**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 438 and 457**

**[CMS–2408–F]**

**RIN 0938–AT40**

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

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule advances CMS' efforts to streamline the Medicaid and Children's Health Insurance Program (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 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:**

*Effective Date:* These regulations are effective on December 14, 2020, except for the additions of §§ 438.4(c) (instruction 4) and 438.6(d)(6) (instruction 7), which are effective July 1, 2021.

*Compliance Dates:* States must comply with the requirements of this rule beginning December 14, 2020, except for §§ 438.4(c), 438.6(d)(6), 438.340, and 438.364. States must comply with §§ 438.4(c) and 438.6(d)(6) as amended effective July 1, 2021 for Medicaid managed care rating periods starting on or after July 1, 2021. States must comply with § 438.340 as amended for all Quality Strategies submitted after July 1, 2021. As § 438.340 applies to CHIP through an existing cross-reference in § 457.1240(e), separate CHIPs must also come into compliance with the requirements of § 438.340 as amended for all Quality Strategies submitted after July 1, 2021. States must comply with § 438.364 for all external quality reports submitted on or after July 1, 2021. Because § 438.364 applies to CHIP through an existing cross reference in § 457.1250(a), separate CHIPs must also come into compliance with the requirements of § 438.364 for external quality reports submitted on or after July 1, 2021.

**FOR FURTHER INFORMATION CONTACT:**

John Giles, (410) 786–5545, for Medicaid Managed Care provisions.

Carman Lashley, (410) 786–6623, for the Medicaid Managed Care Quality provisions.

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

**SUPPLEMENTARY INFORMATION:**

## 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 in this final rule.

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 one of two primary authorities:

- Through a state plan amendment that meets standards set forth in section 1932 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.

The above 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 2016 final Medicaid managed care regulations.

In the November 14, 2018 **Federal Register** (83 FR 57264), we published the ''Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care'' proposed rule (the 2018 proposed rule) which included proposals designed to streamline the Medicaid and CHIP managed care regulatory framework to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. This 2018 proposed rule was intended to ensure that the Medicaid and CHIP managed care 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.

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 intended to 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 few improvements in outcomes for beneficiaries. As part of the agency's broader efforts to reduce administrative burden, we undertook an analysis of 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 review process culminated in the November 14, 2018 proposed rule. After reviewing the public comments to the 2018 proposed rule, this final 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. Medicaid Managed Care Provisions of the Rule and Analysis of and Responses to Public Comments*

We received a total of 215 timely comments from state Medicaid and CHIP agencies, advocacy groups, health care providers and associations, health insurers, managed care plans, health care associations, and the general public. The following sections, arranged by subject area, include a summary of the comments we received and our responses to those comments. In response to the November 14, 2018 proposed rule, some commenters chose to raise issues that were beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments.

1. Standard Contract Requirements (§ 438.3(t))

In the 2016 final rule, we added a new provision at § 438.3(t) requiring that contracts with a managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (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. The Medicare crossover claims process is limited to fee-for service-claims for Medicare Parts A and B; it does not include services covered by Medicare Advantage plans under Medicare Part C.

Since publication of the 2016 final rule, we 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 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. When a Medicaid managed care plan enters into a crossover agreement with Medicare, as required in § 438.3(t), we then send to that plan all the Medicare FFS crossover claims for their Medicaid managed care enrollees, 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. Some states requested regulation changes to permit states to send the appropriate crossover claims to their managed care plans; that is, states would receive the CMS crossover file and then forward to each Medicaid managed care plan only those crossover claims for which that plan is responsible. 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 proposed to revise § 438.3(t) to remove the requirement that managed care plans must enter into a COBA directly with Medicare and instead would require a state's 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 crossover claims it receives from Medicare to each MCO, PIHP, or PAHP, as appropriate. Additionally, we proposed to require, if the state elects to use a methodology other than requiring

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

the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that the state's methodology would have to 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.

The following summarizes the public comments received on our proposal to revise § 483.3(t) and our response to those comments.

*Comment:* Many commenters supported the proposed addition of state flexibility to use alternate mechanisms to send crossover claims to managed care plans. Commenters stated that the changes would provide states and plans more flexibility while continuing to promote better coordination of benefits for dually eligible individuals and reducing burden on the providers who serve them.

*Response:* We appreciate the support for the proposed change to the regulation.

*Comment:* One commenter supported the proposed rule but added that it is necessary for CMS to ensure that any alternative state crossover methodology separates Medicare claims from Medicaid rate setting and actuarial soundness.

*Response:* While Medicare Part A or Part B cost-sharing payments—which are Medicaid costs—must be factored into Medicaid rate setting if a Medicaid plan is responsible for covering them, we agree that other costs for the provision of Medicare covered services should not be. Nothing in our proposal or the revision to § 438.3(t) that we finalize here will impact the processes for Medicaid rate-setting or determination of actuarial soundness.

*Comment:* One commenter supported the proposed changes but offered a note of caution relating to potentially opening the door to subpar manual processes that states might adopt that could incur additional costs and unnecessary complexity.

*Response:* As discussed in this final rule, the regulations at § 438.3(t) finalized in 2016 established a crossover process in which providers only bill once, rather than multiple times. The revision to § 438.3(t) that we are finalizing here maintains a process in which providers only bill once (to Medicare), because the regulation only applies when the state enters into a COBA but allows greater state flexibility in how that claim is routed from Medicare to Medicaid and Medicaid managed care plans. We agree that automated processes are usually optimal and create efficiencies for states, plans, and providers. We encourage states that adopt alternate methodologies to use automated processes as appropriate to achieve efficient and economical systems. Regardless of the method chosen by a state, the provider role in the crossover claim submission process is not changed by this proposal.

*Comment:* Some commenters noted concern that the proposed changes would have on plans and providers that operated across state lines. One commenter noted that Medicaid managed care plans that operate in multiple states would need to develop and maintain different processes in different states. Another commenter who supported the proposed changes noted that it may pose challenges for providers that furnish services in multiple states.

*Response:* We carefully considered the benefits of national uniformity for Medicaid managed care plans and providers that serve multiple states. In this instance, we believe that states should have the flexibility to adopt the methodology that works best within their state to ensure that the appropriate MCO, PIHP, or PAHP will receive all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. This flexibility will allow states to maintain current processes and not incur unnecessary costs or burden to providers and beneficiaries to conform to a new mandated process. We note here that this revision to § 438.3(t) does not require states to change their current cross over claim handling processes; it merely provides states with an option. Regardless of which methodology a state chooses to implement, it should not have any effect on providers, who should be able to submit their claims once and have it routed to the appropriate MCO, PIHP, or PAHP for adjudication.

*Comment:* One commenter who objected to the proposed changes requested clarification about how it intersects with a similar provision in section 53102(a)(1) of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, enacted February 9, 2018) concerning procedures for states processing prenatal claims when there is a known third party liability.

*Response:* We do not believe that § 438.3(t), as amended here, conflicts with the third party liability requirements added by section 53102(a)(1) of the BBA of 2018. We note that section 53102(a)(1) of the BBA of 2018 applies when the provider bills Medicaid directly for a prenatal claim. As further discussed in our June 1, 2018 Informational Bulletin to states,[2] that provision requires states to use standard cost avoidance when processing prenatal claims. Thus if the state Medicaid agency has determined that a third party is likely liable for a prenatal claim, it must reject, but not deny, the claim returning the claim back to the provider noting the third party that the Medicaid state agency believes to be legally responsible for payment. If a provider billed Medicaid for a prenatal claim for a dually eligible individual, the state would be required to reject the claim but note that Medicare is the liable third party, as Medicare would be the primary payer.

By contrast, the regulation in § 438.3(t), which is triggered because the state enters into a COBA with Medicare, applies when the provider bills Medicare for any Part A or B service under Medicare FFS for a dually eligible individual for which there is cost-sharing covered by Medicaid. Medicare would generate the crossover consistent with the COBAs in place. If the state has elected to require its Medicaid managed care plans to enter into a COBA with Medicare, then Medicare would forward the crossover claims to the Medicaid managed care plan. If the state has elected under § 438.3(t) to use a different methodology for ensuring that the appropriate managed care plan receives the applicable crossover claims, then Medicare would forward the crossover claims to the state pursuant to the state's COBA with Medicare; the state would then forward that crossover claim to the Medicaid managed care plan for payment. If a state adopts an alternate methodology as provided in § 438.3(t), the state must ensure that the submitting provider is promptly informed on the state's remittance advice that the claims have not been denied, but instead, has been sent to the MCO, PIHP, or PAHP for consideration.

*Comment:* One commenter requested that CMS add regulatory language at § 438.3(t) stating that ''The coordination methodology also must ensure that dually eligible individuals are not denied Medicaid benefits they would be eligible to receive if they were not also eligible for Medicare benefits.''

*Response:* We agree that it is essential that dually eligible individuals are not denied Medicaid benefits they would be eligible to receive if they were not also eligible for Medicare benefits; however, this is outside the scope of this regulation, which is limited to how states must ensure the appropriate managed care plan receives all

[2] See *https://www.medicaid.gov/federal-policy-guidance/downloads/cib060118.pdf.*

applicable crossover claims for which it is responsible. We note that there is no regulation in part 438 that authorizes denial of Medicaid-covered services for an enrollee who is eligible for those services based on the enrollee's eligibility as well for Medicare.

*Comment:* One commenter suggested providing Medicare eligibility data to MCOs, PIHPS, and PAHPs through data feeds, file transfers, or an online portal for efficient coordination of benefits, to improve care coordination and outcomes. One commenter encouraged free and timely access to all clinical and administrative data to promote coordination among managed care plans. The commenter suggested creating a standardized process by which managed care organizations can receive timely claims and clinical data from both Medicaid and Medicare. The commenter noted that the proposed changes may limit full integration in instances where a beneficiary in a Medicaid managed long term care plan is enrolled in an unaligned (that is, offered by a separate organization) Medicare Advantage plan such as a Dual Eligible Special Needs Plan offered by a different organization than offers the Medicaid plan in which the person is enrolled.

*Response:* We appreciate the value of making such data available to plans. We are separately exploring whether we have authority to do so within existing limits, such as those established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted August 21, 1996). For the comment on enrollment in different managed care plans for Medicaid and Medicare, we note that the Medicare crossover process is limited to Original Medicare (Medicare Part A and B). Claims for cost sharing for a Medicare Advantage enrollee are beyond the scope of this regulation.

*Comment:* One commenter requested that we itemize all claim inclusion and exclusion selection criteria for professional claim services.

*Response:* We do not have the authority to make the requested change. The National Uniform Claims Committee (NUCC), which establishes the standards for 837 professional claims and the CMS–1500 form, has chosen not to array professional and DME claims by type of bill (TOB), as happens with institutional claims, which are under the purview of the National Uniform Billing Committee (NUBC).

*Comment:* One commenter requested that we allow plans to continue their COBA with, and receive crossover claims directly from, Medicare in states where plans already did so as required under the 2016 final rule.

*Response:* As we proposed the amendment and are finalizing it here, § 438.3(t) does not require any changes for states and MCOs, PIHPs, and PAHPs that are already complying with the 2016 final rule. This final rule amends § 438.3(t) to provide states with additional flexibility to adopt a different methodology to ensure that the appropriate MCO, PIHP, or PAHP will receives all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible, subject to some limited parameters to ensure that the applicable provider is provided information on the state's remittance advice. This additional flexibility might result in states developing and using more efficient and economical processes for handling cross-over claims applicable to Medicaid managed care enrollees.

*Comment:* One commenter who supported the proposed changes encouraged CMS to monitor states that adopt alternative methodologies to ensure that providers still receive payments in a timely manner.

*Response:* While this regulation does not establish a timeframe for the state to forward the crossover claim to its managed care plan, we note that the existing regulations on timely claims payment in the Medicaid FFS context apply. Specifically, § 447.45(d)(4)(ii) specifies that the state Medicaid agency must pay the Medicaid claim relating to a Medicare claim within 12 months of receipt or within 6 months of when the agency or provider receives notice of the disposition of the Medicare claim. A state that uses an alternative methodology under § 438.3(t) and receives crossover claims from Medicare would need to ensure payment within this timeframe. To do so, the state would need to forward crossover claims to a Medicaid plan and ensure the plan pays it within 6 months of when the state initially received it.

*Comment:* A few commenters who opposed the proposed changes recommended that, if the regulation is finalized as proposed and a state elects to devise its own system, the state be required to promptly educate participating health care providers about any ensuing changes in the state's updated remittance advice. One commenter expressed concern that some health care providers would not be promptly made aware of the new requirements to submit multiple claims to the managed care plan for payment consideration, resulting in unpaid claims through no fault of their own, and that this would be antithetical to CMS' ''Patients Over Paperwork'' initiative.

*Response:* We believe that provider education is critical whenever a state implements changes to how crossover claims are routed to the Medicaid managed care plan responsible for processing them. We encourage states to conduct such education prior to implementing any process changes.

For the concern that without education, providers would not know where to submit claims for Medicare cost-sharing, this provision is designed to remove from providers the burden of having to identify the Medicaid managed care plan in which each dually eligible patient is enrolled, and submit the bill for the Medicare cost-sharing to the correct plan. Under our proposed regulation, the crossover claim is still routed to the Medicaid managed care plan. States may continue to require that plans enter into a COBA with Medicare to route crossover claims directly to the plan. In the alternative, states that elect to receive crossover claims from Medicare (or elect any other methodology than having the Medicaid managed care plans enter into COBAs with Medicare) would route the claims to the plan and issue remittance advice to the applicable provider. In both cases, the claims will be routed to the Medicaid managed care plan; there is no need for the provider to take any action to identify or submit the crossover claim to the plan. We believe this is fully in line with our ''Patients over Paperwork'' initiative.

We also sponsor an enhanced secondary COBA feed (also known as the ''Medicaid Quality project''), which is available to states that have a COBA and participate in the Medicare crossover process. This secondary feed ensures that states receive a complete array of Medicare FFS adjudicated Part A and B claims for individuals that the states submitted to CMS on their eligibility file. The state must be in receipt of the normal crossover claims file to be eligible to receive the second enhanced COBA feed.

*Comment:* One commenter who opposed the proposed changes expressed concern that any process in which there is an intermediary would create confusion and delay. The commenter noted that a smoothly operating crossover claim process reduces burden on providers, and may make them more willing to serve Qualified Medicare Beneficiaries and other dually eligible individuals. The commenter suggested simplifying and streamlining the procedures so that all crossover claims can be handled promptly by one entity, either the state

Medicaid agency or the MCO. The commenter also noted that when CMS adopted § 438.3(t), it allowed states time to have Medicaid managed care plans get COBAs in place, and that if more time is needed, the better course would be to extend the time for enforcement rather than to modify the regulation.

*Response:* We share the preference for reducing the complexity of the crossover claim process and agree with the commenter that complexity in the crossover process can be a disincentive to serving dually eligible individuals. The § 438.3(t) regulatory language that we proposed and are finalizing requires that if a state uses an alternate methodology, it must ensure that the appropriate managed care plan (that is, the MCO, PIHP, or PAHP whose contract covers the services being billed on the claim) receives all applicable crossover claims, and ensure the remittance advice conveys that the claim is forwarded rather than denied. In either scenario, the provider is relieved of the burden of determining which entity—the state or Medicaid managed care plan—is liable for the Medicare cost-sharing.

*Comment:* Several commenters opposed the proposed changes and requested we leave the current regulatory requirements in place. Many of these commenters noted that the flexibility in the proposed change could increase provider administrative burden and confusion when states indicate multiple denials on the state's remittance advice to providers (that is, when they forward a crossover claim to an MCO, PIHP, or PAHP) and that it would create further confusion when the Medicaid managed care plan then processed the claim and notified the provider on the plan's remittance advice. Some also expressed concern that alternate methodologies would increase provider practice costs—especially for small practices.

*Response:* As noted in the proposed rule and in this final rule, an important factor prompting the proposed change was that some states and providers raised concerns after the original provision was finalized in the 2016 final rule requiring a state to abandon effective alternative processes would actually add to provider burden and increase risk of payment delays. We believe that state flexibility would permit carefully crafted alternative arrangements to continue in a way that benefits providers, plans, and states. We reiterate that this proposal retains a system in which providers are only required to bill once (to Medicare), and that the claim will be transferred to Medicaid or the Medicaid managed care plan to address the payment of Medicare cost-sharing.

To address the commenter's concern about when states indicate multiple denials on the state's remittance advice, we are clarifying our intent by finalizing § 438.3(t) with additional text specifying that the state's remittance advice must inform the provider that the claim was not denied by the state but was redirected to a managed care plan for adjudication. We regret that our intent was not clear in the proposed rule and believe this clarification will minimize provider confusion and reduce the risk of providers inadvertently perceiving forwarded claims as denied.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.3(t) as proposed with one modification to clarify that when a state elects not to require its managed care plans to enter into COBAs with Medicare, the remittance advice issued by the state must indicate that the state has not denied payment but that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration. In addition, we are finalizing the regulation text with slight grammatical corrections to use the present tense consistently.

2. Actuarial Soundness Standards (§ 438.4) [3]

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

Before the 2016 final rule was published, we 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 in that 2016 final rule 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 us 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 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 may prevent the state from realizing a lower rate that could have been available through the state's 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. 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 proposed 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 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 us or the public of the change. We noted that the rate range option at proposed paragraph (c) would allow states to certify a rate range per rate cell subject to specific limits and

[3] In *Texas* v. *United States,* No. 7:15–cv–151–O, slip op. at 40, 62 (N.D. Tex. Mar. 5, 2018), appeal docketed, No. 18–10545 (5th Cir. May 7, 2018) (''Texas''), six states challenged the portion of the regulation previously codified at 42 CFR 438.6(c)(1)(i)(C) (2002) (now codified in portions of 42 CFR 438.2, 438.4), defining ''actuarially sound capitation rates'' as capitation rates ''that . . . [h]ave been certified . . . by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board,'' on the basis that Actuarial Standard of Practice (''ASOP'') 49 defines ''actuarially sound capitation rates'' to mean rates that account for all fees and taxes, including the Health Insurance Provider Fee (''HIPF''). In a decision issued on March 5, 2018, the court declared the challenged portion of the regulation to be ''set aside'' under the Administrative Procedure Act, 5 U.S.C. 706(2)(B) through (C). Texas, slip op. at 62. In its decision, the court specifically allowed CMS to ''continue to use ASOP 49 to make internal decisions whether capitation rates are 'actuarially sound,' '' and only ''cannot use ASOP 49 to . . . require Plaintiffs to pay the HIPF.'' Texas, slip op. at 21. As of July 2019, the court had not issued a final judgment. The government has appealed the court's March 5, 2018 decision; during the pendency of the appeal, the government is complying with the court's order.

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, we noted that an actuary must certify the upper and lower bounds of the rate range as actuarially sound and would require states to demonstrate in their rate certifications how the upper and lower bounds of the rate range were actuarially sound.

