissible under these proposed rules, including that the aggregate payments added to Medicaid managed care contracts as pass-through payments must be budget neutral to the aggregate payments transitioned from Medicaid FFS. Therefore, we are not projecting a specific fiscal impact to state or federal governments, or the Medicaid program, as we expect the net financial impact of the proposed provision to be budget neutral. We request public comments on our assumptions and analysis here.

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. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We believe that all Medicaid managed care plans have annual revenues in excess of $38.5 million; therefore, we do not believe that this proposed rule will have a significant economic impact on a substantial number of small businesses. We seek comment on this belief.

In addition, section 1102(b) of the Act requires CMS to prepare an RIA 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 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 most hospitals, including small rural hospitals. The proposed provisions in this rule place no direct requirements on individual hospitals, and we note that any impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs, PIHPs, and PAHPs. We expect that any additional burden (or burden reduction) on small rural hospitals should be negligible. We seek comment on this analysis and our assumptions. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (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 is approximately $150 million. We believe that this proposed rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Many of the revisions to part 438 outlined in this proposed rule are expected to reduce administrative burden; therefore, if the rule is finalized as proposed, we expect that this rule would, on net, be an E.O. 13771 deregulatory action.

D. Alternatives Considered

One alternative we considered was leaving the 2016 final rule as it is today; however, since the rule was finalized in 2016, we continued to hear from stakeholders that the 2016 final rule was overly prescriptive and included provisions that were not cost-effective for states to implement. As a result, we undertook a review of the current regulations to ascertain if there were ways to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule is the result of that review and seeks to streamline the managed care regulations by reducing unnecessary

and duplicative administrative burden and further reducing federal regulatory barriers to help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

We are seeking comment on a number of requirements included in this proposed rule to identify potential alternatives to proposed provisions.

E. Uncertainties

We have attempted to provide a framework for common definitions and processes associated with the statutory provisions being implemented by this rule. It is possible that some states may need to use alternative definitions to be consistent with state law, and we are seeking comment on these kinds of issues with the intent to modify and add to the common terminology proposed in this rule as appropriate based on the comments received.

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

F. Accounting Statement

As discussed in this RIA, the benefits, costs, and transfers of this proposed rule are identified in Table 4.

TABLE 4—ACCOUNTING STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
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; greater incentives for payment approaches that are based on the utilization and delivery of services to enrollees covered under the contract, or the quality and outcomes of such services; improved support for delivery system reform that is focused on improved care and quality for Medicaid beneficiaries; and improved health outcomes for Medicaid enrollees through improved care coordination and case management, as well as improved access to care.						
Costs							
Annualized Monetized $ millions/year	−30.97			2017		Annual	
Non-Quantified	Costs to state or federal governments should be negligible. Burden and/or burden reduction estimates associated with the activities (other than information collection as defined in the Paperwork Reduction Act) that would be necessary for generating the benefits listed above.						
Transfers							
Non-Quantified	Relative to the current pass-through payment baseline, this proposed rule permits states to incorporate new pass-through payments under a new transition period when states are transitioning some or all services or eligible populations from a FFS delivery system into a managed care delivery system; however, the net financial impact to state and federal governments, and the Medicaid program, must be zero given the proposed requirements in this rule that aggregate pass-through payments under the new transition period must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments in Medicaid FFS. Therefore, we are not projecting a specific fiscal impact to state or federal governments, as we expect the net financial impact of the proposed provision to be budget neutral.						

List of Subjects

42 CFR Part 438

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

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, 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 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 438.3 is amended by revising paragraph (t) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement (COBA) with Medicare for Medicaid, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must specify the methodology by which the State would ensure that the appropriate MCO, PIHP, or PAHP would receive all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. If the State elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the State's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

* * * * *

■ 3. Section 438.4 is amended by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 438.4 Actuarial soundness.

* * * * *

(b) * * *

(1) Have been developed in accordance with the standards specified

in § 438.5 of this chapter and generally accepted actuarial principles and practices. Any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of Federal financial participation (FFP) associated with the covered populations in a manner that increases Federal costs consistent with paragraph (d) of this section.

* * * * *

(c) *Option to develop and certify a rate range.* (1) Notwithstanding the provision at paragraph (b)(4) of this section, the State may develop and certify a range of capitation rates per rate cell as actuarially sound, when all of the following conditions are met:

(i) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range.

(ii) Both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements of this part.

(iii) The upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05.

(iv) The rate certification documents the State's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range.