Specifically in § 438.4(c)(1), we proposed 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 proposed these specific conditions and limitations on the use of rate ranges to address our concerns noted in this final rule; 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 stated in the proposed rule our belief that the proposed conditions and limitations on the use of rate ranges struck the appropriate balance between prudent fiscal and program integrity and state flexibility. We invited comment on these specific proposals and whether additional conditions should be considered to ensure that rates are actuarially sound.

Under proposed § 438.4(c)(2)(i), states certifying a rate range would be required to document the capitation rates payable to each managed care plan, 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 us prior to the start of the rating period and 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 +/− 1.5 percent range allowed under existing § 438.7(c)(3); we proposed to codify this as § 438.4(c)(2)(ii). We noted that this provision would enable us to give states the flexibility and administrative simplification to use certified rate ranges. We noted in the proposed rule that while the use of rate ranges is not standard practice in rate development, our proposal would align 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 acknowledged that our proposal had 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, while finalizing § 438.7(c)(3) to allow *de minimis* changes of +/− 1.5 percent to provide some administrative relief to states for small changes in the capitation rates. This change was intended to provide some flexibility with rates while eliminating the ambiguity created by rate ranges in 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 had used rate ranges to increase or decrease rates paid to the managed care plans without providing further notification to us 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 through 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 were 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).

We noted how the specific risks described in the proposed rule concerned us, and as such, were the reason for specific conditions and limitations on the use of rate ranges that we proposed. Our rate range proposal was 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 noted that states would need to demonstrate that the entirety of rate ranges (that is, lower and upper bound) compliant with our proposal are actuarially sound. 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 noted that we believed 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 believed that our proposal struck the right balance between enabling state flexibility and our statutory responsibility to ensure that managed care capitation rates are actuarially sound, we noted that our approach may reintroduce undue risk in Medicaid rate-setting.

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

The following summarizes the public comments received on our proposal to add § 438.4(c) and our responses to those comments.

*Comment:* Many commenters supported the proposed option to develop and certify a 5 percent rate range, stating it allows for increased flexibility in rate setting. Commenters noted that the rate range proposal will remove ambiguities in determining actuarial soundness and will put appropriate limits on unsustainable rates. Some commenters specifically noted support for the requirements to recertify rates when there are changes made within the approved rate range and for states to document the specific rates for each managed care plan. Commenters also noted support for the proposal that states cannot pay managed care plans at different rates within the range based on IGT agreements. Several commenters noted that the specific conditions proposed by CMS must be implemented and strictly enforced to ensure that actuarial soundness is achieved within the rate ranges. A few commenters urged CMS to adopt all of the conditions set forth in § 438.4(c) if rate ranges are finalized.

*Response:* We continue to believe, particularly with the support of commenters, that the 5 percent, or +/ − 2.5 percent from the midpoint, rate range will permit increased flexibility in rate setting, while the specific conditions proposed will also ensure that the rates are actuarially sound. The proposed parameters and guardrails carefully strike a balance between state flexibility and program integrity and we are finalizing them, with some modifications as discussed in response to other comments.

*Comment:* Several commenters opposed the proposal to allow states to certify rate ranges and urged CMS not to finalize it. Some of these commenters expressed concerns that rate ranges decrease transparency, do not ensure that rates are actuarially sound, and do not enable CMS to ensure the adequacy of state and Federal investments in patient care. Some commenters noted that our proposal represents diminished Federal oversight of the adequacy of payment rates to Medicaid managed care plans and that it would result in lower payments to managed care plans, which could limit patient access to care. One commenter specifically expressed concern that wider rate ranges may result in lower rates to managed care plans and in turn result in contracts being awarded to less qualified plans, which may lead to early contract terminations, plan turnover, and instability for beneficiaries; this commenter also noted that such plans may be unable to pay competitive market rates, which could reduce patient access to care. Commenters also stated that the rate range provision is unnecessary since the existing +/ − 1.5 percent adjustment under § 438.7(c)(3) is adequate to provide states with administrative flexibility. One commenter expressed concern that the rate range proposal would result in reduced services for enrollees and instability for managed care plans and providers.

*Response:* We understand commenters' concerns related to the use of rate ranges in Medicaid managed care. We also acknowledge our own fiscal and program integrity concerns which were noted in the 2016 final rule, as well as in the 2018 proposed rule. However, we proposed this rate range provision because we heard from states that this was a critical flexibility to reduce administrative burden in state Medicaid programs. We developed our proposal to carefully strike a balance between state flexibility and program integrity. Balancing this flexibility with the fiscal and program integrity concerns was the driving reason for including comprehensive guardrails around the use of rate ranges in the proposal and this final rule. To ensure appropriate Federal oversight, we specifically proposed parameters to ensure that rate ranges: (1) Do not inappropriately use IGTs to draw down additional Federal dollars with no correlating benefit to the Federal Government or the Medicaid program; (2) are bounded at the upper and lower ends with rates that are actuarially sound consistent with the regulations at §§ 438.4 through 438.7; and (3) strike the appropriate balance between prudent fiscal and program integrity and state flexibility. With regard to this last point, we specifically proposed that states using rate ranges must document in the rate certification the criteria used to select the specific rate within the range for each managed care plan under contract with the state. The guardrails finalized in § 438.4(c) will enable CMS to review the establishment and use of rate ranges by states and ensure that all rates actually paid to managed care plans are actuarially sound. To address specific concerns about unsound capitation rates, this final rule requires both the upper and lower bounds of the rate range to be actuarially sound; therefore, actuarially unsound rates would not be consistent with § 438.4(c).

We agree with commenters that the existing regulation that permits a +/ − 1.5 percent adjustment to certified rates can help states appropriately address mid-year programmatic changes or mid-year rate adjustments. However, we also believe that the additional option to certify a rate range can be helpful to states, especially in circumstances where states are competitively bidding the capitation rates. We also agree with commenters that rate ranges can obfuscate payment rates, and that is why we included specific guardrails around the use of rate ranges in the proposed rule and are finalizing those requirements. For

example, § 438.4(c)(1)(i) requires that the state's rate certification identify and justify the assumptions, data, and methodologies used to develop the upper and lower bounds of the rate range. Also, § 438.4(c)(2)(i) requires that states document the capitation rates, prior to the start of the rating period, for the managed care plans at points within the rate range, consistent with the state's criteria for paying managed care plans at different points within the rate range. This means that the contract and rate certification must be submitted for CMS approval before the rating period begins. We specifically included this timing requirement to limit the obfuscation of rates. We believe that the guardrails we proposed and are finalizing, such as these two examples, provide a level of transparency on the use of rate ranges and provide a mechanism to avoid obfuscation, especially since this regulation requires the actuary to describe and justify the assumptions, data, and methodologies used to develop the rate range in the actuarial certification.

We understand that several commenters were concerned that rate ranges could be used to lower payments to managed care plans, thereby leading to reduced services for enrollees and instability for managed care plans and providers; however, we have incorporated safeguards to prevent such outcomes. Under § 438.4(c)(1)(ii), both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements in part 438. Actuarially sound capitation rates must provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. Since the lower bounds of rate ranges must also be actuarially sound and developed in accordance with the regulations in part 438 governing actuarial soundness and rate development, we believe that rates within the range must all be actuarially sound. Under § 438.4(c) as finalized, states using rate ranges must also document the criteria for paying managed care plans at different points within the rate range and must document the capitation rates prior to the start of the rating period—this means that the criteria used to set managed care plans' capitation rates must be documented prior to the start of the rating period. We believe that these requirements will ensure that states are not arbitrarily reducing payments to managed care plans. We also want to reiterate that the regulations in 42 CFR part 438 contain other beneficiary protections meant to ensure that plans are not arbitrarily reducing services to managed care enrollees. For example, § 438.210 requires that the services covered under the managed care contract must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid. We would also highlight the requirements in § 438.206 regarding the timely availability of services that states and managed care plans must ensure for all managed care enrollees.

*Comment:* Several commenters supported the proposal to allow rate ranges but recommended that the range be expanded beyond 5 percent. Some commenters requested that CMS expand the rate range provision to 10 percent. Commenters also requested that CMS restore rate ranges to pre-2016 regulatory levels, noting their belief that limits on a rate range are not necessary if the requirement of paying actuarially sound rates remains in place. Several commenters also recommended a narrower rate range to ensure the actuarial soundness of the final rates and recommended that actuaries be required to consider specific factors in determining the width (or size) of the rate range, such as maturity of the program, credibility/quality of the base data, amount of statistical variability in the underlying claim distribution, and size of the population. Commenters suggested additional rate ranges with a width (or size) of +/−2 percent (total range of 4 percent) or +/−3 percent (total range of 6 percent) from the midpoint, or two times the risk margin reflected in the capitation rates as alternatives to our proposal. Some commenters considered the proposed 5 percent range to be overly broad and recommended smaller ranges for the rates to remain actuarially sound. Some commenters gave specific scenarios by which the proposed 5 percent rate range may be insufficient and recommended that CMS not finalize a prescriptive +/− rate range to permit additional state flexibility.

*Response:* We are declining to adopt any of these specific recommendations, as some commenters requested wider permissible ranges, while other commenters requested narrower permissible ranges. Because of the mix of public comments on this topic, we believe that we struck the right balance in the proposed rule by permitting a rate range up to 5 percent, or +/−2.5 percent from the midpoint, between the lower and upper bound. We believe that 5 percent, or +/−2.5 percent from the midpoint, is a reasonable rate range to permit the administrative flexibility requested by states and also to ensure that all rates within the entire rate range are actuarially sound. We proposed, and are finalizing, regulatory requirements that the rate certification identify and justify the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range (paragraph (c)(1)(i)), and that both the upper and lower bounds of the rate range are certified as actuarially sound (paragraph (c)(1)(ii)). We believe that the 5 percent, or +/−2.5 percent from the midpoint, rate range is more appropriate to ensure that these requirements can be satisfied, rather than an unspecified limit, or a limit that is so wide that it would not be possible to find both the upper and lower bounds of the rate range to be actuarially sound.

Regarding comments about the factors used in determining a rate range, such as maturity of the program, credibility/quality of the base data, amount of statistical variability in the underlying claim distribution, and size of the population, we believe that such factors would be permissible for actuaries to consider as part of the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range in accordance with generally accepted actuarial principles and practices, and the requirements for rate setting in §§ 438.4, 438.5, 438.6, and 438.7. If actuaries use these factors in determining the rate range, it would be appropriate to document these factors in the rate certification as required under § 438.4(c)(1)(i) and (ii). However, we decline to require that actuaries must consider these factors when determining the width (or size) of the rate range, as such an approach is overly prescriptive. We believe that actuaries may consider other factors when identifying and justifying the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range.

*Comment:* Some commenters submitted technical recommendations about the rate range option, including that the calculation of the rate range should exclude risk adjustments and pass-through payments, that states should be able to apply or adjust risk adjustment mechanisms outside of setting the certified rate range, that the calculation of rate ranges should not reflect incentive payments for managed care plans, and that state budget factors should not influence the calculation of rates within the rate range. Other commenters recommended that administrative expenses should not be

subject to rate range variances. A few commenters recommended that certain government-mandated costs be considered outside of the rate range, including the Health Insurance Provider Fee (HIPF). One commenter also recommended that rate ranges be limited to include only underlying benefit changes.

*Response:* Under § 438.4(c)(1)(ii), both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements of part 438. This means that the calculation of the rate range under § 438.4(c) must include all of the components of the capitation rate that are currently required to be included in the rate development and certification under §§ 438.4, 438.5, 438.6, and 438.7. This includes pass-through payments, administrative expenses, taxes, licensing and regulatory fees, government-mandated costs (including the HIPF and other taxes and fees), and underlying benefit costs, which are all required components of developing the capitation rates under our existing regulations.[4] We agree that it would be inappropriate to include the specific incentive payments for managed care plans made under § 438.6(b)(2) in the calculation of the rate range, as per longstanding policy since the 1990's, those incentive arrangements are provided in excess of the approved capitation rate and are already limited to 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. We also agree that it would be inappropriate for state budget factors to influence the calculation of rates within the rate range since such factors are not considered valid rate development standards (that is, state budget factors are not relevant to the costs required to be included in setting the capitation rates in accordance with §§ 438.4, 438.5, 438.6, and 438.7).

Regarding comments about risk adjustment, we generally agree with commenters that risk adjustment mechanisms can be applied outside of setting the certified rate range, consistent with existing Federal regulations at § 438.7(b)(5). While the state's actuary is required to certify rate ranges and must describe the risk adjustment methodology in the certification and certify the methodology, the state's actuary is not required to certify *risk-adjusted rate ranges* (that is, the rate ranges with the risk adjustment methodologies applied to reflect the actual payments potentially available to the managed care plan). The Federal requirements for including risk adjustment mechanisms in the capitation rates are found in § 438.7(b)(5). As part of the 2016 final rule, we acknowledged that risk adjustment methodologies can be calculated and applied after the rates are certified (81 FR 27595); therefore, we finalized specific standards for retrospective risk adjustment methodologies at § 438.7(b)(5)(ii). Further, the regulation at § 438.7(b)(5)(iii), which we finalized in the 2016 final rule, provides that a new rate certification is not required when approved risk adjustment methodologies are applied to the final capitation rates because the approved risk adjustment methodology must be adequately described in the original rate certification; payment of rates as modified by that approved risk adjustment methodology would be within the scope of the rate certification that adequately describes the risk adjustment mechanism. We also clarified in the 2016 final rule, under the requirements in § 438.7(c)(3), that the application of a risk adjustment methodology that was approved in the rate certification under § 438.7(b)(5) did not require a revised rate certification for our review and approval (81 FR 27568). However, we noted that the payment term in the contract would have to be updated as required in § 438.7(b)(5)(iii). Requirements for risk adjustment and risk sharing mechanisms in § 438.6 must also be met. Therefore, as long as the Federal requirements are met for risk adjustment, we agree that such mechanisms can be appropriately applied outside of the certified rate range (meaning, applied to the rates after calculation of the rate range), consistent with existing Federal regulations and our analysis in the 2016 final rule.

*Comment:* One commenter recommended that CMS describe the permitted rate range in terms of a percentage.

*Response:* We confirm for this commenter that the permissible rate range is expressed as a percentage. Section 438.4(c)(1)(iii), as finalized in this rule, requires that the upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05. This means that the upper bound of the rate range cannot exceed the lower bound of the rate range by more than 5 percent, or +/− 2.5 percent from the midpoint.

*Comment:* A few commenters requested clarification on the use of the *de minimis* +/− 1.5 percent range that is currently codified in § 438.7(c)(3). Commenters requested detail on whether the proposal to allow rate ranges adds new parameters on the use of the *de minimis* flexibility that is currently codified in § 438.7(c)(3). Commenters also requested clarity on how the new rate range provision and the +/− 1.5 percent flexibility can be used together.

*Response:* As proposed and finalized, § 438.4(c) does not add or require additional parameters on the use of the +/− 1.5 percent adjustment as permitted under § 438.7(c)(3) for any state that does not use rate ranges. However, under § 438.4(c)(2)(ii), states that use rate ranges are not permitted to modify the capitation rates under § 438.7(c)(3). States are permitted to either use the rate range option under § 438.4(c)(1) or use the *de minimis* +/− 1.5 percent range that is currently codified in § 438.7(c)(3), but states are not permitted to use both mechanisms in combination. As noted in the 2018 proposed rule, we believe that this prohibition on using rate ranges in combination with the *de minimis* revision permitted under § 438.7(c)(3) is necessary to ensure program integrity and guard against other fiscal risks. As finalized at § 438.4(c)(1)(i), the rate certification must identify and justify the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range. The rate range cannot be wider than 5 percent, or +/− 2.5 percent from the midpoint; the *de minimis* revision permitted under § 438.7(c)(3) cannot be used in combination with this rate range. It is our belief that the upper and lower bounds of a 5 percent rate range can remain actuarially sound as long as all of the Federal requirements for rate development, including the requirements we are finalizing in § 438.4(c), are met. If states were permitted to use rate ranges in combination with the *de minimis* revision permitted under § 438.7(c)(3), this could result in final rates that are outside of the 5 percent range, and this is not permitted. As provided in this rule in a separate response, we continue to believe that 5 percent is a reasonable rate range to permit the administrative flexibility requested by states. We believe that the 5 percent rate range is appropriate to ensure that the rate development requirements in part 438

[4] While proceedings in *Texas* v. *United States*, No. 7:15–cv–151–O, slip op. (N.D. Tex. Mar. 5, 2018), appeal docketed, No. 18–10545 (5th Cir. May 7, 2018) (''Texas''), are ongoing, CMS will not require that the HIPF be accounted for in capitation rates for the six plaintiff states in Texas (Indiana, Kansas, Louisiana, Nebraska, Texas, and Wisconsin) in order for such rates to be approved as actuarially sound under 42 CFR 438.2 & 438.4(b)(1).

can be satisfied, rather than a wider rate range where it may not be possible to find both the upper and lower bounds of the rate range to be actuarially sound.

*Comment:* Several commenters expressed concern about the requirement to recertify modified rates within the rate range, noting that recertification is too rigid and is burdensome for both states and the Federal Government. One commenter requested that additional documentation could be provided rather than a requirement to recertify rates. A few commenters expressed concern that states cannot modify capitation rate ranges using the *de minimis* flexibility in § 438.7(c)(3) and requested that CMS allow states to employ both approaches to increase flexibility and reduce the need for recertification when rates change because of minor programmatic changes. Some commenters requested that mid-year rate changes be permitted within the rate range during the rating year without the need to recertify the rates to reduce burden and actuarial costs for states. Some commenters also recommended that CMS permit *de minimis* modifications to rates used within the 5 percent rate range.

*Response:* We disagree with commenters that states should be able to use the *de minimis* rule in § 438.7(c)(3) in combination with a rate range. We proposed and are finalizing a prohibition on such combinations in § 438.4(c)(2)(ii). States may use either the rate range option under § 438.4(c) or use the *de minimis* +/−1.5 percent range that is currently codified in § 438.7(c)(3), but states are not permitted to use both mechanisms in combination. As noted in the 2018 proposed rule, we proposed § 438.4(c)(2)(ii) to enable appropriate state flexibility and administrative simplification without compromising program integrity or other fiscal risks. It is our belief that the upper and lower bounds of a 5 percent, or +/−2.5 percent from the midpoint, rate range should be permissible only as long as all of the Federal requirements for rate development are met. If states were permitted to use rate ranges in combination with the *de minimis* revision permitted under § 438.7(c)(3), this could result in final rates that are outside of the 5 percent range and therefore could result in a rate that is not actuarially sound. We continue to believe that 5 percent is a reasonable rate range to permit the administrative flexibility requested by states, but also to ensure that each rate within the entire rate range is actuarially sound. We believe that the 5 percent rate range is appropriate to ensure that the rate development requirements in part 438 can be satisfied, rather than a wider rate range where it may not be possible to find both the upper and lower bounds of the rate range to be actuarially sound.

However, we are persuaded that our proposal at § 438.4(c)(2)(iii), which required states to recertify capitation rates for modifications of the capitation rates within the rate range, regardless of whether the modification was for minor programmatic changes or a material error, was too rigid and would likely add unnecessary administrative burden and costs for states. We reached this conclusion for minor changes within the rate range that would not result in scenarios where such changes resulted in capitation rates outside of the 5 percent, or +/−2.5 percent from the midpoint, range. Therefore, we are finalizing § 438.4(c)(2)(iii) as permitting changes (increases or decreases) to the capitation rates per rate cell within the rate range up to 1 percent during the rating period without submission of a new rate certification, provided that such changes are consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at § 438.4(b)(1). Just as we do not permit rate ranges in combination with the *de minimis* revision permitted under § 438.7(c)(3), we will not permit any changes that could result in final rates that are outside of the 5 percent range or in rate ranges that have upper and lower bounds that are larger than 5 percent apart.

Any modification to the capitation rates within the rate range greater than the permissible +/−1 percent amount will require states to provide a revised rate certification for CMS approval that demonstrates compliance with the criteria proposed and finalized at § 438.4(c)(2)(iii)(A) through (C). We believe that this modification to what we proposed for this regulation will address commenters' concerns related to mid-year programmatic changes or mid-year rate adjustments. We note that the permissible +/−1 percent standard under § 438.4(c)(2)(iii) is slightly smaller than the *de minimis* standard (+/−1.5 percent) for changes that do not require a new rate certification under § 438.7(c)(3) when rate ranges are not used. We believe that it is appropriate to use the smaller amount under § 438.4(c)(2)(iii) when rate ranges are used because when states use rate ranges, they are already afforded additional flexibility, as rates are permissible within the upper and lower bounds of the rate range, than they are afforded when certifying the rates to a specific point. We believe that the ability to make a permissible +/−1 percent change provides states flexibility to make small changes while easing the administrative burden of rate review for both states and CMS. Further, permitting small changes facilitates CMS' review process of rate certifications in accordance with the requirements for actuarially sound capitation rates because we would not require revised rate certifications for minor programmatic changes that result in minor and potentially immaterial changes to the capitation rates; therefore, CMS' review of rate certifications can be more focused on substantial issues that impact the capitation rates.

*Comment:* Commenters requested clarification on the acceptable criteria for paying managed care plans at different points within the rate range. Specifically, commenters requested if rates can vary based on state negotiations with managed care plans or a competitive bidding process.

*Response:* We note that capitation rates, including permissible rate ranges under § 438.4(c), must comply with all rate setting requirements in §§ 438.4, 438.5, 438.6, and 438.7. This means, as finalized 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. Under this final rule, § 438.4(b)(1) also requires 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 (see section I.B.2.b. of this final rule for a discussion of this provision in § 438.4(b)(1)). We clarify this here to ensure that commenters are aware that the standards for capitation rate development, including the development of rate ranges under § 438.4(c), do not change with the use of rate ranges under § 438.4(c). Regarding the acceptable criteria for paying managed care plans at different points within the rate range, which must be documented in the rate certification documents under § 438.4(c)(1)(iv), we confirm that such criteria could include state negotiations with managed care plans or a competitive bidding process, as long as states document in the rate certification how the negotiations or the competitive bidding process produced different points within the rate range. For example, if specific, documentable components of the capitation rates varied because of state negotiations or a competitive bidding process, the rate

certification must document those specific variations, as well as document how those variations produced different points within the rate range, to comply with § 438.4(c)(1)(iv) and (c)(2)(i). We understand that capitation rate development necessarily involves the use of actuarial judgment, such as adjustments to base data, trend projections, etc., and that could be impacted by specific managed care plan considerations (for example, one managed care plan's utilization management policies are more aggressive versus another managed care plan's narrow networks); under this final rule, states must document such criteria as part of the rate certification to comply with § 438.4(c)(1)(iv) and (c)(2)(i).

*Comment:* Several commenters recommended that CMS add minimum transparency requirements on the use of rate ranges. A few commenters recommended that states be required to provide managed care plans with the CMS approved rate ranges and the data underlying those rate ranges prior to bidding, with sufficient time and opportunity for managed care plans' review and input. Some commenters recommended that states be required to provide a comment period for managed care plans to review the rate ranges. One commenter recommended that CMS engage with managed care plans through a technical expert panel to develop appropriate standards for rate ranges. Another commenter recommended that CMS hold a public comment period during which stakeholders can raise issues related to rate ranges before and during the bidding process each year. Commenters also recommended that CMS require a dispute resolution process when states and managed care plans do not agree on the rate ranges. One commenter recommended that CMS require states to conduct studies to ensure that the rate ranges are sufficient to facilitate patient access to care.

*Response:* In the proposed rule, we specifically requested public comment on whether additional conditions or limitations on the use of rate ranges would be appropriate to help mitigate the risks we identified. Based on the comments we received, we understand that commenters have significant concerns about the lack of transparency inherent in the use of rate ranges. The lack of transparency in the use of rate ranges has also been a significant concern for us; when we finalized the 2016 final rule, we explained that elimination of rate ranges would make the rate setting and the rate approval process more transparent (81 FR 27567). Further, we explained how the requirement to develop and certify as actuarially sound each individual rate paid per rate cell to each managed care plan with enough detail to understand the specific data, assumptions, and methodologies behind that rate would enhance the integrity of the Medicaid rate setting process (81 FR 27567). We agree with commenters that a significant level of transparency is necessary, particularly if states are using rate ranges for competitive bidding purposes. We believe that managed care plans and other stakeholders should have access to the necessary information and data to ensure that rates are actuarially sound, and we believe that such transparency will also help to ensure that competitive bids are appropriately based on actual experience and appropriately fund the program, and that the bids are actuarially sound. Providing managed care plans with approved rate ranges prior to bidding, with sufficient time and opportunity for managed care plans' review and input, along with the data underlying those rate ranges ensures that there is transparency in the setting and use of rate ranges.

Therefore, we are finalizing a requirement at § 438.4(c)(2)(iv) to require states, when developing and certifying a range of capitation rates per rate cell as actuarially sound, to post specified information. States are required under § 438.10(c)(3) to operate a public website that provides certain information. As finalized, § 438.4(c)(2)(iv) requires that states must post on their websites specified information prior to executing a managed care contract or contract amendment that includes or modifies a rate range. We are including this standard to ensure that managed care plans and stakeholders have access to the information with sufficient time and opportunity for review and input, and to ensure that the information is available to meaningfully inform plans' execution of a managed care contract with the state.

At § 438.4(c)(2)(iv)(A) through (C), we are finalizing the list of information that must be posted on the state's website required by § 438.10(c)(3): (A) The upper and lower bounds of each rate cell; (B) a description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, the specific assumptions used for the upper and lower bounds of each rate cell; and (C) a description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, the specific data and methodologies used for the upper and lower bounds of each rate cell. We believe that these requirements ensure that managed care plans and stakeholders have access to a minimum and standard level of information, for reasons outlined in the public comments. We believe that these requirements are also appropriate and necessary to ensure a minimum level of transparency when states utilize rate ranges under § 438.4(c). We also believe that this level of information will help to ensure that capitation rates are appropriately based on actual experience and are actuarially sound since plans will have access to such information prior to executing a managed care contract.

Regarding the public comments recommending public comment periods, technical expert panels, dispute resolution processes, and specific studies on access to care, we decline to adopt these specific recommendations. While we believe that states should seek broad stakeholder feedback, we do not believe that it is necessary to create new and expansive Federal requirements to accomplish this goal. In our experience, states are already working with many stakeholder groups, including their managed care plans, and we believe that states should continue to have discretion in how they convene stakeholder groups and obtain stakeholder feedback to inform Medicaid managed care payment policy. If states want to utilize public comment periods, technical expert panels, or conduct specific studies on access to care to help inform their rate setting, including rate ranges, states are welcome to utilize such approaches. We also understand that commenters are interested in Federal dispute resolution processes; however, we do not believe that is an appropriate role for CMS in the Medicaid program. When plans and/or other stakeholders do not agree on rates, we would refer those groups to the state Medicaid agencies to appropriately address specific rate setting concerns. Since state Medicaid agencies are the direct administrators of the Medicaid program in their respective states, we believe that this approach is more appropriate.

*Comment:* Some commenters expressed concern that requiring states to document the capitation rates at points within the rate range prior to the start of the rating period is too rigid and unrealistic. Commenters noted that the time and labor-intensive process of developing and certifying actuarially sound rates can, and often does, result in unexpected delays that push the

process into the rating period for which the rates are being developed. Commenters recommended extending flexibility to states around submission timing in a manner that maintains proper CMS oversight and is consistent with current CMS practice. One commenter further recommended that if the timing requirement is finalized, it should be delayed by 3 years.

*Response:* We acknowledge that our proposed requirement in § 438.4(c)(2)(i) that states document the capitation rates at points within the rate range prior to the start of the rating period means, as a practical matter, that states electing to use rate ranges must submit contracts and rate certifications to us prior to the start of the rating period. We also note that section 1903(m)(2)(A)(iii) of the Act and § 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 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 us. This requirement is necessary and appropriate to ensure that rate ranges are not used to shift costs onto the Federal Government and to protect fiscal and program integrity. As we noted in the 2018 proposed rule, one of the goals of the guardrails we proposed, and are finalizing here, for use of rate ranges is to prevent states from using rate ranges to make significant retroactive changes to the contracted rates at or after the end of the rating period; this goal is served by the requirement that rate ranges and the specific rates per cell be documented and provided to CMS prior to the beginning of the rating period. While we are not prohibiting outright all retroactive rate changes, the limits on when rates can be changed under § 438.4(c)(2) will necessarily limit the types of retroactive changes that raise the most issues. As we noted in the 2016 final rule and the 2018 proposed rule, we do not believe that retroactive 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 managed care plans or to some providers without adding corresponding new obligations under the contract. We do not believe that such changes are consistent with actuarially sound rates and represent cost-shifting to the Federal Government.

Because of these specific concerns, we decline to adopt commenters' recommendations about the timing guardrails included in § 438.4(c), including the recommendation that we delay this proposal by 3 years. We are finalizing the rule with the requirement in § 438.4(c)(2)(i) that states document the capitation rates (consistent with the requirements for developing and documenting capitation rates) at points within the rate range prior to the start of the rating period. However, since rate ranges were previously prohibited under the 2016 final rule (and before this final rule), we believe a transition period is appropriate to allow states that elect to utilize the rate range option at § 438.4(c) time to appropriately develop rate ranges and submit the rate certifications and contracts in advance of the start of a rating period. Therefore, we are delaying the effective date of this provision to rating periods starting on or after July 1, 2021.

*Comment:* A few commenters expressed concern about the proposal to prohibit states 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. One commenter expressed concern that the proposal is too restrictive on states' ability to make use of non-Federal share sources and that our proposal constrains states' authority under sections 1902(a)(2) and 1903(w) of the Act to draw upon a variety of state and local sources to fund the non-Federal share of medical assistance costs, including in the managed care context. One commenter stated that the prohibition on varying payments within a certified rate range based on the existence of IGT arrangements is an expansive Federal restriction on the longstanding ability of states to make use of a variety of non-Federal share sources to improve reimbursement to safety-net providers in managed care. Commenters recommended that the regulation be amended to allow using IGT agreements in conjunction with other criteria for paying managed care plans at different points within the rate range.

*Response:* We disagree that our proposal unnecessarily constrains states' authority under sections 1902(a)(2) and 1903(w) of the Act to draw upon a variety of state and local sources to fund the non-Federal share of medical assistance costs, as our proposal does not limit states from using permissible sources of the non-Federal share to fund costs under the managed care contract. Under § 438.4(c)(1)(v), the state is not permitted to use as a criterion for paying managed care plans at different points within the rate range either of the following: (1) The willingness or agreement of the managed care plans or their network providers to enter into, or adhere to, IGT agreements; or (2) the amount of funding the managed care plans or their network providers provide through IGT agreements. This prohibition is specific to states using amounts transferred pursuant to an IGT agreement to pay managed care plans at different points within the rate range under § 438.4(c) and is not a prohibition on states' authority to use permissible sources of the non-Federal share to fund costs under the managed care contract. Further, we explicitly clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a state elects to use rate ranges or not. Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations.

We are concerned that without these specific parameters in the regulation, states could try to use rate ranges to inappropriately use IGTs to draw down additional Federal dollars with no correlating benefit to the Federal Government or the Medicaid program. To address commenters' concerns related to increasing levels of provider reimbursement for safety-net providers, we note that states can use the authority for state directed payments under § 438.6(c) to direct specific payments to providers. However, we clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a state elects to direct payments under § 438.6(c). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations. These financing requirements similarly apply when a state elects to direct payments under § 438.6(c). We understand that safety-

net providers play a critical role in serving underserved populations in states, including Medicaid managed care enrollees. We also understand that safety-net providers are critical to maintaining network adequacy and adequate access to care in many communities, including rural areas of the state, and we do not believe our proposal unnecessarily constrains states' authority under sections 1902(a)(2) and 1903(w) of the Act to draw upon a variety of state and local sources to fund the non-Federal share of medical assistance costs, as our proposal does not limit states from using permissible sources of the non-Federal share to fund costs under the managed care contract.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.4(c) as proposed with the following modifications:

- At § 438.4(c)(2)(iii), we are finalizing authority for a state to make changes to the capitation rates within the permissible rate range of up to 1 percent of each certified rate within the rate range without the need for the state to submit a revised rate certification. Under final § 438.4(c)(2)(iii), a state may increase or decrease the capitation rate per rate cell within the rate range up to 1 percent of each certified rate during the rating period provided that any changes of the capitation rate within the permissible +/− 1 percent amount 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). Any modification to the capitation rates within the rate range greater than the permissible +/− 1 percent amount will require states to provide a revised rate certification for CMS approval and to meet the requirements listed in paragraphs (c)(2)(iii)(A) through (C).
- At § 438.4(c)(2)(iv), we are finalizing a requirement that states, when developing and certifying a range of capitation rates per rate cell as actuarially sound, must post the following specified information on their public websites: (A) The upper and lower bounds of each rate cell; (B) a description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, the specific assumptions used for the upper and lower bounds of each rate cell; and (C) a description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, the specific data and methodologies used for the upper and lower bounds of each rate cell.

States certifying a rate range must document the capitation rates payable to each managed care plan prior to the start of the rating period for the applicable MCO, PIHP or PAHP under § 438.4(c)(2)(i). As noted previously in this final rule, this requirement means that states electing to use a rate range would have to submit rate certifications to us *prior to the start of the rating period* and must comply with all other regulatory requirements including § 438.4, except § 438.4(b)(4) as specified. In order to publish additional guidance needed to implement this requirement, we are delaying the effective date of this provision until the first contract rating period beginning on or after July 1, 2021. States that elect to adopt rate ranges must comply with § 438.4(c) as amended effective July 1, 2021 for Medicaid managed care rating periods starting on or after July 1, 2021.

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 must necessarily be built into the relevant service components of the rate. 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) and the 2016 final rule (81 FR 27566) 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 which 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. Under the 2016 final rule, such practices, when not supported by the application of valid rate development standards, were not permissible. We further explained that the regulation did 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 stated 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. We explained in the 2018 proposed rule that 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 proposed to revise § 438.4(b)(1) and added a new paragraph § 438.4(d) to clearly specify our standards for actuarial soundness. We did not propose changes to the existing regulatory requirement 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 but proposed to revise the remainder of § 438.4(b)(1).

We proposed 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 proposed 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 a new proposed paragraph (d). Our proposal was 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. The proposed revisions to § 438.4(b)(1) used the phrase ''assumptions, methodologies, and factors'' to cover all methods and data used to develop the actuarially sound capitation rates.

In conjunction with our proposed revisions to § 438.4(b)(1), we also proposed a new paragraph (d) to provide specificity regarding the rate development practices that increase Federal costs and vary with the rate of FFP. We proposed in § 438.4(d) a regulatory requirement for 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. We explained that this evaluation would have to be conducted for the entire managed care program and include all managed care contracts for all covered populations. We proposed to require this evaluation across the entire managed care program and all managed care contracts for all covered populations to protect against state contracting practices in their Medicaid managed care programs that may cost-shift to the Federal Government. We noted that 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 our proposal.

We also proposed at § 438.4(d)(1) to list specific rate development practices that increase Federal costs and would be 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 proposed § 438.4(d)(1) to be explicit about certain rate development practices that increase Federal costs and vary with the rate of FFP. Our proposal was to explicitly prohibit the listed rate development practices under any and all scenarios; we also noted that the rate development practices under § 438.4(d)(1) were not intended to represent an exhaustive list of practices that increase Federal costs and vary with the rate of FFP, as we recognized that there may be additional capitation rate development practices that have the same effect and would also be prohibited under our proposed rule. In the 2018 proposed rule, we explained our goal of ensuring that the regulatory standards for actuarial soundness clearly prevent cost-shifting from the state to the Federal Government.

Finally, in § 438.4(d)(2), we proposed to specify that we 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 paragraph (d)(1), represent actual cost differences based on the characteristics and mix of the covered services or the covered populations. We noted that our proposal was consistent with proposed revisions to § 438.7(c)(3), to add regulatory text to specify that adjustments to capitation rates would be subject to the requirements at § 438.4(b)(1), and 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 our regulatory requirements. We requested public comments on our revisions to § 438.4(b)(1) and new § 438.4(d), including on whether these changes were sufficiently clear regarding the rate development practices that are prohibited in § 438.4(b)(1).

The following summarizes the public comments received on our proposal to revise § 438.4(b)(1) and add § 438.4(d) and our responses to those comments.

*Comment:* Many commenters supported the proposal to prohibit certain rate development practices and to require a state to provide written documentation that rate variations are based on actual cost differences. Many commenters also opposed this proposal and noted that there are often legitimate and actuarially sound reasons for varying pricing assumptions between rate cells that are independent of differing levels of FFP. Commenters stated that there are valid actuarial reasons where varying rating components would be supported by actuarial experience and data. Commenters recommended that were CMS to finalize the proposed amendments to § 438.4(b)(1) and (d), we do it in a way that would allow states to continue to have differentials in margins, payment levels, and MLR remittance thresholds for higher FFP contracts when those differences are justified in data and actuarial experience.

Commenters stated that valid rate development practices would be prohibited under the proposal, including using a lower margin assumption for populations with more stable costs, varying MLR thresholds based on actual administrative cost differences, adjusting the underwriting gain used, and using higher reimbursement for highly specialized providers or services or in areas where it is difficult to recruit providers. Commenters stated that the proposal is too prescriptive and duplicative of current requirements and recommended that CMS allow states to use assumptions that reflect different levels of risk so that rate cells are appropriately funded. Commenters stated that restricting actuarial variables from being determined by certain program characteristics will result in rates that are not actuarially sound. A few commenters also believed that the proposal could unintentionally result in new cost-shifting to the Federal Government, such as requiring higher margin assumptions for certain populations or requiring higher levels of provider reimbursement in specific

programs. One commenter requested that the regulation differentiate situations where rate development assumptions are intended to increase Federal costs from those where such an outcome is incidental and that CMS should only prohibit the former.