(v) The State does not use as a criterion for paying MCOs, PIHPs, and PAHPs at different points within the rate range any of the following:

(A) The willingness or agreement of the MCOs, PIHPs, or PAHPs or their network providers to enter into, or adhere to, intergovernmental transfer (IGT) agreements; or

(B) The amount of funding the MCOs, PIHPs, or PAHPs or their network providers provide through IGT agreements.

(2) When a State develops and certifies a range of capitation rates per rate cell as actuarially sound consistent with the requirements of this paragraph (c), the State must:

(i) Document the capitation rates, prior to the start of the rating period, for the MCOs, PIHPs, and PAHPs at points within the rate range, consistent with the criteria in paragraph (c)(1)(iv) of this section.

(ii) Not modify the capitation rates under § 438.7(c)(3).

(iii) Not modify the capitation rates within the rate range, unless the State provides a revised rate certification, which demonstrates that—

(A) The criteria in paragraph (c)(1)(iv) of this section, as described in the initial rate certification, were not applied accurately;

(B) There was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or

(C) Other adjustments are appropriate and reasonable to account for programmatic changes.

(d) *Capitation rate development practices that increase Federal costs and vary with the rate of Federal financial participation (FFP).* The determination that differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs increase Federal costs and vary with the rate of FFP associated with the covered populations must be evaluated for the entire managed care program and include all managed care contracts for all covered populations.

(1) Capitation rate development practices that increase Federal costs and vary with the rate of FFP are prohibited, including but not limited to, the following:

(i) A State may not use higher profit margin, operating margin, or risk margin when developing capitation rates for any covered population, or contract, than the profit margin, operating margin, or risk margin used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP;

(ii) A State may not factor into the development of capitation rates the additional cost of contractually required provider fee schedules, or minimum levels of provider reimbursement, above the cost of similar provider fee schedules, or minimum levels of provider reimbursement, used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; and

(iii) A State may not use a lower remittance threshold for a medical loss ratio for any covered population, or contract, than the remittance threshold used for the covered population, or contract, with the lowest average rate of FFP.

(2) CMS may require a State to provide written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts, not otherwise referenced in paragraphs (d)(1)(i) through (iii) of this section, represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

■ 4. Section 438.5 is amended by revising paragraph (c)(3)(ii) to read as follows:

§ 438.5 Rate development standards.

* * * * *

(c) * * *

(3) * * *

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years after the last day of the rating period for which the deficiency was identified.

* * * * *

■ 5. Section 438.6 is amended—

■ a. In paragraph (a) by adding the definitions of ''State plan approved rates'' and ''Supplemental payments'' in alphabetical order;

■ b. By revising paragraphs (b)(1), (c)(1)(iii), and (c)(2); and

■ c. By adding paragraphs (c)(3) and (d)(6).

The revisions and additions read as follows:

§ 438.6 Special contract provisions related to payment.

(a) * * *

* * * * *

State plan approved rates means amounts calculated as a per unit price of services described under CMS approved rate methodologies in the Medicaid State plan.

Supplemental payments means amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the State plan or under a waiver thereof and are in addition to the amounts calculated through an approved State plan rate methodology.

* * * * *

(b) * * *

(1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be documented in the contract and rate certification documents for the rating period prior to the start of the rating period, and must be developed in accordance with § 438.4, the rate development standards in § 438.5, and generally accepted actuarial principles and practices. Risk-sharing mechanisms may not be added

or modified after the start of the rating period.

* * * * *

(c) * * *

(1) * * *

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates as defined in paragraph (a) of this section. Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.

(B) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using rates other than the State plan approved rates defined in paragraph (a) of this section.

(C) Provide a uniform dollar or percentage increase for network providers that provide a particular service under the contract.

(D) Adopt a maximum fee schedule for network providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(E) Adopt a cost-based rate, a Medicare equivalent rate, a commercial rate, or other market-based rate for network providers that provide a particular service under the contract.

(2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

(ii) Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i), (ii), and (c)(1)(iii)(B) through (E) of this section must have written approval prior to implementation. Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(iii)(A) of this section do not require written approval prior to implementation but are required to meet the criteria in paragraphs (c)(2)(ii)(A) through (F) of this section. To obtain written approval, a State must demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in § 438.340;

(E) Does not condition network provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the network provider entering into or adhering to intergovernmental transfer agreements; and

(F) May not be renewed automatically.