Several commenters recommended that instead of prohibiting certain rate development practices, CMS should instead require documentation and justification that variations related to margin, provider reimbursement, or MLR are actuarially valid. One commenter recommended that CMS only require such documentation in circumstances when we believe that the variation is related to FFP. One commenter expressed concern that the requirement to provide documentation duplicates existing policy. One commenter requested clarification on whether the written justification is part of the rate certification process and supporting documents, the managed care contract review, or is an additional requirement.

*Response:* Our goal in proposing these revisions to § 438.4(b)(1) and (d) was to clarify 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. Our proposal was also intended to eliminate any ambiguity in the regulations and to clearly specify 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 remain committed to these goals, and to our overarching goals of improving fiscal and program integrity within Medicaid managed care rate setting. However, we believe it is appropriate to finalize the proposal with changes to address the concerns of commenters that our proposal was too restrictive and overlooked scenarios by which our prohibited rate development practices under proposed § 438.4(d) may be actuarially appropriate in limited circumstances.

We reiterate that our overarching policy goal of prohibiting variation in capitation rates associated with the FFP for a particular population, which we explained in the 2015 proposed rule, 2016 final rule, and the 2018 proposed rule, has not changed and is not changing as part of this final rule. Specifically, 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 finalized, 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. Also in the 2016 final rule (81 FR 27566), we provided additional guidance and clarification in response to public comments 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; that discussion included an example where rate certifications 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 note that setting minimum provider payment requirements for covered populations under the managed care contract is permissible as long as such requirements apply broadly, are not selectively applied to only those covered populations eligible for higher percentages of FFP, are supported by valid rate development standards that represent actual cost differences in providing covered services to the covered populations, and do not shift costs to the Federal Government. In the 2016 final rule, we explained how § 438.4(b)(1), as adopted there, required 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). In the 2018 proposed rule (83 FR 57268), we clarified our policy that § 438.4(b)(1) was intended to prohibit variances in capitation rates based on the rate of FFP, even if such variances in capitation rates were the result of variances in provider reimbursement that pre-date the differences in FFP for different covered populations. We explained that our current proposal would eliminate ambiguity on this point and eliminate any potential loophole in § 438.4(b)(1) by more clearly specifying the scope of the prohibition. We reiterate these published statements here as part of this final rule and remind commenters that CMS has not changed our position on this topic. As finalized with the amendments in this final rule, § 438.4(b)(1) prevents states from cost-shifting onto the Federal Government and prohibits any variances in capitation rates associated with the rate of FFP for different covered populations. Further, we explicitly clarify here that § 438.4(b)(1) is not premised on nor require a state's intention to shift costs to the Federal Government; we believe that an intent to cost shift is immaterial compared to the actual effect of cost shifting.

Therefore, as part of this final rule, we are finalizing amendments to § 438.4(b)(1) to codify this policy clearly. Section 438.4(b)(1), as amended, continues to require that capitation rates be developed in accordance with the standards specified in § 438.5 and generally accepted actuarial principles and practices. We are also finalizing the proposed new and revised regulation text 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 and 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. We are not finalizing the text proposed in paragraph (d)(1) to address the concerns from commenters that proposed § 438.4(d)(1) was too restrictive and overlooked scenarios where the proposed list of prohibited rate development practices may be actuarially appropriate.

We will generally use the list of prohibited rate development practices in interpreting the prohibition finalized in paragraph (b)(1) and we will consider the state's documentation and justification in applying the prohibition. We originally proposed § 438.4(d)(1) in conjunction with our proposed revisions to § 438.4(b)(1) to provide specificity regarding the rate development practices that we believed increased Federal costs and varied with the rate of FFP; however, based on public comments, we agree with commenters that there could be legitimate and actuarially sound reasons for varying pricing assumptions between rate cells that are (and must be) independent of differing levels of FFP, and that there could be valid actuarial reasons for an actuary to vary rating components that would be supported by actuarial experience and data. Therefore, as part of this final rule, we are not finalizing the list of rate development practices that we proposed in § 438.4(d)(1). We agree with the commenters that we are unable to

predict every future scenario and there might be situations where one or more of the items on that list of rate development practices is actuarially appropriate. We remind commenters that it is still our view that these rate development practices generally increase Federal costs and vary with the rate of FFP. As such, in situations where one of those practices is not actuarially appropriate and where it increases Federal costs, we will apply § 438.4(b)(1) to deny rates that have been developed based on such practices. To fully evaluate scenarios where differences in the assumptions, methodologies, or factors used to develop capitation rates appear to vary with the rate of FFP, we believe that we will need additional information and explanation from the state. If states or actuaries intend to utilize these rate development practices, we need to be able to require written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations. We had originally proposed a requirement for submission of information and documentation for this purpose under § 438.4(d)(2). Since we are not finalizing § 438.4(d), we are finalizing this proposed standard as part of the new text in § 438.4(b)(1). To address commenters' request for clarity, we note that such written documentation and justification would be required as part of CMS' review of the rate certification.

We are finalizing the introduction in proposed paragraph (d) as part of the new text in § 438.4(b)(1) that the evaluation of compliance with § 438.4(b)(1) be on a program-wide basis, including all managed care contracts and covered populations. The final rule continues to prohibit any differences in the assumptions, methodologies, or factors used to develop capitation rates that vary with the rate of FFP associated with a covered population in a manner that increases Federal costs. To ensure that this requirement is met, the final rule 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 finalizing this requirement for an evaluation across the entire managed care program and all managed care contracts for all covered populations to protect against any potential loopholes where state managed care contracting practices may cost-shift to the Federal Government. Specifically, as noted in the proposed rule, this requirement 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 § 438.4(b)(1).

*Comment:* A few commenters noted that risk margin differences can apply between TANF, ABD, and LTSS populations and expressed concern that the proposal would require inappropriate comparisons between populations that have legitimate cost differences. Other commenters provided that the proposed regulation may have the unintended effect of causing actuaries to increase margins on disabled or LTSS populations to maintain justifiable higher margin assumptions for non-LTSS populations, which could increase Federal and state costs for the Medicaid program. Commenters stated that from an actuarial standpoint, the percentage risk margin may appropriately vary by population characteristics due to insurance risk differences. Commenters also explained that populations may have very different PMPM costs and, in particular, that expansion populations may require higher risk margins to account for unknown risks associated with a population not previously covered by the Medicaid program. Commenters recommended that CMS monitor for inappropriate rate setting practices or require additional documentation if we believe that cost-shifting is occurring, but these commenters recommended that CMS not finalize the proposal prohibiting specific rate development practices. One commenter stated that existing CMS authority enables us to enforce appropriate rate setting and that the proposed revisions to § 438.4(b)(1) and (d) are unnecessary.

*Response:* We understand the issues raised by commenters and reiterate that to the degree the pricing assumptions are based on actual cost differences in providing covered services to the covered populations under the contract, these varying pricing assumptions would be permissible under § 438.4(b)(1) as valid rate development factors. To the degree that varying pricing assumptions represent actual cost differences in providing covered services to the covered populations, we would find the assumptions to be consistent with valid rate development standards. If a population has documented higher costs, supported by actual experience, we would not find the pricing assumptions to be in violation of finalized § 438.4(b)(1), even if the higher cost population is also one with a higher FFP percentage. However, we emphasize that varying pricing assumptions must not include using a rate development practice that increases Federal costs and varies with the rate of FFP when not supported by valid rate development standards that represent actual cost differences in providing covered services to the covered populations. As finalized in this rule under § 438.4(b)(1), 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 unless those variances represent actual cost differences in providing covered services to the covered population.

Under the regulations governing rate setting at §§ 438.4 through 438.7, including as revised in this final rule, states and actuaries can vary the pricing assumptions based on actual cost differences in providing covered services to the covered populations under the contract, but the prohibition on shifting costs to the Federal Government through use of such variances remains. We also believe that there are other tools that can be used to mitigate the issues that were raised by commenters without inappropriately shifting costs onto the Federal Government and running afoul of § 438.4(b)(1). Although we are not finalizing a list of specifically prohibited rate development practices (as proposed at § 438.4(d)), it is still our view that these rate development practices generally increase Federal costs and vary with the rate of FFP, and as such, are generally prohibited under § 438.4(b)(1) as finalized in this rule. If states or actuaries intend to utilize these rate development practices (for example, higher margin assumptions for non-LTSS populations), we will require written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

*Comment:* Several commenters provided that our proposal to restrict capitation rate development practices that are based on minimum levels of

provider reimbursement would likely result in unintended consequences for states seeking to comply with the provisions under at least two scenarios: (1) States would be required to decrease provider reimbursement rates to the lowest common denominator of the lowest FFP contracts, which could diminish access to care for some Medicaid populations; or (2) States would be required to increase provider reimbursement rates to the highest common denominator of the higher FFP contracts for the lowest FFP contracts, which could increase Federal and state Medicaid expenditures. Commenters also provided that many states have contracts for a specific population, such as a population at the average FMAP rate, with state statute setting the rate structure at the state's FFS rates; in these circumstances, this proposal would make the state's FFS rate structure the standard by which other managed care contracts would be evaluated, which may not be actuarially appropriate. A few commenters also expressed concern that fee schedule variation is limited under the proposal and noted that there is often a need to increase the fee schedules for certain provider types to meet network adequacy and encourage provider participation. These commenters expressed concern that such limitations on provider fee schedules may unfairly burden managed care plans. Commenters urged CMS not to finalize this provision as part of the proposal.

*Response:* We understand the issues raised by commenters and reiterate that to the degree the pricing assumptions are based on actual cost differences in providing covered services to the covered populations under the contract, these varying pricing assumptions would be permissible under § 438.4(b)(1) as valid rate development factors. To the degree that varying pricing assumptions represent actual cost differences in providing covered services to the covered populations, we would find the assumptions to be consistent with valid rate development standards. If a population has documented higher costs, supported by actual experience, we would not find the pricing assumptions to be in violation of finalized § 438.4(b)(1). However, in our experience in reviewing and approving capitation rates, we have seen rate certifications that set minimum provider payment requirements for the managed care plans for covered populations eligible for higher percentages of FFP. We note here that such practices, when they shift costs to the Federal Government and when not supported by the application of valid rate development standards, are not permissible. Any differences among capitation rates according to covered populations must not shift costs to the Federal Government and must be based on valid rate development standards rather than network provider reimbursement requirements that apply to covered populations eligible for higher percentages of FFP even in cases where provider reimbursement requirements for such populations are mandated by state statute. Furthermore, we reiterate that setting minimum provider payment requirements for covered populations under the managed care contract is not permissible if such requirements shift costs to the Federal Government, even if such differential provider payments are authorized under § 438.6(c). For example, we have seen one state use § 438.4(b)(1) to vary provider reimbursement for covered populations eligible for higher percentages of FFP, as mandated by state law and not on valid rate development standards, and this state has stated that when such arrangements pre-date differences in FFP, the regulation should not be read to prohibit the resulting capitation rates. Our proposal and the amendment to § 438.4(b)(1) we are finalizing here eliminates that particular argument as a potential loophole. Regardless of when the differential rates were started, § 438.4(b)(1) as amended in this rule requires that differential rates be based on valid rate development standards and that they not shift costs to the Federal Government; such non-compliant differential rates must be eliminated. As revised, § 438.4(b)(1) prevents states from cost-shifting onto the Federal Government and prohibits any variances in capitation rates based on the rate of FFP for different covered populations, regardless of whether arrangements that vary provider reimbursement are mandated by state statute and/or pre-date the differences in FFP for different covered populations. We note that this state also stated that the different rates were intended to better align Medicaid rates with commercial rates but did not demonstrate that differential provider payments for one covered population was a valid rate development factor. As noted above in a previous response to public comments in this section, setting minimum provider payment requirements for covered populations under the managed care contract is permissible as long as such requirements apply broadly, are not selectively applied to covered populations eligible for higher percentages of FFP, are supported by valid rate development standards that represent actual cost differences in providing covered services to the covered populations and do not shift costs to the Federal Government. We note that varying pricing assumptions based on provider payment requirements mandated by state legislation that shift costs to the Federal Government do not constitute actual cost differences in providing covered services.

To the extent that states need to enhance reimbursement for specific providers or specific services, we believe that states can utilize other means to accomplish that goal, such as enhancing fees for covered services across all of their programs rather than varying fee schedules only for higher FMAP populations. We also understand that some states may have legislatively mandated fee schedules; however, as long as such states comply with all applicable regulatory requirements and are not including additional costs or mandating higher levels of reimbursement for higher FMAP populations, states can comply with mandated fee schedules and this regulation without a conflict. Mandated fee schedules that comply with all applicable regulatory requirements and do not result in higher payment for higher FMAP populations may be used as the basis for rate setting for the managed care contracts. We emphasize that varying pricing assumptions must not include using a rate development practice that increases Federal costs and varies with the rate of FFP when not supported by valid rate development standards that represent actual cost differences in providing covered services to the covered populations regardless of whether such differences are mandated by state legislation. As finalized in this rule under § 438.4(b)(1), 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.

Although we are not finalizing a list of prohibited rate development practices (as proposed at § 438.4(d)), it is still our view that these rate development practices generally increase Federal costs and vary with the rate of FFP, and as such, are prohibited in most cases under § 438.4(b)(1) as finalized in this rule. If states or actuaries intend to utilize these rate development practices, we will require written documentation and justification that any differences in the assumptions, methodologies, or

factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

*Comment:* A few commenters expressed concern with the proposal (at proposed § 438.4(d)(1)(iii)) that states may not use a lower MLR remittance threshold for expansion populations than the MLR remittance threshold used for TANF, ABD, and LTSS contracts. Commenters stated that it is impractical and not actuarially sound to use an average MLR remittance threshold without acknowledging the actual costs of each managed care program and covered population. One commenter noted that remittance thresholds vary as a function of the administrative load of a product and is unrelated to the FFP for the program. Some commenters expressed concern that the proposal will force states to reduce MLR remittance thresholds for all managed care contracts, which will increase Federal Medicaid costs. Some commenters also stated that there are valid actuarial reasons to establish a higher MLR remittance threshold for LTSS populations, and that states should not be prohibited from designing such reasonable approaches based on actuarially sound practices. Commenters provided that the administrative costs for an LTSS program as a percent of revenue is lower than an expansion program (managed care plan covering the Medicaid benefits for the expansion population). As such, if a minimum MLR threshold is developed with an equal likelihood of being triggered by each program, the LTSS MLR threshold would need to be higher for the LTSS program.

*Response:* We agree with commenters and acknowledge that our proposed rule failed to account for varying MLR thresholds for high-cost populations, such as LTSS populations. We agree that if a minimum MLR threshold is developed with an equal likelihood of being triggered, the MLR may need to be higher for LTSS programs because the administrative costs, as a percent of revenue, may be lower. Under § 438.4(b)(1) as finalized here, we will require states to provide valid reasons for varying the MLR threshold component in contracts where the FFP percentages are different. For approval of rates that are developed using such different MLR thresholds, a state could demonstrate that it has used factors to develop rates based on valid rate development standards and not on differences that increase Federal costs and vary with the rate of FFP, and it has applied the same methodologies for developing the administrative costs within the capitation rate, and therefore, the corresponding MLR remittance threshold is based on those same underlying methodologies. In such a situation, we would not find this approach to be a violation of § 438.4(b)(1) despite the different MLR thresholds used in setting the rates for high and low FMAP populations.

We emphasize that varying pricing assumptions must not include using a rate development practice that increases Federal costs and varies with the rate of FFP when not supported by valid rate development standards that represent actual cost differences in providing covered services to the covered populations. We note that varying pricing assumptions based only on provider payment requirements mandated by state legislation do not constitute actual cost differences in providing covered services. As finalized in this rule under § 438.4(b)(1), 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. Although we are not finalizing a list of prohibited rate development practices (as proposed at § 438.4(d)(1)), it is still our view that these rate development practices generally increase Federal costs and vary with the rate of FFP, and as such, are prohibited in most cases under § 438.4(b)(1) as finalized in this rule. If states or actuaries intend to utilize these rate development practices, we will require written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

*Comment:* One commenter expressed concern that the proposal does not account for recent statutory changes made by section 4001 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271, enacted October 24, 2018), which allows states to retain a larger share of the remittances collected from managed care plans by remitting funds back to the Federal Government for expansion enrollees at the state's standard rate of FFP, provided that certain statutory conditions are met.

*Response:* Section 4001 of the SUPPORT for Patients and Communities Act, enacted October 24, 2018, amended section 1903(m) of the Act to add a new paragraph (m)(9). Section 1903(m)(9) provides a time-limited opportunity (after fiscal year 2020 but before fiscal year 2024) for states that collect an MLR remittance from their Medicaid managed care plans for the eligibility group described in section 1902(a)(10(A)(i)(VIII) to apply the state's regular Federal medical assistance percentage (FMAP) match rate (calculated pursuant to section 1905(b) of the Act) to determine the Federal share of that remittance instead of the higher FMAP match rate specified under 1905(y) for use in connection with the Medicaid expansion group. Since this statutory provision is limited to requirements on the amounts paid to the Federal Government on certain MLR remittances within the specified parameters of the statute, and not related to varying the remittance thresholds for specific populations or contracts, section 4001 of the SUPPORT for Patients and Communities Act is outside the scope of this final rule. Specifically, we clarify for this commenter that this final rule does not implicate the requirements under section 4001 of the SUPPORT for Patients and Communities Act regarding the amounts paid to the Federal Government on certain MLR remittances.

*Comment:* A few commenters requested clarification regarding whether the proposal would apply to CHIP programs.

*Response:* We clarify here that our proposal under § 438.4(d) was never intended to and our amendment of § 438.4(b)(1) does not apply to CHIP programs. The CHIP requirements for rate development are found in § 457.1203, which does not incorporate or reference the Medicaid managed care regulations on actuarial soundness and rate setting.

*Comment:* A few commenters expressed concern that CMS refers to a list of prohibited rate development practices that are ''including but not limited to'' certain practices. These commenters expressed concern that this non-exhaustive list requires additional clarification and recommended that specific rate development practices be identified through notice and comment rulemaking.

*Response:* The list of specific rate development practices that we proposed to prohibit outright in proposed § 438.4(d) is not being finalized. However, should such practices be used and result in rates that violate the standard we proposed and are finalizing in the amendment of § 438.4(b)(1), the

resulting rates will not be approved. We confirm for commenters that should we find it necessary to prohibit specific rate development practices in the future, we would do so through notice and comment rulemaking. Here, however, we are limiting how rates must be developed to ensure that differences in the assumptions, methodologies, and factors used to develop rates are based on valid rate development factors that represent actual cost differences and do not vary with the rate of FFP in a manner that increases Federal costs.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing our proposed amendments to § 438.4(b)(1) with modifications and are not finalizing the proposed addition of § 438.4(d); specifically, we are finalizing amendments to § 438.4(b)(1) as follows:

- At § 438.4(b)(1), we are finalizing the proposal to add regulation text to provide 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 and that 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.
- At § 438.4(b)(1), we are finalizing that the evaluation of compliance with § 438.4(b)(1) be on a program-wide basis, including all managed care contracts and covered populations. The final rule will require 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. This provision was proposed as part of the introduction text to paragraph (d).
- At § 438.4(b)(1), we are also finalizing the authority for CMS to 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 represent actual cost differences based on the characteristics and mix of the covered services or the covered populations. This provision was proposed as part of paragraph (d)(2).
- At § 438.4(b)(1), we are not finalizing any references to paragraph (d).

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 paragraph (c)(2) regarding base data. 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 will 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 provided 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 when a state's base data must be in compliance. To remove this ambiguity, we proposed to replace the word ''from'' at § 438.5(c)(3)(ii) with the phrase ''after the last day of.'' The preamble of the 2016 final rule used the term ''discovered'', while the regulatory text used the term ''identified.'' We proposed to retain the term ''identified'' in the regulatory text since we believed this term to be more appropriate in this context. We explained that our 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 was 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 (CY) 2018 did 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 CY 2021 would need to use base data that is compliant with § 438.5(c)(2).

The following summarizes the public comments received on our proposal to revise § 438.5(c)(3)(ii) and our responses to those comments.

*Comment:* A few commenters supported the proposed language change. One of these commenters supported the proposal to use the term ''identified'' in § 438.5(c)(3)(ii) instead of the word ''discover,'' which was used in the preamble of the 2016 final rule to describe the regulation. One of these commenters also urged CMS to ensure that the base data used by a state submitting a corrective action be improved to meet the standards in § 438.5 and recommended that CMS enforce these requirements. One of these commenters also requested that the base data be required to include all available and emerging experience, such as pharmacy utilization experience.

*Response:* We agree with commenters that the term ''identified'' in the regulatory text is appropriate, and therefore, we used it in the proposed rule and this final rule. We also agree with commenters that states and actuaries should be utilizing base data that is compliant with the standards and requirements set forth in the 2016 final rule, and we assure commenters that CMS is enforcing those rules. While we also agree with commenters that our base data standards should include the use of appropriate available and emerging experience, we did not propose any changes to the standards governing base data and are not finalizing any changes to those standards in § 438.5(c)(1) and (2). We remind commenters that the general rule for base data at § 438.5(c)(2) already requires states and their actuaries to use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data must also be in accordance with actuarial standards for data quality.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendment to § 438.5(c)(3)(ii) as proposed.

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 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. The 2015 proposed rule inadvertently omitted the requirement that risk-sharing mechanisms be computed on an actuarially sound basis but we finalized § 438.6(b)(1) with that standard included in the 2016 final rule (81 FR 27578). 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.

We explained in the 2018 proposed rule how we expect states to identify and apply risk-sharing requirements prior to the start of the rating period because they are intended to address the uncertainty inherent in setting capitation rates prospectively. Because we believed that the 2016 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 adoption and use of risk-sharing mechanisms. 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, or revise a medical loss ratio (MLR) requirement, after the claims experience for a rating period became known to the state and the managed care plan. As noted in the 2018 proposed rule, 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.

We also acknowledged in the 2018 proposed rule how, 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. We explained that when this occurs, states should comply with § 438.7(c)(2), which 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 proposed 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. We also proposed 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.

In the proposed rule, we acknowledged 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 meant, as a practical matter, that states electing to use risk-sharing mechanisms would have to submit contracts and rate certifications to us prior to the start of the rating period. We noted 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 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 us. We have, 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, section 2087.

The following summarizes the public comments received on our proposal to amend § 438.6(b)(1) and our responses to those comments.

*Comment:* Several commenters supported the proposed amendment that risk-sharing mechanisms be documented in a state's contract and rate certification documents prior to the start of the rating period. Commenters noted that doing so would improve transparency and facilitate CMS' oversight of these risk-sharing mechanisms. One commenter noted the proposed amendment to § 438.6(b)(1) would promote a more reliable and predictable method for risk-adjusting payments to managed care plans. Commenters also stated that risk-sharing mechanisms should be documented in the contract prior to the start of the rating period to provide certainty to both states and their contracted managed care plans.

*Response:* We appreciate commenters' support and agree that risk-sharing mechanisms should be documented in a state's contract(s) and rate certification(s) prior to the start of the rating period for all of the reasons commenters provided. As risk-sharing mechanisms are intended to address the uncertainty inherent in setting capitation rates prospectively, we believe that states should develop risk-sharing requirements prior to the start of the rating period and that risk-sharing mechanisms should be developed in accordance with actuarially sound principles and practices.

*Comment:* Several commenters stated that retroactive adjustments should not be limited to adjustments to rates but should also apply to risk-sharing mechanisms. These commenters stated that states transitioning new populations or services into managed

care programs, such as LTSS, are more likely to need retroactive adjustments to payment structures due to the unknown risks in covering new populations in managed care for the first time.

*Response:* We disagree with commenters on permitting retroactive adjustments to risk-sharing mechanisms. We do not believe that it is appropriate to modify risk-sharing mechanisms between states and plans after the claims experience for a rating period is known, because such retroactive changes undercut the need for states and plans to address uncertainty prospectively. We are not foreclosing retroactive adjustments to rates when appropriate. As provided by § 438.7(c)(2), if the state determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions, and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS. These types of changes are distinct from application of a previously set risk-sharing mechanism that is retrospective. While CMS will not permit a retroactive change to the risk-sharing mechanism under this final rule, the state can pursue a retroactive change to the capitation rates if the requirements under § 438.7(c)(2) are satisfied.

*Comment:* Commenters requested that CMS clarify the difference between risk adjustment and risk mitigation. One commenter requested that CMS create definitions for risk adjustment and risk mitigation. Commenters also requested that CMS clarify that the proposed change in this section does not apply to risk adjustments as permitted in § 438.7(b)(5). Another commenter noted that the new language explicitly prohibiting retroactively adding or modifying risk-sharing mechanisms may be seen as not allowing retroactive rate adjustments and requested that CMS add language to this section that clearly states retroactive rate adjustments under § 438.7(c)(2) are still permitted.

*Response:* First, we clarify here that risk-sharing mechanisms, which can include a risk mitigation strategy, are a distinct and separate concept from risk adjustment. We note that ''risk mitigation'' is not a phrase used in part 438. Risk adjustment is defined at § 438.5(a) as a methodology to account for the health status of enrollees via relative risk factors when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the state. The requirements regarding risk adjustment are found at §§ 438.5(g) and 438.7(b)(5). Risk-sharing mechanisms, on the other hand, are any means, mechanism, or arrangement that has the effect of sharing risk between the MCO, PIHP, or PAHP, and the state. A risk mitigation strategy is a means to protect the state, or the managed care plan, against the risk that assumptions (not only based on health status of enrollees) underlying the rate development will not match later actual experience. In other words, ''risk-sharing'' is about the aggregate actual experience, while ''risk adjustment'' is about paying based on the health status of enrollees at the individual level and how health status is assumed to result in higher costs.

Second, we explain how the regulations that address these concepts interact or do not interact. We confirm here that § 438.6(b)(1), including the proposed change that we are finalizing here, does not regulate and has no impact on risk adjustment as addressed in §§ 438.5(g) and 438.7(b)(5). We also confirm that our proposed change to § 438.6(b)(1) does not impact states' ability to revise or adjust capitation rates retroactively under § 438.7(c)(2) when unexpected events or programmatic changes occur during a rating period that necessitate a retroactive change or adjustment to the previously paid rates. Section 438.7(c)(2) clarifies that the retroactive adjustment (or change) to capitation rates 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. Changes to a risk-sharing mechanism are not changes to the capitation rates themselves; they are changes to an arrangement or mechanism that results in a separate payment from a state to a managed care plan or a remittance to a state from a managed care plan.

Section 438.6(b)(1) applies to any and all mechanisms or arrangements that have the effect of sharing risk between the MCO, PIHP, or PAHP, and the state on an aggregate level. We believe that this concept includes risk mitigation strategies and other arrangements that protect the state or the MCO, PIHP, or PAHP against the risk that the assumptions used in the initial development of capitation rates are different from actual experience. Common risk mitigation strategies include a medical loss ratio (MLR) with a remittance, a risk corridor, or a risk-based reconciliation payment. Under § 438.6(b)(1), we included a non-exhaustive list of risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits. We also defined risk corridor in § 438.6(a) as a risk-sharing mechanism in which states and MCOs, PIHPs, or PAHPs may share in profits and losses under the contract outside of a predetermined threshold amount. Because the regulations in part 438 do not use the term ''risk mitigation strategy,'' we do not believe it is necessary to define the term or add it to the regulations. Section 438.6(b)(1) is clear that all risk-sharing mechanisms are subject to its scope.

*Comment:* One commenter requested CMS add risk pools to the list of risk-sharing arrangements in § 438.6(b)(1) to clarify that such arrangements are subject to actuarial soundness requirements and must be documented in the managed care contract prospectively.

*Response:* If a risk pool is used as a mechanism to share risk between the MCO, PIHP, or PAHP, and the state, then we agree with commenters that a risk pool is subject to the requirements in § 438.6(b)(1). We reiterate that any mechanism, strategy, or arrangement that protects the state or the MCO, PIHP, or PAHP against the risk that the assumptions used in the initial development of capitation rates are different from actual experience is subject to the requirements in § 438.6(b)(1). We decline to add a specific mention of ''risk pools'' into the regulations because we believe that § 438.6(b)(1) adequately indicates that it applies to all risk-sharing mechanisms and only lists certain mechanisms as examples.

*Comment:* One commenter requested clarification from CMS regarding whether restrictions on profits are to be considered a risk-sharing mechanism, including minimum MLR requirements and contractual profit caps. Another commenter requested that the proposed risk-sharing mechanism be open to modifications while CMS is reviewing the rates, so that if CMS does not accept the initially proposed risk-sharing mechanism, then the state can modify and propose to CMS an alternative, acceptable strategy.

*Response:* We confirm that a minimum MLR requirement with a remittance would be considered a risk-sharing mechanism and subject to the requirements in § 438.6(b)(1). We also

confirm that additional restrictions on profits or contractual profit caps would also be considered risk-sharing mechanisms under this regulation. To the degree that arrangements (like the examples provided by the commenter or other arrangements) function to explicitly share risk between states and managed care plans, such arrangements would be risk-sharing mechanisms and subject to the requirements in § 438.6(b)(1). Regarding possible modifications to a risk-sharing mechanism while CMS is reviewing the rates, we confirm for commenters that such modifications would only be possible prior to the start of the rating period to comply with the final regulation text. The requirements in § 438.6(b)(1) to document the risk-sharing mechanism in the contract and rate certification documents prior to the start of the rating period, as well the prohibition on adding or modifying risk-sharing mechanisms after the start of the rating period, would apply to states, plans, and CMS. If states are seeking CMS review and approval prior to the start of the rating period, CMS and states can work toward modifications that would ensure that arrangements are reasonable, appropriate, and compliant with Federal requirements, as long as such modifications are in place and documented in the contract and rate certification documents for the rating period prior to the start of the rating period and CMS' approval of such documents.

*Comment:* Several commenters opposed the proposed change and requested CMS allow states flexibility to retroactively adjust risk-sharing mechanisms. Commenters expressed concern that the proposed section may restrict states from employing important tools for paying plans in a volatile health care environment. Commenters noted that the addition of new technologies, drugs, and populations to the Medicaid managed care program often require retroactive adjustment of plan payments. Commenters further noted that rates may be adjusted, but states have also effectively employed risk-sharing mechanisms to ensure that plans receive appropriate payment. Commenters stated that continuing to allow retroactive addition or modification of risk-sharing mechanisms will allow states to pay plans adequately when substantial coverage changes occur mid-year. A few commenters noted that states often make adjustments to rates to address disease outbreaks, launches of high-cost prescription drugs, other unforeseen circumstances that increase benefit costs, and refinements to risk adjustment methodologies that improve rate accuracy. One commenter requested CMS allow for appropriate flexibility for states to make applicable retroactive modifications to risk-sharing mechanisms through the development of an exception process as an option to account for either lack of performance or unforeseen events that detrimentally impact performance or trend.

*Response:* We disagree with commenters about permitting retroactive adjustments to risk-sharing mechanisms, and we also disagree with creating an exception process to permit such retroactive adjustments to risk-sharing arrangements. We do not believe that it is appropriate to modify risk-sharing mechanisms between states and plans after the claims experience for a rating period is known, as we believe that this approach undercuts the need for states and plans to address uncertainty prospectively using risk-sharing mechanisms. As discussed in the proposed rule and in our responses here, we have specific concerns that permitting modification of risk-sharing mechanisms after claims experience for a rating period is known could be used inappropriately to shift costs onto the Federal Government.

We note that we are not foreclosing retroactive rate adjustments (that is, changes to the rates themselves as opposed to changes to the risk-sharing mechanism) when appropriate, such as when substantial coverage changes occur mid-year, adjustments are necessary to address disease outbreaks, launches of high-cost prescription drugs, or other unforeseen circumstances that increase benefit costs (some of the examples provided by commenters). We agree that it would be appropriate to implement retroactive rate adjustments to accommodate unexpected programmatic changes; however, modifying existing risk-sharing mechanisms, or adding new risk-sharing mechanisms, after claims experience for a rating period is known is not the appropriate tool for states to use to address such concerns. States should adjust rates using the appropriate requirements under § 438.7(c)(2) to address unexpected events that necessitate a retroactive adjustment (that is, change) to previously paid rates. As provided by § 438.7(c)(2), if the state determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions, and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.6(b)(1) as proposed.

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. We explicitly clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a state elects to direct payments under § 438.6(c). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations.

Due to the frequency and similarities of these types of directed payment arrangements, we proposed to specifically address them in an amendment to § 438.6. At § 438.6(a), we proposed 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 Medicaid plan. We also proposed 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. We explicitly noted how, 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 explained in the proposed rule 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 proposed to include a statement to this effect under proposed paragraph (c)(1)(iii)(A). We noted in the proposed rule our view that a rate described in the approved rate methodology section of the state plan reflects only the per unit price of particular services. Supplemental payments are not calculated or paid based on the number of services rendered on behalf of an individual beneficiary, and therefore, would be separate and distinct from state plan approved rates under our proposal. We also proposed 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 proposed to redesignate current paragraph (c)(1)(iii)(A) as paragraph (c)(1)(iii)(B) and to revise the regulation to distinguish a minimum fee schedule for network providers that provide a particular service using rates other than state plan approved rates from those using state plan approved rates. To accommodate our proposal, we also proposed to redesignate current paragraphs (c)(1)(iii)(B) and (C) as paragraphs (c)(1)(iii)(C) and (D), respectively.

We also noted that 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. 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 proposed to add a new § 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 explained how authorizing these additional types of payment models for states to implement would eliminate the 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.

Along with the proposed changes in § 438.6(c)(1)(iii)(A), we also proposed 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 provider reimbursement 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 will have already justified the rate methodology associated with particular services in the Medicaid state plan (or a state plan amendment) to receive approval by us 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 proposed to eliminate the prior approval requirement for payment arrangements that are based on state plan approved rates. To do so, we proposed to redesignate existing paragraph (c)(2)(ii) as (c)(2)(iii), to add a new paragraph (c)(2)(ii), and to redesignate paragraphs (c)(2)(i)(A) through (F) as paragraphs (c)(2)(ii)(A) through (F), respectively. We also proposed 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 proposed to delete the remaining regulatory text from current paragraph (c)(2)(i).

In proposed new paragraph (c)(2)(ii), we specified prior approval requirements for payment arrangements under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(B) through (E). We proposed amended paragraph (c)(2)(ii) as explicitly providing that payment arrangements under paragraph (c)(1)(iii)(A) do not require prior approval from us; we proposed to retain the requirement that such payment arrangements meet the criteria in paragraphs (c)(2)(ii)(A) through (F). We justified this proposed revision as a means to 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 paragraphs (c)(2)(ii)(A) through (F), we proposed to keep in place the existing requirements for our approval to be granted.

In the 2016 final rule, we specified at § 438.6(c)(2)(ii)(C) that contract arrangements which direct expenditures made by the MCO, PIHP, or PAHP under paragraph (c)(1)(i) or (ii) for delivery system or provider payment initiatives may not direct the amount or frequency of expenditures by managed care plans. At that time, 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. These innovative payment models are based on the state directing 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. Therefore, we proposed 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 paragraph (c)(1)(i) or (ii). As a conforming change, we proposed to redesignate existing § 438.6(c)(2)(ii)(D) as § 438.6(c)(2)(iii)(C).

Under existing § 438.6(c)(2)(i)(F) (which we proposed to redesignate as § 438.6(c)(2)(ii)(F)), a contract arrangement directing a managed care plan's expenditure may not be renewed automatically. While § 438.6(c)(2)(i)(F) does not permit an 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 will vary or change over the term of the arrangement.

In the 2018 proposed rule, we stated 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. We noted that 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. We reiterated our position from the CIB that we interpret the regulatory requirements under § 438.6(c) to permit multi-year payment arrangements when certain criteria were met. The CIB identified the criteria for multi-year approvals of certain directed payment arrangements, and we proposed to codify those criteria in a new § 438.6(c)(3).

Specifically, we proposed 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 our 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 noted that in addition to codifying criteria for the approval of multi-year payment arrangements, the proposed new paragraph (c)(3)(i) would address any potential ambiguity on the narrow issue of the permissibility of states to enter into multi-year payment arrangements with managed care plans.

Finally, in alignment with our guidance in the November CIB, we proposed to specify at paragraph (c)(3)(ii) that the approval of a payment arrangement under paragraph (c)(1)(iii) would be for one rating period only. We explained that while we understood 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 believed that more traditional payment arrangements and fee schedules permitted under paragraph (c)(1)(iii) should continue to be reviewed and evaluated on an annual basis by both states and us. We explained how it was important to continue ensuring that such payment arrangements under paragraph (c)(1)(iii) are consistent with states' and our goals and objectives for directed payments under Medicaid managed care contracts.

We proposed several revisions in § 438.6(c) including specifying different types of potential directed payments such as arrangements based on a Medicare equivalent rate, a commercial rate, a cost-based rate, or other market-based rate (§ 438.6(c)(1)(iii)(E)) and permitting states to direct the amount or frequency of expenditures by deleting existing § 438.6(c)(2)(ii)(C). Some commenters were supportive, some were not, and others raised related policy issues with state directed payments that we believe warrant additional consideration. For example, several commenters stated that these proposals increased flexibility for states to design directed payment arrangements which would help drive innovation and enable states to better optimize their programs to accommodate their own unique policy and demographic conditions. Other commenters noted that Medicare, commercial, and market-based rates would, in some cases, reduce provider reimbursement rates and jeopardize quality and access to Medicaid services. A few commenters were concerned about the ability of managed care plans to manage risk as it relates to state-directed payment arrangements. One commenter stated that the regulatory requirements under § 438.6(c) were too rigid for managed care plans and can degrade the utility and effectiveness of value-based arrangements.