(iii) Any contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(i) or (ii) of this section must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers; and

(C) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

(3) *Approval timeframes.* (i) Approval of a payment arrangement under paragraph (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the payment arrangement in the contract as a multi-year payment arrangement, including a description of the payment arrangement by year, if the payment arrangement varies by year.

(B) The State has developed and described its plan for implementing a multi-year payment arrangement, including the State's plan for multi-year evaluation, and the impact of a multi-year payment arrangement on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year payment arrangement without CMS prior approval. If the State determines that changes to the payment methodology, or magnitude of the payment, are necessary, the State must obtain prior approval of such changes under paragraph (c)(2) of this section.

(ii) Approval of a payment arrangement under paragraph (c)(1)(iii) of this section is for one rating period.

(d) * * *

(6) *Pass-through payments for States transitioning services and populations from a fee-for-service delivery system to a managed care delivery system.* Notwithstanding the restrictions on pass-through payments in paragraphs (d)(1), (3), and (5) of this section, a State may require the MCO, PIHP, or PAHP to make pass-through payments to network providers that are hospitals, nursing facilities, or physicians under the contract, for each rating period of the transition period for up to 3 years, when Medicaid populations or services are initially transitioning from a fee-for-service (FFS) delivery system to a managed care delivery system, provided the following requirements are met:

(i) The services will be covered for the first time under a managed care contract and were previously provided in a FFS delivery system prior to the first rating period of the transition period.

(ii) The State made supplemental payments, as defined in paragraph (a) of this section, to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first year of the transition period.

(iii) The aggregate amount of the pass-through payments that the State requires the MCO, PIHP, or PAHP to make is less than or equal to the amounts calculated in paragraphs (d)(6)(iii)(A), (B), or (C) of this section for the relevant provider type for each rating period of the transition period. In determining the amount of each component for the calculations contained in paragraphs (d)(6)(iii)(A) through (C), the State must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the transition period.

(A) *Hospitals.* For inpatient and outpatient hospital services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for hospital services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for hospital services made in the State's FFS delivery system.

(B) *Nursing facilities.* For nursing facility services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for nursing facility services that are being transitioned from payment in a FFS

delivery system to the managed care contract by the total amount paid through payment rates for nursing facility services made in the State's FFS delivery system.

(C) *Physicians.* For physician services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for physician services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for physician services made in the State's FFS delivery system.

(iv) The State may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are initially transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

* * * * *

■ 6. Section 438.7 is amended by revising paragraph (c)(3) and adding paragraph (e) to read as follows:

§ 438.7 Rate certification submission.

* * * * *

(c) * * *

(3) The State may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and § 438.4(b)(4), up to 1.5 percent without submitting a revised rate certification, as required under paragraph (a) of this section. However, any changes of the capitation rate within the permissible range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at § 438.4(b)(1). Notwithstanding the provisions in paragraph (c) of this section, CMS may require a State to provide documentation that modifications to the capitation rate comply with the requirements in §§ 438.3(c) and (e), and 438.4(b)(1).

* * * * *

(e) *Provision of additional guidance.* CMS will issue guidance, at least annually, which includes all of the following:

(1) The Federal standards for capitation rate development.

(2) The documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms.

(3) The documentation required to determine that the capitation rates have been developed in accordance with the requirements of this part.

(4) Any updates or developments in the rate review process to reduce State burden and facilitate prompt actuarial reviews.

(5) The documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistent with the requirements of §§ 438.4 through 438.8.

■ 7. Section 438.8 is amended—

■ a. In paragraph (e)(4) by removing the phrase ''fraud prevention as adopted'' and adding in its place the phrase ''fraud prevention consistent with regulations adopted''; and

■ b. Revising paragraph (k)(1)(iii).

The revision reads as follows:

§ 438.8 Medical loss ratio (MLR) standards

* * * * *

(k) * * *

(1) * * *

(iii) Fraud prevention activities as defined in paragraph (e)(4) of this section.

* * * * *

■ 8. Section 438.9 is amended by revising paragraph (b)(2) to read as follows:

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPS.

* * * * *

(b) * * *

(2) The actuarial soundness requirements in § 438.4, except § 438.4(b)(9).

* * * * *

■ 9. Section 438.10 is amended by—

■ a. Revising paragraphs (d)(2) and (3);

■ b. Removing paragraph (d)(6)(iv);

■ c. Revising paragraph (f)(1);

■ d. In paragraph (g)(2)(ii)(B) by removing the reference ''paragraph (g)(2)(i)(A) of this section'' and adding in its place the reference ''paragraph (g)(2)(ii)(A) of this section'' and

■ e. Revising paragraphs (h)(1)(vii) and (h)(3).

The revisions read as follows:

§ 438.10 Information requirements.

* * * * *

(d) * * *

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees must include taglines in the prevalent non-English language in the State, explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials that are critical to obtaining services must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost, include taglines in the prevalent non-English languages in the State and in a conspicuously visible font size explaining the availability of written translation or oral interpretation to understand the information provided, and include the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost.

* * * * *

(f) * * *

(1) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider. Notice to the enrollee must be provided by the later of 30 calendar days prior to the effective date of the termination, or 15 calendar days after receipt or issuance of the termination notice.

* * * * *

(h) * * *

(1) * * *

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

* * * * *

(3) Information included in—

(i) A paper provider directory must be updated at least—

(A) Monthly, if the MCO, PIHP, PAHP, or PCCM entity does not have a mobile-enabled, electronic directory; or

(B) Quarterly, if the MCO, PIHP, PAHP, or PCCM entity has a mobile-enabled, electronic provider directory.

(ii) An electronic provider directory must be updated no later than 30 calendar days after the MCO, PIHP, PAHP, or PCCM entity receives updated provider information.

* * * * *

■ 10. Section 438.56 is amended by revising the heading of paragraph (d)(5), and paragraphs (d)(5)(i) and (iii), to read as follows:

§ 438.56 Disenrollment: Requirements and limitations.

* * * * *

(d) * * *

(5) *Use of the MCO's, PIHP's, PAHP's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO's, PHIP's, or PAHP's grievance system before making a determination on the enrollee's request.

* * * * *

(iii) If, as a result of the grievance process, the MCO, PIHP, or PAHP approves the disenrollment, the State agency is not required to make a determination in accordance with paragraph (d)(4) of this section.

* * * * *

■ 11. Section 438.68 is amended by—

■ a. Revising paragraph (b)(1) introductory text, and paragraph (b)(1)(iv);

■ b. Removing paragraph (b)(1)(viii); and

■ c. Revising paragraph (b)(2).

The revisions read as follows:

§ 438.68 Network adequacy standards.

* * * * *

(b) * * *

(1) At a minimum, a State must develop a quantitative network adequacy standard for the following provider types, if covered under the contract:

* * * * *

(iv) Specialist (as designated by the State), adult and pediatric.

* * * * *

(2) *LTSS.* States with MCO, PIHP, or PAHP contracts which cover LTSS must develop a quantitative network adequacy standard for LTSS provider types.

* * * * *

§ 438.236 [Amended]

■ 12. Section 438.236 is amended in paragraph (b)(3) by removing the term ''contracting health care professionals'' and adding in its place the term ''network providers.''

■ 13. Section 438.242 is amended by revising paragraph (c)(3) to read as follows:

§ 438.242 Health information systems.

* * * * *

(c) * * *

(3) Submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under § 438.818.

* * * * *

■ 14. Section 438.334 is amended by –

■ a. Revising paragraphs (b) and (c)(1) introductory text;

■ b. Redesignating paragraphs (c)(1)(i) and (ii), as paragraphs (c)(1)(ii) and (iii), respectively;

■ c. Adding a new paragraph (c)(1)(i);

■ d. Revising newly redesignated paragraph (c)(1)(ii), and paragraphs (c)(2) and (3); and

■ e. Adding new paragraph (c)(4).

The revisions and additions read as follows:

§ 438.334 Medicaid managed care quality rating system.

* * * * *

(b) *Quality rating system.* CMS, in consultation with States and other stakeholders and after providing public notice and opportunity to comment, will develop a framework for a Medicaid managed care quality rating system (QRS), including the identification of a set of mandatory performance measures and a methodology, that aligns where appropriate with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the Medicare Advantage 5-Star Rating System, and other related CMS quality rating approaches.

(c) * * *

(1) A State may implement an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The alternative quality rating system includes the mandatory measures identified in the framework developed under paragraph (b) of this section; and,

(ii) The ratings generated by the alternative quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the framework developed under paragraph (b) of this section to the extent feasible, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

* * * * *

(2) Prior to implementing an alternative quality rating system, or modification of an alternative quality rating system, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and,

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) Upon request, a State must submit to CMS a copy of the alternative quality rating system framework, including the performance measures and methodology to be used in generating plan ratings; documentation of the public comment process specified in paragraphs (c)(2)(i) and (ii) of this section, including issues raised by the Medical Care Advisory Committee and the public, any policy revisions or modifications made in response to the comments, and the rationale for comments not accepted; and other information specified by CMS to demonstrate compliance with this paragraph (c).