Based on the diverse range of public comments and our continued experience with state directed payments since the proposed rule was published in November 2018, we have decided not to finalize the revisions proposed at § 438.6(c)(1)(iii)(E) and (c)(2)(ii)(C) in this final rule. However, we will consider addressing these and other state directed payment policies in future rulemaking. We thank commenters for their valuable input and will use it to inform our future rulemaking.

The following summarizes the public comments received on our proposal to amend § 438.6(a) and (c) and our responses to those comments.

*Comment:* Several commenters supported the changes to § 438.6(a), including the addition of a definition for state plan approved rates and the additional clarification in § 438.6(c)(1)(iii)(A) that supplemental payments are not, and do not constitute, state plan rates. Several commenters disagreed with proposed § 438.6(c)(1)(iii)(A) and recommended that CMS revise the proposed definitions of state plan approved rates and supplemental payments to acknowledge the legitimacy and importance of supplemental payments in the Medicaid program. One commenter recommended that we define or explain our meaning for ''per unit''. One commenter requested that CMS confirm that state plan approved rates also include state plan approved payments that are based on a provider's actual or projected costs. One commenter requested that CMS clarify whether the proposed definition of supplemental payments in § 438.6(a) included disproportionate share hospital (DSH) or graduate medical education (GME) payments.

*Response:* We do not agree with commenters that further revisions are needed to address the role of supplemental payments in the Medicaid program; we believe that our policies

finalized in this final rule, specifically to define the term ''supplemental payments'' for purposes of part 438, including § 438.6, and to adopt (in § 438.6(d)(6)) a period for pass-through payments to be used for states transitioning new services or new populations to Medicaid managed care, demonstrate that CMS understands the role of supplemental payments in the Medicaid program. We note that our proposed definition of ''supplemental payments'' may not have been as clear as it could be, so we are finalizing the definition by adding ''or demonstration'' to recognize 1115 demonstration authority as well as waiver authority.

Regarding the definition of ''per unit,'' we have reconsidered the use of that term and acknowledge that this definition may not have been clear. To correct this, we have revised the definition to remove ''per unit'' and instead, reference amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan. Moreover, we explicitly clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a state elects to direct payments under § 438.6(c). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations.

We agree with commenters that clarification is needed regarding whether ''supplemental payments,'' as the term is defined and used in § 438.6, includes DSH or GME payments. It was never our intent to include DSH or GME payments in our definition of supplemental payments for the purposes of Medicaid managed care under part 438. Therefore, we are finalizing the definition of supplemental payments at § 438.6(a) with an additional sentence stating that DSH and GME payments are not, and do not constitute, supplemental payments. We note that DSH and GME payments would not meet the definition, finalized at § 438.6(a), of state plan approved rates because such payments are not calculated as amounts for specific covered services identifiable as having been provided to an individual beneficiary. We are also finalizing a technical change to the definition of supplemental payments by revising the phrase ''amounts calculated through an approved state plan rate methodology'' to ''state plan approved rates.'' This revision eliminates ambiguity and uses terminology that is being finalized in this final rule.

We also believe that the definition of state plan approved rates should include the clarification that was proposed in § 438.6(c)(1)(iii)(A) that supplemental payments are not, and do not constitute, state plan approved rates as they are not directly attributable to a covered service furnished to an individual beneficiary. We are finalizing the definition of the term ''state plan approved rates'' in § 438.6(a) with this clarifying sentence included in the definition instead of at paragraph (c)(1)(iii)(A).

*Comment:* A few commenters requested clarification on the difference between a state plan approved rate and a supplemental payment. Commenters noted that in some states there are situations where there is a per unit price set at an amount higher than the Medicaid fee schedule for a class of providers, and this higher price has been approved in the state plan. The difference between the higher rate and the Medicaid fee schedule amount is paid retrospectively, but the total payment is still based on the number of units incurred for the applicable services. Commenters questioned whether rates in this situation would be a state plan approved rate or a supplemental payment.

*Response:* As finalized in this rule, state plan approved rates means amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary described under the CMS approved rate methodologies in the Medicaid state plan. We confirm for commenters that state plan approved rates can include payments that are higher than the traditional Medicaid FFS fee schedule for a specific class of providers when the payment methodology has been approved in the state plan and is for specific covered services identifiable as having been provided to an individual beneficiary. We have also revised the definition to note that supplemental payments are not, and do not constitute, state plan approved rates. Supplemental payments approved under a Medicaid state plan are often made to providers in a lump sum and often cannot be linked to specific covered services provided to an individual Medicaid beneficiary; therefore, supplemental payments are not directly attributable to a covered service furnished to an individual beneficiary. We understand that some payment methodologies are calculated retrospectively for specific reasons, such as when payments are made based on a provider's actual costs. We emphasize that payment amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary must be directly tied to the provision of covered services to Medicaid beneficiaries, which is why these payment amounts are consistent with our definition of ''state plan approved rates'' under part 438, including § 438.6 (and why these payment amounts are not considered supplemental payments for the purposes of § 438.6).

*Comment:* A few commenters requested clarification that state plan approved rates include FFS payments that are described and approved in the state plan when the payment is for a specific service or benefit provided to enrollees covered under a contract.

*Response:* As finalized in this rule, state plan approved rates means amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary described under approved rate methodologies in the Medicaid state plan. As defined here, the term ''state plan approved rates'' includes Medicaid FFS payments for a specific service or benefit provided to enrollees when the payment methodology results in amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary and has been approved in the state plan. As long as the payment amounts are calculated for specific covered services identifiable as having been provided to an individual beneficiary and described under CMS approved rate methodologies in the state plan, the payment amounts will meet our definition for state plan approved rates under § 438.6(c).

*Comment:* Some commenters recommended changing the language in proposed § 438.6(a) to indicate that state plan approved rates means amounts paid on a ''per claim'' basis by the state in its FFS Medicaid delivery system to providers for services as described under CMS approved rate methodologies in the Medicaid state plan. Other commenters recommended changing the language for supplemental payments to mean amounts paid separately 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 state plan approved rates. One commenter requested that CMS consider changing the proposed definition of supplemental payments to be 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; are not for a specific service or benefit provided to a specific enrollee covered under the contract; and are in addition to the amounts calculated through an approved state plan rate methodology.

*Response:* After reviewing the specific recommendations made by commenters, we do not believe that these specific revisions to the definitions are necessary. However, we have reconsidered the use of ''per unit'' and acknowledge that this may not have been clear. To correct this, we have revised the definition to remove ''per unit'' and instead, reference amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan. The recommendation to use the term ''per claim'' instead of ''per unit'' in the definition for state plan approved rates is also not necessary as we are not finalizing the term ''per unit'' as described elsewhere. The other recommendations add the phrases ''paid separately'' and ''are not for a specific service or benefit provided to a specific enrollee covered under the contract'' to the definition of supplemental payments. These recommendations do not add clarity to the definition, and we believe that these same concepts are already present in our proposed definitions in § 438.6(a). For example, in the definition of supplemental payments, we proposed and are finalizing the phrase ''and are in addition to'' which could include whether the payment amounts are paid separately or not. We also do not believe that it is necessary to add the phrase ''are not for a specific service or benefit provided to a specific enrollee covered under the contract'' to the definition of supplemental payments because we believe that our proposed definition is broad enough to include this concept, especially since the definition for state plan approved rates means that payments are calculated as amounts calculated for specific covered services identifiable as having been provided to an individual beneficiary and supplemental payments are paid in addition to those state plan approved rates. We are also finalizing a technical change to the definition of supplemental payments by revising the phrase ''amounts calculated through an approved State plan rate methodology'' to ''State plan approved rates.'' This revision eliminates ambiguity and uses terminology that is being finalized in this final rule.

*Comment:* Many commenters supported the proposals that eliminate the prior approval requirement for payment arrangements that use state plan approved rates, allowing states to mirror FFS rates in their managed care plans and develop rates tied to a variety of payment options. Commenters noted that the proposals reduce states' and CMS' administrative burden and create greater flexibility for states to develop stable, long-term payment strategies that can be applied equally in both FFS and managed care delivery systems. Commenters noted that the proposals allow for flexibility that can help states and CMS focus on those payment methodologies that are truly unprecedented or novel, while bringing financial predictability to safety-net providers who rely on Medicaid funding. Some commenters opposed the proposed changes to eliminate prior approval for state plan approved rates, stating that the proposals do not provide a mechanism for frequent and consistent oversight or ensure that the proposals will provide access to care.

*Response:* We agree that our modifications to § 438.6(c)(2)(ii) will reduce state and Federal burden by eliminating the requirement that states obtain written prior approval for payment arrangements that have already been approved by CMS in the Medicaid state plan. We disagree with commenters that our proposed changes would increase unintended risk or a lack of Federal oversight because we are only eliminating the prior approval requirement for those payment arrangements which have already been reviewed and approved by CMS under the Medicaid state plan. We do not believe that a duplicative review and approval process has value or provides any necessary additional Federal oversight. We believe that prudent program management is necessary to efficiently and effectively administer the Medicaid program and eliminating unnecessary and duplicative review processes will improve states' efforts to implement payment arrangements that meet their local goals and objectives. To ensure appropriate oversight and prudent program management, we have initiated a review of state-directed payments and may issue future guidance and/or rulemaking based on the findings of this evaluation. This review was initiated based on our experience reviewing state requests for state-directed payments, as we have seen proposals for significant changes to provider reimbursement, which may in turn have an impact on program expenditures.

*Comment:* A few commenters requested clarification on whether prior approval under § 438.6(c) would be required if a state implemented a uniform percentage increase for managed care plan provider payments concurrently with an increase to the state's FFS rates. These same commenters noted that the managed care plan provider payments would not match the state's FFS rates and that the per unit prices of services for managed care and FFS would vary.

*Response:* In the scenario described by the commenters, the state's requirement for managed care plans to provide a uniform increase to health care providers would be consistent with § 438.6(c)(1)(iii)(C) as proposed and finalized, which permits states to require their managed care plans to provide a uniform dollar or percentage increase for providers that provide a particular service covered under the contract, provided that the other requirements in § 438.6(c) are met. Section 438.6(c)(2)(ii), as finalized in this rule, requires that contract arrangements that direct the managed care plan's expenditures under § 438.6(c)(1)(iii)(B) through (D) must have written approval from CMS prior to implementation. This means that the uniform percentage increase for managed care plan provider payments would require prior approval. We note that a state-directed payment mandating a managed care plan pay the state's FFS rates is authorized under § 438.6(c)(1)(iii)(A) and prior approval would not be required under § 438.6(c)(2)(ii), as amended in this rule under this section.

*Comment:* A few commenters requested clarification on the requirement of written approval for state-directed payments under proposed § 438.6(c)(1)(iii)(A). These commenters noted that the proposed regulation states that these arrangements ''do not require written approval prior to implementation'' and questioned if these arrangements ever require written approval from CMS.

*Response:* If the state requires managed care plans to adopt a minimum fee schedule for network providers that provide a particular service covered under the contract using state plan approved rates as defined in § 438.6(a), written approval is not required from us under § 438.6(c)(2)(ii), as amended in this rule. This means that states may implement these specific payment arrangements, which have already been reviewed and approved by CMS under the Medicaid state plan,

without obtaining any additional approvals from CMS under § 438.6(c). However, this exemption from the prior approval requirement only applies to required use by managed care plans of the state plan approved rates for the FFS program. If the state requires a managed care plan to apply increases or other adjustments to those state plan approved rates, it is not an arrangement described in paragraph (c)(1)(iii)(A), and therefore, paragraph (c)(2)(ii) would apply and require prior written approval.

*Comment:* One commenter requested that CMS confirm that the evaluation requirement at § 438.6(c)(2)(ii)(D) and the prohibition against automatic renewal at § 438.6(c)(2)(ii)(F) are inapplicable to state direction that a managed care plan use the state plan minimum fee schedules under § 438.6(c)(1)(iii)(A). If CMS will still require documentation of these factors, this commenter recommended CMS allow that documentation to be incorporated into the traditional rate certification submission to avoid duplicative administrative review processes.

*Response:* Under § 438.6(c)(2)(ii), contract arrangements that require managed care plans to adopt a minimum fee schedule for network providers that provide a particular service under the contract using state plan approved rates do not require prior approval from us; however, we proposed and are finalizing that such directed payment arrangements must meet the criteria described in § 438.6(c)(2)(ii)(A) through (F). These criteria include that states have an evaluation plan that measures the degree to which the payment arrangement advances at least one the state's quality goals and objectives, and that such payment arrangements are not renewed automatically. We confirm here, only for payment arrangements that utilize minimum fee schedules based on state plan approved rates (as specified in § 438.6(c)(1)(iii)(A)), that while there is no regulatory requirement for the submission of any documentation from the state to demonstrate that state directed arrangements described in § 438.6(c)(1)(iii)(A) meet the criteria described in § 438.6(c)(2)(ii)(A) through (F), these criteria apply and CMS may require states to submit evidence of compliance with the criteria in § 438.6(c)(2)(ii)(A) through (F) if we have reason to believe the state is not complying with the requirements. Because the requirement to comply with these criteria, even if written approval from us is not required, applies nonetheless to arrangements described in § 438.6(c)(1)(iii)(A), we expect that states will maintain their evaluation plans and will continue monitoring and evaluating these payment arrangements. Further, the other criteria listed in § 438.6(c)(2)(ii), such as the prohibition related to IGTs, continue to apply even if we do not require the state to document that compliance to us, and we may require states to submit evidence of compliance with the criteria in § 438.6(c)(2)(ii)(A) through (F) if we have reason to believe the state is not complying with the requirements. Under the plain language of § 438.6(c)(2)(ii), all contract arrangements that direct a managed care plan's expenditures, regardless of whether the payment arrangement requires prior approval under § 438.6(c)(2), must meet the criteria listed in paragraphs (c)(2)(ii)(A) through (F). In addition, we clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations. These financing requirements similarly apply when a state elects to direct payments under § 438.6(c), including § 438.6(c)(1)(iii)(A).

*Comment:* One commenter recommended that CMS provide guidance to states on adopting the Medicaid FFS outpatient drug reimbursement methodology as a minimum fee schedule or a separate and distinct cost-based rate for pharmacy payments in the Medicaid managed care program.

*Response:* Under § 438.6(c)(1)(iii)(A), states are permitted to contractually require their managed care plans to adopt a minimum fee schedule for providers that provide a particular service covered under the contract using state plan approved rates. The state plan approved rates, under the definition finalized at § 438.6(a), can include the Medicaid FFS outpatient drug reimbursement methodologies that are approved by CMS and in the Medicaid state plan. States may implement payment arrangements under paragraph (c)(1)(iii)(A), which have already been reviewed and approved by CMS under the Medicaid state plan, without obtaining any additional approvals from us under § 438.6(c). If cost-based rate methodologies are approved in the Medicaid state plan, states could implement the payment arrangements under paragraph (c)(1)(iii)(A) if the contract requirement is implemented as a minimum fee schedule and if it comports with other regulatory requirements. We note that after consideration of the overall goals and purposes of § 438.6(c), we have reconsidered our proposal in § 438.6(c)(1)(iii)(E) to permit states to direct their Medicaid managed care plans to use a cost-based rate, Medicare-equivalent rate, commercial rate, or other market-based rate as explained elsewhere in this regulation.

*Comment:* Commenters requested that CMS finalize the proposals at § 438.6(c) with the condition that such arrangements only be applied in a manner that accounts for potential adverse effects on access to care or other unintended impacts to dental benefits. Commenters requested that states be required to consult and seek public comment from dental plans and providers prior to including dental services in a value-based payment model.

*Response:* We proposed and are finalizing additional types of payment arrangements that states may direct their managed care plans to use for paying providers that furnish covered services, to enable states to achieve specific state goals and objectives related to Medicaid payment, access to care, and other delivery system reforms at a local level. Under § 438.6(c)(2), we require that states demonstrate that the arrangement complies with specific criteria prior to implementing the payment arrangements. One of those criteria is that the payments advance at least one of the goals and objectives in the state's Medicaid managed care quality strategy (such as an access to care, or quality of care, goal and/or objective); another is that the state has an evaluation plan to assess the degree to which the payment arrangements achieve the state's objectives. While it might be theoretically possible for a state to design and mandate a particular provider payment arrangement that does not consider access to care as part of setting the provider payment, there are other regulatory requirements (such as required quantitative network adequacy standards) in part 438 that ensure that states consider access to care in contracting with managed care plans. We believe that our regulations, including § 438.6(c) and other requirements in part 438, are sufficient to ensure that payment arrangements account for potential adverse effects on access to care or other unintended impacts; therefore, we decline to adopt

additional conditions as part of this final rule.

We also decline to adopt new regulations or new requirements that states consult and seek public comment from plans and providers before mandating a payment arrangement that is permitted under § 438.6(c). While we believe that states should be seeking broad stakeholder feedback when developing and implementing delivery system reforms and performance payment initiatives, we do not believe that it is necessary to create new Federal requirements to accomplish this goal. In our experience, states are already working with many stakeholder groups when designing and implementing new payment requirements for providers in the managed care context, and we believe that states should continue to have discretion in how they convene stakeholder groups and obtain stakeholder feedback to inform state Medicaid policy in this specific area.

*Comment:* One commenter requested that CMS clarify that states may set minimum payment rates for providers within a class that meet certain criteria. The commenter noted that such criteria could include the provision of a particular type of service, such as a public health service.

*Response:* We agree that states are permitted to establish state-directed payments and direct them equally, and using the same terms of performance, for a class of providers providing services under a contract. We explained this in the 2016 final rule (81 FR 27586) and our position on this standard has not changed since the 2016 final rule, and we agree that states could develop minimum payment rates under § 438.6(c) for a class of providers in accordance with the requirements in § 438.6(c)(2)(ii)(B).

*Comment:* A few commenters were concerned about the ability of managed care plans to manage risk as it relates to state-directed payment arrangements. Commenters recommended that CMS confirm that managed care plans retain the ability to manage risk effectively and have discretion in managing their contracts relating to minimum fee schedules and pay increases, as well as maximum fee schedules. Commenters recommended that CMS require states to consult with managed care plans prior to implementing state directed payments. One commenter stated that the regulatory requirements under § 438.6(c) were too rigid for managed care plans and can degrade the utility and effectiveness of value-based arrangements. Commenters also noted that plans, similar to states, should be given the flexibility to deploy specific tactics aimed at encouraging the provision of high-quality and cost-efficient care, and that CMS can continue to add value in this area by disseminating various state approaches and sharing both policy and operational best practices.