(4) The Secretary, in consultation with States and other stakeholders, shall issue guidance which describes the criteria and process for determining if an alternative QRS system is substantially comparable to the Medicaid managed care quality rating system in paragraph (b) of this section.

* * * * *

■ 15. Section 438.340 is amended—

■ a. By revising paragraphs (b)(2), (b)(3)(i), and (b)(6);

■ b. By removing paragraph (b)(8);

■ c. By redesignating paragraphs (b)(9), (10), and (11), as paragraphs (b)(8), (9) and (10), respectively;

■ d. By revising paragraph (c)(1)(ii); and

■ e. In paragraph (c)(3)(ii) by removing the reference ''paragraph (b)(11)'' and adding in its place the reference ''paragraph (b)(10)''.

The revisions read as follows:

§ 438.34 Managed care State quality strategy.

* * * * *

(b) * * *

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2).

(3) * * *

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, PAHP, and PCCM entity described in

§ 438.310(c)(2) with which the State contracts, including but not limited to, the performance measures reported in accordance with § 438.330(c). The State must identify which quality measures and performance outcomes the State would publish at least annually on the website required under § 438.10(c)(3); and,

* * * * *

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. States must identify this demographic information for each Medicaid enrollee and provide it to the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2) at the time of enrollment.

* * * * *

(c) * * *

(1) * * *

(ii) If the State enrolls Indians in the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2), consulting with Tribes in accordance with the State's Tribal consultation policy.

* * * * *

■ 16. Section 438.358 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 438.358 Activities related to external quality review.

* * * * *

(b) * * *

(1) * * *

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

* * * * *

■ 17. Section 438.362 is amended by adding paragraph (c) to read as follows:

§ 438.362 Exemption from external quality review.

* * * * *

(c) *Identification of exempted MCOs.* The State must annually identify, on the website required under § 438.10(c)(3) and in the same location as the EQR technical reports per § 438.364(c)(2)(i), the names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period.

■ 18. Section 438.364 is amended by revising paragraph (d) to read as follows:

§ 438.364 External quality review results.

* * * * *

(d) *Safeguarding patient identity.* The information released under paragraph (c) of this section may not disclose the identity or other protected health information of any patient.

■ 19. Section 438.400 is amended in paragraph (b) by revising paragraph (3) of the definition of ''Adverse benefit determination'' to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

* * * * *

(b) * * *

Adverse benefit determination * * *

(3) The denial, in whole or in part, of payment for a service. A denial, in whole or in part, of a payment for a service because the claim does not meet the definition of a ''clean claim'' at § 447.45(b) of this chapter is not an adverse benefit determination.

* * * * *

■ 20. Section 438.402 is amended by revising paragraph (c)(3)(ii) to read as follows:

§ 438.402 General requirements.

* * * * *

(c) * * *

(3) * * *

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing.

■ 21. Section 438.406 is amended by revising paragraph (b)(3) to read as follows:

§ 438.406 Handling of grievances and appeals.

* * * * *

(b) * * *

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

* * * * *

■ 22. Section 438.408 is amended by revising paragraph (f)(2) to read as follows:

§ 438.408 Resolution and notification: Grievances and appeals.

* * * * *

(f) * * *

(2) *State fair hearing.* The enrollee must have no less than 90 calendar days and no more than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution to request a State fair hearing.

* * * * *

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 23. The authority citation for part 457 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 24. Section 457.1207 is revised to read as follows:

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E) and (g)(2)(xii) of this chapter do not apply.

■ 25. Section 457.1233 is amended by revising paragraphs (b) and (d) to read as follows:

§ 457.1233 Structure and operation standards.

* * * * *

(b) *Subcontractual relationships and delegation.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, and PCCM entity complies with the subcontractual relationships and delegation requirements as provided in § 438.230 of this chapter.

* * * * *

(d) *Health information systems.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242 of this chapter, except that the applicability date of § 438.242(e) of this chapter does not apply. The State is required to submit enrollee encounter data to CMS in accordance with § 438.818 of this chapter.

* * * * *

■ 26. Section 457.1240 is amended by revising paragraph (b) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(b) *Quality assessment and performance improvement program.* The State must require, through its contracts, that each MCO, PIHP, and PAHP must establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in § 438.330 of this chapter, except that:

(1) The terms of § 438.330(d)(4) of this chapter (related to dually eligible beneficiaries) do not apply.