*Response:* We agree with commenters that managed care plans should have adequate authority and flexibility to be able to effectively manage risk and have discretion in managing their contracts with providers. This was part of our rationale for adopting the limits on pass-through payments and state-directed payments in § 438.6 in the 2016 final rule (81 FR 27587–27592). We also agree with commenters that plans should be able to deploy specific tactics aimed at encouraging the provision of high-quality and cost-efficient care. However, while we do not agree with commenters that additional revision to § 438.6(c) is necessary at this time, after consideration of the overall goals and purposes of § 438.6(c) and public comments, we have reconsidered our proposal to delete existing § 438.6(c)(2)(ii)(C) which prohibits states from directing the amount or frequency of expenditures made by managed care plans under § 438.6(c)(1)(i) or (ii). While we stated in the proposed rule that this provision may have created unintended barriers to states pursuing innovative payment models, after further consideration, we believe the § 438.6(c) criteria established in the 2016 final rule struck the appropriate balance between the need for autonomy by managed care plans and flexibility for state Medicaid agencies (81 FR 27582 and 27583). Further, we believe retaining this provision will achieve our goal of ensuring managed care plans have the authority and flexibility to effectively manage risk and discretion in managing their contracts with providers. We acknowledge that state direction of provider payments by managed care plans, as permitted under § 438.6(c), can require that managed care plans adopt specific payment parameters for specified providers and can require that managed care plans participate in specified value-based purchasing or performance improvement initiatives; however, we believe that managed care plans retain the ability to reasonably manage risk and still have adequate discretion in managing their contracts with providers, even in circumstances where states may require managed care plans to adopt specific parameters for provider payment. We discussed these issues in the 2016 final rule and why the specific permitted payment arrangements and criteria identified in § 438.6(c) struck the appropriate balance between the need for autonomy by managed care plans and flexibility for state Medicaid agencies (81 FR 27582 and 27583).

Section § 438.6(c) is not intended to take discretion away from managed care plans in managing their risk; rather, § 438.6(c) is intended to help states implement delivery system and provider payment initiatives under Medicaid managed care contracts and permit states to direct specific payments made by managed care plans to providers under certain circumstances to assist states in furthering the goals and priorities of their Medicaid programs. We believe that the payment requirements under § 438.6(c) can assist both states and managed care plans in achieving their overall objectives for delivery system and payment reform and performance improvement without compromising managed care plans' ability to manage risk with their providers. We also note that the requirements under § 438.6(c) do not prohibit managed care plans from adopting their own (or additional) value-based payment arrangements that are aimed at encouraging the provision of high-quality and cost-efficient care. We expect states and managed care plans to work together in developing and implementing delivery system reforms that will be the most impactful for each state's local needs.

We also decline to require that states consult managed care plans before implementing a payment arrangement under § 438.6(c). While we believe that states should be seeking broad stakeholder feedback, including from managed care plans, when developing and implementing delivery system reforms and performance payment initiatives, we do not believe that it is necessary to create new Federal requirements to accomplish this goal. In our experience, states are already working with many stakeholder groups, including managed care plans, when designing and implementing new payment requirements under § 438.6(c), and we believe that states should continue to have discretion in how they convene stakeholder groups and obtain stakeholder feedback to inform state Medicaid policy.

*Comment:* Several commenters supported the allowance of multi-year approval of directed payment arrangements under certain conditions in § 438.6(c)(3). Commenters praised the added flexibility, citing that these payment arrangements encourage providers to make multi-year commitments to quality outcomes and

savings goals, reduce administrative burden, and support the expansion of value-based payment models. A few commenters urged CMS to expand the proposal permitting multi-year approvals at § 438.6(c)(3)(i) to include payment arrangements under paragraph (c)(1)(iii); commenters suggested that this would require a state to explicitly identify the payment arrangement in a contract as multi-year, describe its implementation plan including multi-year evaluation, and seek CMS approval for changes. Commenters noted that annual approvals for directed payments are challenging for states because of the lack of data to support the required annual evaluation to renew payment arrangements. One commenter requested that CMS reconsider the requirement that state-directed payments under § 438.6(c)(1)(iii) be approved annually because states generally implement minimal changes to fee schedules from one year to the next and delays in CMS approval of directed payments create uncertainty for states, managed care plans, and the provider community.

*Response:* We agree with commenters that multi-year approval of specific payment arrangements listed at paragraphs (c)(1)(i) and (ii) can reduce administrative burden and support the expansion of value-based payment models. We also agree that multi-year approval of payment arrangements listed at paragraphs (c)(1)(i) and (ii) can encourage providers to make multi-year commitments to quality outcomes. We also understand that commenters would like the option for multi-year approval for payment arrangements listed at paragraph (c)(1)(iii); however, we decline to adopt this recommendation. We continue to believe that the approval of a payment arrangement under paragraph (c)(1)(iii) should be for one rating period. As we explained in our proposed rule (83 FR 57272), while we understand and acknowledge that value-based purchasing payment arrangements and those tied to larger delivery system reform efforts can be more complex, 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 to ensure that the payments are consistent with states' and CMS' goals and objectives for directed payments under Medicaid managed care contracts. Based on our experience with implementing state directed payments, states have been submitting proposals to CMS for significant changes to provider fee schedules under § 438.6(c)(1)(iii), particularly for uniform dollar or percentage increases, and we believe at this time that we should continue to monitor these payment arrangements on an annual basis. Moreover, to ensure appropriate oversight and prudent program management, we have initiated a review of state-directed payments and may issue future guidance and/or rulemaking based on the findings. This review was initiated based on our experience reviewing state requests for state-directed payments, as we have seen proposals for significant changes to provider reimbursement, which may in turn have an impact on program expenditures.

Regarding commenters' concerns about the lack of data to support the required annual evaluation in § 438.6(c)(2), we understand that states will not always have finalized evaluation results before requesting the next year's approval; however, we expect states to have a finalized evaluation plan. As noted in the November 2017 CIB, directed payments must have an evaluation plan to assess the degree to which the directed payment arrangement achieves its objectives. The basis and scope of the evaluation plan should be commensurate with the size and complexity of the payment arrangement. For example, a state implementing a minimum fee schedule to promote access to care may be able to utilize existing mechanisms to evaluate the effectiveness of the payment arrangement, such as external quality review (EQR) or an existing consumer or provider survey. States also have the ability to identify performance measures that are most appropriate for this evaluation and may wish to consider using performance measures currently being used by the state or other existing measure sets in wide use across the Medicaid, CHIP, and Medicare programs to facilitate alignment and reduce administrative burden.

Regarding commenters' concerns related to delays in CMS approval of directed payments, we committed in our November 2017 CIB to a timely review process for states. CMS committed to process § 438.6(c) preprints that do not contain significant policy or payment issues within 90 calendar days after receipt of a complete submission. Since publishing this CIB, we have continued to be committed to this timeframe, and in our recent experience in processing and approving § 438.6(c) payment arrangements, we are generally working with states to approve these payments within 90 calendar days.

*Comment:* Some commenters recommended that CMS consider automatic renewals of payment arrangements if either the state or the managed care plan can attest that the key characteristics of the payment arrangement that were used to make the initial determination remain in place. Commenters stated that an automatic renewal option would encourage more participation among physicians and physician specialty groups in various value-based contracts.

*Response:* We do not agree with commenters that we should permit automatic renewals of payment arrangements under § 438.6(c). Section 438.6(c)(2)(ii)(F), which was adopted in the 2016 final rule, prohibits payment arrangements under § 438.6(c) from being renewed automatically. In the 2016 final rule, we explained that because we sought to evaluate and measure the impact of these payment reforms, such agreements could not be renewed automatically (81 FR 27583). Automatic renewal is not consistent with our view that these payment arrangements must be reviewed to ensure that the requirements in § 438.6(c)(2) are met and continue to be met. Our policy on this issue has not changed. Under § 438.6(c)(3), we are finalizing in this rule, the option for states to seek multi-year approval of specific payment arrangements listed at paragraphs (c)(1)(i) and (ii), as we believe this will encourage more providers to make commitments to quality outcomes and support the expansion of value-based payment models. These payment arrangements will continue to be reviewed on a periodic basis.

*Comment:* One commenter requested that CMS clarify in § 438.6(c)(3) that a state does not need prior CMS approval to adjust for inflation or rebase an approved multi-year payment threshold.

*Response:* We do not agree with commenters that prior approval is not needed to adjust rates for inflation or when states rebase rates for an approved payment methodology, as this is not consistent with paragraph (c)(3)(i)(C) as proposed and finalized. Under this final rule, the state must affirm that it will not make changes to the payment methodology, or magnitude of the payment, described in the managed care contract for all years of the multi-year payment arrangement without our prior approval. If a state plans to adjust the payments for inflation or rebase a previously approved payment arrangement, the state must obtain prior approval of such changes under paragraph (c)(2), consistent with the text in paragraph (c)(3)(i)(C). This approach is consistent with our view that these payment arrangements must be

reviewed to ensure that the requirements in § 438.6(c)(2) are met, including that the payments continue to be consistent with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

*Comment:* One commenter requested clarification on whether state directed payments under § 438.6(c)(1)(iii)(A) are subject to approval for one rating period or are excluded from this limitation because they are already approved under the state plan rate methodology.

*Response:* Under § 438.6(c)(2)(ii) as finalized, payment arrangements under paragraph (c)(1)(iii)(A) do not require written prior approval from CMS; therefore, the approval timeframes in § 438.6(c)(3) are not applicable to those payment arrangements.

*Comment:* A few commenters requested that CMS establish time parameters for CMS' review and approval of state directed payment proposals.

*Response:* While we decline to adopt commenters' request to establish specific time parameters for our review and approval of payment arrangements under § 438.6(c), we committed in our November 2017 CIB to a timely review process for states. We committed to process § 438.6(c) preprints that do not contain significant policy or payment issues within 90 calendar days after receipt of a complete submission. Since publishing this CIB, we have continued to be committed to this timeframe, and in our recent experience in processing and approving § 438.6(c) payment arrangements, we are generally working with states to approve these payments within 90 calendar days.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.6(a) and (c) as proposed with the following modifications:

- At § 438.6(a), included a sentence in the definition of supplemental payments that states DSH and GME payments are not, and do not constitute, supplemental payments; and included a technical change to the definition of supplemental payments by revising the phrase ''amounts calculated through an approved State plan rate methodology'' to ''State plan approved rates.''
- At § 438.6(a), included a sentence (which had been proposed to be codified in § 438.6(c)(1)(iii)(A)) in the definition of state plan approved rates that a state's supplemental payments contained in a state plan are not, and do not constitute, state plan approved rates under our definition.
- At § 438.6(a), deleted the phrase ''per unit price for services'' and replaced it with ''for specific services identifiable as having been provided to an individual beneficiary''.
- At § 438.6(c)(1)(iii)(A), finalizing the provision without the sentence that states supplemental payments contained in a state plan are not, and do not constitute, state plan approved rates.

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

In the 2016 final rule, and the 2017 ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' 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).[5] We noted that 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 were not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments to the provision of specific 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) was 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 under the current law.

We used the 2016 final rule to identify the pass-through payments in managed care contract(s) and rate certification(s) that were 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

[5] 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).

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 were the most common provider types to which states made supplemental payments within Federal UPLs under state plan authority in Medicaid FFS.

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. We have understood that some states would like to begin to transition some services or eligible populations from FFS to managed care but would also like to continue to make supplemental payments to hospitals, physicians, or nursing facilities. In the 2018 proposed rule, we acknowledged the challenges associated with transitioning supplemental payments into payments based on the delivery of services or value-based payment structures. We acknowledged 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 recognized that implementing value-based payment structures or other delivery system reform initiatives, and addressing transition issues, including ensuring adequate base rates, are 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 proposed 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. We explained that when we refer to transitioning services from FFS Medicaid to Medicaid managed care plan(s) for purposes of our proposal at § 438.6(d)(6), we are referring to both when a state expands the scope of its managed care program in terms of services (for example, covering behavioral health services through 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 delivery systems).

Specifically, we proposed 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 transition period for pass-through payments (''pass-through payment transition period''); (2) the state made supplemental payments, as defined in § 438.6(a), 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 those specific services that will be covered for the first time under a Medicaid managed care contract (this 12-month period is identified in § 438.6(d)(2) and used in calculating 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 paragraph (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 proposed 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 proposed paragraphs (d)(6)(iii)(A) through (C) to address the maximum aggregate pass-through payment amounts permitted to be directed to hospitals, nursing facilities, and physicians for each rating period of the specified 3-year pass-through payment transition period; that is, we proposed three paragraphs to identify 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 new paragraph (d)(6), we proposed that 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 was less than or equal to the amounts calculated as described in proposed paragraph (d)(6)(iii)(A), (B), or (C) for the relevant provider type. In § 438.6(d)(6)(iii), we proposed that for determining the amount of each component for the calculations contained in proposed 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 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. Under our proposal for this calculation, the state would also be required 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. Our proposal referred to the most common provider types to which states made supplemental payments within Federal UPLs under state plan authority in Medicaid FFS. In the proposed rule, we provided the following four basic steps for making the calculation:

- *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, excluding supplemental payments, paid 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 making these calculations, 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.

In the proposed rule, we provided 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:

$$Permissible\ Aggregate\ Payment\ Amounts = (Medicaid\ FFS\ Supplemental\ Payments\ Paid\ to\ Provider\ Type\ X) \times \left(\frac{Amounts\ Paid\ in\ Medicaid\ FFS\ to\ Provider\ Type\ X\ through\ Medicaid\ for\ Transitioning\ Services}{Total\ Amounts\ Paid\ in\ Medicaid\ FFS\ to\ Provider\ Type\ X\ for\ All\ Services}\right)$$

In the proposed rule, we also provided an example to help demonstrate how the calculation would be performed. In the example, we assumed 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 assumed 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 assumed that CY 2016 was 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 would be transitioned to a managed care contract; therefore, we assumed the pass-through payments were to be made during 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 an existing managed care program (that is, for enrollees who are already enrolled in managed care for other services).

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 for 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 multiplies the $20 million in actual supplemental payments paid by 60 percent (the ratio identified in step 2), resulting in $12 million. The $12 million is the amount used in Step 4 as the total amount that the state would be permitted under our proposal 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.

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 proposed, in § 438.6(d)(6)(iv), to allow states a transition period of up to 3 years to transition FFS supplemental payments into payments linked to services and utilization under the managed care contract. We proposed 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). We noted that 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 explained that we believed that the proposed 3-year pass-through payment transition period was appropriate because the services (and corresponding supplemental payments) would not yet have been transitioned at all into managed care contracts; therefore, we believed that 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 have already been 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 invited comment on whether the 3-year pass-through payment transition period was an appropriate amount of time.

Unlike the 2016 final rule, our proposal did not set a specific calendar date by which states must end pass-through payments; rather, our proposal provided 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. We noted that 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.

The following summarizes the public comments received on our proposal to amend § 438.6(d)(6) and our responses to those comments.

*Comment:* Many commenters supported the proposal to allow states to include new pass-through payments which encourage providers to participate in new managed care arrangements. Commenters noted that allowing states to have a set period of time to transition away from existing FFS supplemental payment programs when the state moved services (or populations) into a managed care program will be helpful in preventing abrupt reductions in services or access to providers because of the lack of supplemental payments. Commenters noted that pass-through payments are critical for ensuring that safety-net providers remain profitable enough to continue to treat their patients. Commenters also noted that states have long used these payments to combat provider shortages in areas of need by increasing reimbursement for providers who accept a proportionally large number of Medicaid patients.

*Response:* We agree that the new pass-through payment transition period under § 438.6(d)(6) can assist states with transitioning some or all services or eligible populations from a FFS delivery system into a managed care delivery system. We believe the new pass-through payment transition period will provide states, network providers, and managed care plans time and flexibility to integrate such payment arrangements into permissible managed care payment structures. States can use the transition period to avoid unnecessary disruption to any safety-net provider systems that they have developed in their Medicaid programs when the state moves services or populations into managed care. We understand that some states have previously used pass-through payments to increase reimbursement for safety-net providers; however, we note that there are other mechanisms that states can use to increase reimbursement to providers in a managed care program that do not implicate the pass-through payment restrictions. For example, states can use the payment arrangements under § 438.6(c) to direct managed care plans to link the delivery of services and quality outcomes for Medicaid managed care enrollees under the managed care contract. However, we reiterate here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a state elects to direct payments under § 438.6(c). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations. These financing requirements similarly apply when a state elects to direct payments under § 438.6(c) or the payment transition periods under § 438.6(d). We continue to view pass-through payments as problematic and not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services to Medicaid beneficiaries covered under the contract. Therefore, while we proposed and are finalizing a pass-through payment transition period under § 438.6(d)(6), that transition period is limited and the amount of pass-through payments permitted during that period is subject to restrictions as outlined in the regulation. In the proposed rule, we provided the 4 step calculation noted above and the proposed regulation text incorporated the steps in paragraphs (d)(6)(iii)(A) through (C) and in paragraph (d)(6)(iv) without affirmatively identifying the process as steps 1 through 4. We are finalizing the regulation with a technical edit to § 438.6(d)(6)(iii)(A) through (C) to clarify that both the numerator and denominator of the ratio described in Step 2 should exclude any supplemental payments as defined in § 438.6(a) made to the applicable providers and counted in Step 11. In paragraphs (d)(6)(iii)(A) through (C), we are also finalizing the text using the phrase ''State plan approved rates'' instead of ''payment rates'' to clarify how those ratios do not include supplemental payments.

We encourage states to plan for how FFS supplemental payments can be incorporated into standard capitation rates or permissible payment arrangements in a managed care program as quickly as possible.

*Comment:* A few commenters requested that CMS clarify how DSH payments will be considered when determining the amount of FFS supplemental payments that can be continued as pass-through payments in managed care. Commenters noted that it appears from the preamble discussion that the new pass-through payment provision is intended to be limited to non-DSH supplemental payments, but the proposed definition of supplemental payments in § 438.6(a) could be interpreted as including DSH payments. A few commenters also requested clarity on the treatment of GME payments when determining the amount of FFS supplemental payments that can be continued as pass-through payments in managed care. Several commenters recommended that CMS allow for GME funding to be distributed to providers directly by the state.

*Response:* We never intended for DSH or GME payments to be included in our proposed definition of supplemental payments in § 438.6(a) and therefore never intended for the pass-through payments subject to the limits in paragraph (d) to apply to DSH or GME payments. As proposed in the 2018 proposed rule, one of the requirements for the new pass-through payment transition period was that the state had previously made supplemental payments, as defined in § 438.6(a), to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first rating period of the transition period. As noted in this final rule in the responses to comments for § 438.6(a) (Definitions), we agree with commenters that the definition of supplemental payments must be revised to clarify that DSH and GME payments are not supplemental payments as that term is defined and used for part 438. DSH and GME payments are made under separate and distinct authorities in the Medicaid program under 42 CFR part 447. As discussed in I.B.4.b. of this final rule, we are finalizing the definition of supplemental payments at § 438.6(a) with a modification to include a sentence in the definition that states

DSH and GME payments are not, and do not constitute, supplemental payments.