(2) The reference to consultation with the Medical Care Advisory Committee

described in § 438.330(c)(1)(i) of this chapter does not apply.

(3) The terms of § 438.334(c)(2)(i) of this chapter (related to consultation with the Medical Care Advisory Committee) do not apply.

(4) The reference to consultation with the Medical Care Advisory Committee described in § 438.334(c)(3) of this chapter does not apply.

(5) In the case of a contract with a PCCM entity described in paragraph (f) of this section, § 438.330(b)(2) and(3), (c), and (e) of this chapter apply.

* * * * *

■ 27. Section 457.1260 is revised to read as follows:

§ 457.1260 Grievance system.

(a) *Statutory basis and definitions*—(1) *Statutory basis.* This section implements section 2103(f)(3) of the Act, which provides that the State CHIP must provide for the application of subsections section 1932(a)(4), (a)(5), (b), (c), (d), and (e) of the Act (relating to requirements for managed care) to coverage, State agencies, enrollment brokers, managed care entities, and managed care organizations. Section 1932(b)(4) of the Act requires managed care plans to establish an internal grievance procedure under which an enrollee, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for covered benefits.

(2) *Definitions.* The following definitions from § 438.400(b) of this chapter apply to this section—

(i) Paragraphs (1) through (5) and (7) of the definition of Adverse benefit determination; and

(ii) The definitions of appeal, grievance, and grievance and appeal system.

(b) *General requirements.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions of § 438.402(a), (b), (c)(2) and (3) of this chapter with regard to the establishment and operation of a grievances and appeals system.

(2) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State external review in accordance with the terms of subpart K of part 457 of this chapter after receiving notice under § 438.408 of this chapter that the adverse benefit is upheld.

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements specified in § 438.408 of this chapter, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review in accordance with the terms of subpart K of this part.

(4) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State external review in accordance with the terms of subpart K of this part, on behalf of an enrollee. When the term ''enrollee'' is used throughout this rule, it includes providers and authorized representatives consistent with this paragraph.

(c) *Timely and adequate notice of adverse benefit determination.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.404(a), (b)(1), (2), and (4) through (6), and (c)(2) through (6) of this chapter.

(2) The notice must explain the enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) of this chapter and the right to request a State external review in accordance with the terms of subpart K of this part.

(3) For termination, suspension, or reduction of previously authorized CHIP-covered services, the MCO, PIHP, or PAHP must provide timely written notice.

(d) *Handling of grievances and appeals.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.406 of this chapter.

(e) *Resolution and notification: Grievances and appeals.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.408(b), (c)(1) and (2), (d), (e)(1), and (f)(3) of this chapter.

(2) Each MCO, PIHP, or PAHP must resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements of this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review in accordance with the terms of subpart K of this part.

(4) For appeals not resolved wholly in favor of the enrollees, the content of the notice of appeal resolution required in § 438.408(e) of this chapter must include the following:

(i) The right to request a State external review in accordance with the terms of subpart K of this part, and how to do so.

(ii) The right to request and receive benefits while the review is pending, and how to make the request.

(iii) That the enrollee may, consistent with State policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(5) An enrollee may request a State external review only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination.

(6) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408 of this chapter and this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review.

(7) The enrollee must request a State external review no later than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution.

(f) *Expedited resolution of appeals.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.410 of this chapter.

(g) *Information about the grievance and appeal system to providers and subcontractors.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.414 of this chapter.

(h) *Recordkeeping requirements.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.416 of this chapter.

(i) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the result of a State external review in accordance with the terms of subpart K of this part reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

■ 28. Section 457.1270 is revised to read as follows:

§ 457.1270 Sanctions.

(a) The State must comply with §§ 438.700 through 438.704, § 438.706(c) and (d), and §§ 438.708 through 438.730 of this chapter.

(b) *Optional imposition of sanction.* If the State imposes temporary

management under § 438.702(a)(2) of this chapter, the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700 of this chapter, or that is contrary to any of the requirements of this subpart.

(2) There is substantial risk to enrollees' health.

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700 of this chapter.

(ii) Until there is an orderly termination or reorganization of the MCO.

(c) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3) of this chapter, and must notify the affected enrollees of their right to terminate enrollment.

■ 29. Section 457.1285 is revised to read as follows:

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of § 438.604(a)(2) and (d)(4) of this chapter do not apply.

Dated: October 31, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2018.

Alex M. Azar II.,

Secretary, Department of Health and Human Services.

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