The existing definition of pass-through payment in § 438.6(a) excludes GME payments. We have not revised that definition since the 2016 final rule so the prohibition on pass-through payments in § 438.6(d) does not apply to GME payments. Further, under existing § 438.60, state Medicaid agencies may make direct payments to network providers for GME costs approved under the state plan without violating the prohibition of additional payments for services covered under managed care contracts.

*Comment:* Some commenters requested that CMS confirm the standard ''12-month period immediately 2 years prior'' that is used in § 438.6(d)(6)(ii) and (iii). These commenters requested that CMS confirm that the first month of the 12-month period used to calculate the maximum aggregate payment is 24 months (and not 36 months) before the first month of the first rating period for the managed care contract into which the new services or populations are moving. Commenters also requested that additional flexibility be applied to the term ''relevant provider type'' to consider more granular provider classifications relevant to a specific supplemental payment mechanism, such as academic medical hospitals. Commenters also requested clarity on whether the transition mechanism will require three equal reductions (33⅓ percent annually) to the calculated aggregate supplemental payment maximum or whether reductions are required under the new transition period.

*Response:* We confirm that the standard ''12-month period immediately 2 years prior'' that is used in § 438.6(d)(6)(ii) and (iii), as well as the 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), means that the first month of the twelve-month period used to calculate the maximum aggregate payment is twenty-four months before the first month under managed care. In the 2018 proposed rule, we provided an example that illustrates our response here: in the example we assumed that CY 2016 was 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 were to be transitioned to a managed care contract; therefore, we noted in the example that the pass-through payments were for CY 2018 (83 FR 57274). If the first month of the managed care contract is January 2018, the first month of the 12-month period described in § 438.6(d)(6)(ii) and (iii) is January 2016.

We understand that commenters would like us to include additional provider types under § 438.6(d)(6)(iii), or that we expand the phrase ''relevant provider type'' that is used in § 438.6(d)(6)(iii) to include more granular provider classifications; however, we decline to make these modifications. As noted in the 2016 final rule (81 FR 27590) and the 2018 proposed rule (83 FR 57272), we focused on the three provider types identified in § 438.6(d) because these were the most common provider types for which states made supplemental payments within Federal UPLs under state plan authority, and we note that these are the provider types for which states have typically sought to continue making payments as pass-through payments under managed care programs. Further, the rules at § 438.6(d)(6) need to be consistent with the existing pass-through payment regulations at § 438.6(d)(3) and (5), which currently recognize pass-through payments for hospitals, nursing facilities, and physicians. We focused on the three provider types identified in § 438.6(d) because these were the most common provider types to which states made supplemental payments within Federal UPLs under state plan authority in Medicaid FFS.

Unlike existing hospital pass-through payments made under § 438.6(d)(3), which requires a phasedown of the pass-through payment amounts over the transition period (up to 10 years), we confirm for commenters that the pass-through payment transition period of 3-years at § 438.6(d)(6) does not require three equal reductions to the calculated aggregate payment maximum. We also confirm that the pass-through payment transition period under § 438.6(d)(6) does not require any reductions or a phase-down across the 3-year transition period. As noted in the proposed rule, 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. The regulation does not require any reductions from one year to the next during the 3-year transition period in § 438.6(d)(6), but once the 3-year transition period ends, all of the pass-through payments must be completely phased out of the managed care contracts and rates because the prohibition in § 438.6(d) applies. We note that states are permitted to phase the pass-through payments down by three equal reductions or otherwise to the aggregate payment maximum, but the regulation we are finalizing does not require or discourage states use of this approach.

*Comment:* A few commenters noted that a state's transition to phasing out pass-through payments may take longer than 3 years and suggested that CMS increase the transition period to 5 years. One commenter urged CMS to allow pass-through payments for network hospitals to be phased out on a longer timeline than the proposed 3-year transition period, until at least July 1, 2027. One commenter suggested that the 3-year transition period was inadequate and that a 10-year transition period was more appropriate under § 438.6(d)(6).

*Response:* We do not agree with commenters that we should increase the length of the pass-through payment transition period under § 438.6(d)(6). We continue to view pass-through payments as problematic and not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services. However, as noted in the 2018 proposed rule, we understand that network providers, states, and managed care plans need adequate time to design and implement payment systems that link provider reimbursement with services when the state is transitioning new services or new populations to a managed care contract. We proposed and are finalizing this amendment to § 438.6(d) to assist with that. However, we still believe that the 3-year pass-through payment transition period provides states with a reasonable amount of 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). Further, states that have not yet transitioned these services (and corresponding supplemental payments) into managed care contracts should be in a better position to design payment structures that appropriately account for these payments during the transition to managed care. We find the commenters' recommended timeframes of 5 years, 10 years, and through July 1, 2027 to be unreasonably long, and we believe that a transition period of these lengths would unnecessarily delay the transition of these payments into allowable payment structures under actuarially sound capitation rates. Therefore, we decline to make modifications to the length of the

transition period and will finalize 3-years at § 438.6(d)(6).

*Comment:* Some commenters stated that pass-through payments should not be prohibited so long as the overall payments made to Medicaid managed care plans are actuarially sound. One commenter noted that our proposal would redefine state supplemental FFS payments and could exclude transitioning pass-through payments to state directed payment arrangements in the future. This commenter requested clarification on whether these pass-through payments under the new transition period could be transitioned into state directed payments at the end of the 3-year transition period. Commenters also requested that CMS collect and make pass-through payment data publicly available so that stakeholders can examine the amount of pass-through payments and to whom they are being made.

*Response:* We disagree with commenters that pass-through payments, beyond those payments permitted under a pass-through payment transition period, should be permissible under Medicaid managed care. As explained in our proposed rule, 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. 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. We have also previously provided a detailed description of our policy rationale (81 FR 27587 through 27592) related to pass-through payments and our position has not changed. Therefore, we will not amend or eliminate the prohibition against pass through payments in § 438.6(d) beyond the specific change we proposed for § 438.6(d)(6) to assist states with transitioning new populations or new services to managed care.

We also disagree with commenters that § 438.6(d)(6) limits the state's ability to transition pass-through payments to state-directed payment arrangements under § 438.6(c). We believe that the pass-through payment transition period under § 438.6(d)(6) provides states with a reasonable amount of 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). Since the 2016 final rule, we have worked with many states to transition some or all of the state's pass-through payments into actuarially sound capitation rates that do not limit the plan's discretion or permissible payment arrangements under § 438.6(c). States can work with their managed care plans and network providers to transition the amounts currently provided through pass-through payments in approvable ways, such as actuarially sound capitation rates that do not limit the plan's discretion or the approaches consistent with § 438.6(c).

Regarding the recommendation that CMS collect and make pass-through payment data publicly available, we have traditionally deferred to states for making specific components of rate development publicly available. We note that pass-through payments are added to the contracted payment rates and considered in calculating the actuarially sound capitation rate; therefore, pass-through payments are a specific component of capitation rate development. As such, we will continue to defer to states on making these amounts publicly available.

*Comment:* A few commenters noted that current CMS regulations apply only to hospitals, nursing facilities, and physicians. These commenters requested that CMS change the terminology from ''physician'' to ''provider'' to ensure that all health care providers are eligible for the pass-through payments. Some commenters requested clarity on whether nurse practitioners are included in the physician pass-through payment category.

*Response:* We understand that commenters would like us to include additional provider types under § 438.6(d)(6)(iii) (such as by replacing the term ''physician'' as used in § 438.6(d)(6)(iii)(C) to the more general and broader term ''provider'') to recognize additional health care providers; however, we decline to make these modifications. As noted in the 2016 final rule (81 FR 27590) and the 2018 proposed rule (83 FR 57272), we focused on the three provider types identified in § 438.6(d) because these were the most common provider types for which states made the majority of supplemental payments within Federal UPLs under state plan authority, and we note that these are the provider types for which states have typically sought to continue making payments as pass-through payments under managed care programs. We also do not want our rules at § 438.6(d)(6) to be inconsistent with the existing pass-through payment regulations at § 438.6(d)(3) and (5), which currently recognize pass-through payments for hospitals, nursing facilities, and physicians.

Regarding the request for clarity on whether nurse practitioners are included in the physician pass-through payment category, we clarify here that nurse practitioners are not included in the physician category for purposes of the pass-through payment transition periods under § 438.6(d). While CMS has not defined the term ''physician'' in regulation for purposes of the pass-through payment transition periods under § 438.6(d), we rely on section 1905(a)(5) of the Act, which incorporates the definition for physician from sections 1861(r)(1) and (r)(2) of the Act, and the implementing regulation at 42 CFR 440.50 to provide meaning for physicians' services for the purpose of medical assistance under Title XIX. Under sections 1861(r)(1) and 1861(r)(2) of the Act, the term ''physician'' means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state in which he or she performs such services, and a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the state in which he or she performs such services and who is acting within the scope of his or her license, to the extent that such services may be performed under state law either by a doctor of medicine or by a doctor of dental surgery or dental medicine if furnished by a physician.

*Comment:* One commenter suggested updating the language in § 438.6(d)(6)(i) to read: ''The Medicaid populations or 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.'' One commenter suggested that § 438.6(d)(6)(i) be clarified to allow new pass-through payments for geographic areas that are newly transitioning to Medicaid managed care.

*Response:* We decline to add the phrase ''The Medicaid population or'' at the beginning of § 438.6(d)(6)(i) because it is not necessary. As proposed and finalized, § 438.6(d)(6) used the phrase ''when Medicaid populations or services are initially transitioning from a FFS delivery system to a managed care delivery system.'' Therefore, we believe that the rule is clear on this point.

Regarding pass-through payments for geographic areas that are newly transitioning to Medicaid managed care,

we confirm that the pass-through payment transition period at § 438.6(d)(6) would be appropriate as long as the conditions and requirements under § 438.6(d)(6)(i) through (iv) are met, including that the populations or 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. When states transition a new geographic area into Medicaid managed care, the services and populations in that new geographic area are newly moving into managed care.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.6(d)(6) as proposed with the following modifications:

- At § 438.6(d)(iii)(A) through (C), included the following sentence, ''Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers'' and using the phrase ''State plan approved rates'' instead of ''payment rates'' to clarify how those ratios do not include supplemental payments.

To ensure states have adequate time to plan and implement a transition from a fee-for-service system to a managed care delivery system, we are delaying the effective date of this provision. States that are initially transitioning populations and services from fee-for-service to managed care must comply with § 438.6(d)(6) as amended effective July 1, 2021 for Medicaid managed care rating periods starting on or after July 1, 2021.

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 diseases (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) but, after careful review, did not do so because of our belief that the underlying analysis regarding the transfer of risk that underpinned the policy in the 2016 final rule was appropriate. We also conducted a literature and data review and did 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 requested public comment on additional data sources that we should review.

The following summarizes the public comments received and our responses to those comments.

*Comment:* Several commenters supported the policy to not extend the availability of FFP for capitation payments made for months that include stays longer than 15 days. Commenters stated that making payments under those circumstances would incentivize the provision of care in institutions rather than community-based settings. Other commenters disagreed with the CMS decision to not extend the availability of FFP for capitation payments made for months that include stays longer than 15 days. These commenters noted that the 15-day limit is not based on an individual's care needs and suggested that the 15-day limitation creates inappropriate incentives around the timing of admissions. Other commenters recommended alternatives to the 15-day policy, such as adjusting the length of stay in the IMD to 25 days.

*Response:* We remind commenters that we did not propose changes to the regulation because we continue to believe that the underlying analysis regarding the transfer of risk that underpinned the policy in the 2016 final rule is appropriate. Our detailed analysis and explanation of the rule can be found in the 2016 final rule at 81 FR 27555 through 27563. In the 2018 proposed rule, we requested public comment on additional data sources that we should review, and these commenters did not provide such data. We also remind commenters that we have developed section 1115(a) demonstration initiatives aimed at (1) improving access to and quality of treatment for Medicaid beneficiaries to address substance use disorders (SUDs) and the ongoing opioid crisis;[6] and (2) designing innovative service delivery systems, including systems for providing community-based services, for adults with a serious mental illness (SMI) or children with a serious emotional disturbance (SED) who are receiving medical assistance.[7] These demonstrations enable states to receive FFP for longer lengths of stay in IMDs within specified parameters. We also note that section 5052 of the SUPPORT for Patients and Communities Act, which provides a state plan option to provide Medicaid coverage for certain individuals with substance use disorders who are patients in certain IMDs from October 1, 2019 through September 30, 2023, may also provide mechanisms to receive FFP for longer lengths of stay in IMDs consistent with section 5052 of the SUPPORT for Patients and Communities Act.

*Comment:* One commenter noted that the 15-day policy has caused confusion in the industry, stating some managed care plans have interpreted this part of the 2016 final rule to mean IMDs should reimburse the managed care plans for the care provided for only the first 15 days if a patient stays beyond day 15. Given the confusion around this issue, the commenter requested that CMS clarify that repayments between IMDs and managed care plans are not covered by the 2016 final rule.

*Response:* There is no requirement in § 438.6(e) that requires IMDs to reimburse managed care plans for the care provided for only the first 15 days if a patient stays beyond day 15; nor does § 438.6(e) address repayment arrangements between a Medicaid managed care plan (that is, a MCO or PIHP) and a provider that is an IMD. Section 438.6(e) only governs the availability of FFP when states make capitation payments to an MCO or PIHP for enrollees aged 21–64 receiving inpatient treatment in an IMD. The rule permits FFP to the state for the capitation payment only if specified conditions are met, including that the length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. Any requirements for repayment from IMDs to managed care plans are not governed by this rule, but instead appear to be within the scope of the contractual arrangements between IMDs and managed care plans.

*Comment:* One commenter requested that CMS confirm that states are not precluded from using the flexibility afforded by § 438.6(e) to collect FFP on

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

[7] SMD #18–011: Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance; available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf.*

capitation payments made for enrollees under age 21 in an IMD when an individual is receiving substance use disorder (SUD) services.

*Response:* CMS does not agree with the commenter that § 438.6(e) permits states to collect FFP on capitation payments made for enrollees under age 21 in an IMD when that individual is receiving SUD services. Section 438.6(e) permits FFP when the state makes a capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an IMD so long as certain conditions outlined in the regulation are met. While § 438.6(e) is not the appropriate authority for enrollees under the age of 21, many states provide inpatient psychiatric and SUD services for individuals under age 21 as part of their state plan, which can include stays in an IMD, subject to the requirements at part 441 Subpart D. In accordance with § 438.3(c) and part 438 subpart J, if the service provided to enrollees under the age of 21 is a Medicaid state plan service and included under the managed care contract, FFP would be available for the monthly capitation payment.

*Comment:* A few commenters made recommendations for additional data sources that CMS should review to support the availability of FFP for capitation payments made for months that include stays in an IMD. One commenter recommended that CMS use the data that we collect as required by the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) to study the effects of the 15-day in-lieu-of provision, which also requires CMS to issue a report in December 2019. One commenter also recommended that CMS use data that becomes available through approved section 1115(a) SUD demonstrations.

*Response:* We agree with commenters that once data becomes available through these potential sources, such data should be used to inform future policy decisions and rulemaking. We will take these recommendations under advisement.

As we did not propose any modifications to § 438.6(e), we are not finalizing any changes to § 438.6(e) under this final rule.

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 without submitting a revised rate certification. We stated in the 2016 final rule that a rate that is within +/− 1.5 percent of a certified rate is also actuarially sound as that percentage is generally not more than the risk margin incorporated into most states' rate development process (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 us to clarify 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 +/− 1.5 percent at any time within the rating period without submitting justification to us. We clarified in the 2018 proposed rule 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 us, unless documentation is specifically requested by us in accordance with our proposed revisions in paragraph (c)(3) (83 FR 57275).

We proposed to amend § 438.7(c)(3) to clarify the scope of permissible changes to the capitation rate per rate cell and the need for a contract modification and rate certification. Proposed § 438.7(c)(3) included 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) also retained 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 included new text to specify that the adjustments would be subject to the requirements at § 438.4(b)(1) and to authorize us 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). We reiterate here that all capitation rates, regardless of whether they are established through the initial rate certification or through a contract amendment, must comply with the requirements in §§ 438.3(c) and (e) and 438.4 through 438.7. Further, we explicitly clarify here that certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities). Such requirements include, but are not limited to, limitations on financing of the non-Federal share applicable to health care-related taxes and bona fide provider-related donations.

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) were not intended to be used by states to shift costs to the Federal Government. To protect against cost shifting and eliminate any potential loophole in § 438.7(c)(3), we proposed that any changes of the capitation rate within the permissible 1.5 percent would be subject to the requirements 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 vary with the rate of FFP associated with the covered populations (see also section I.B.2.b. of this final rule for a discussion of § 438.4(b)(1) and this prohibition on rates varying with the FFP percentage). In addition, § 438.4(b)(1) requires that rates be developed in accordance with § 438.5 and generally accepted actuarial principles and practices; we noted in our proposal that using this cross-reference to regulate mid-year changes of capitation rates within the +/− 1.5 percent range would ensure that such changes were not arbitrary or designed to shift costs to the Federal Government. The proposed amendment to § 438.7(c)(3) would permit us to require documentation that the adjusted rate complied with our proposed requirements and other criteria related to the actuarial soundness of rates.

We also proposed § 438.7(e), which commits us to issuing annual 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 noted in our proposal that such guidance would interpret and provide guidance on the part 438 regulations and specify procedural rules for complying with the regulations; we specifically explained how the guidance would therefore address the information required to be 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.

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

The following summarizes the public comments received on our proposal to amend § 438.7 and our responses to those comments.

*Comment:* A few commenters supported the proposal to allow *de minimis* adjustments without further rate justifications. A few commenters recommended that CMS always require documentation accompanying *de minimis* rate changes as well as certification that revised rates are actuarially sound. A few commenters recommended that CMS should also require documentation that disclosed other *de minimis* changes made during the year that may not have changed the capitation rates. A few commenters requested clarification that the +/−1.5 percent was intended to be calculated as a percentage of the certified rate. One commenter requested that CMS clarify that states cannot use the *de minimis* rate adjustment to reduce rates in this final rule beyond the lower bound of the newly proposed five percent rate range.

*Response:* We disagree with commenters that recommended that CMS always require documentation or a rate certification for any change in the rate, even for *de minimis* rate changes within the +/−1.5 percent threshold, as this approach is not consistent with either our position (explained in the 2016 final rule) that *de minimis* changes of +/−1.5 percent do not affect the actuarial soundness of the capitation rate or our intent to provide additional state flexibility under this final rule. Adopted in the 2016 final rule, § 438.7(c)(3) provides states with the 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 without submitting a revised rate certification. We determined that the fluctuation of +/−1.5 percent did not change the actuarial soundness of a capitation rate and reasoned that the resulting rate will remain actuarially sound (81 FR 27568). Providing states this flexibility to make *de minimis* adjustments around the certified rate eases the administrative burden of rate review on states while meeting our goals of transparency and integrity in the rate-setting process. We also decline to add new regulation text requiring states to document other changes made during the year that may not have changed rates because any changes would have to be included as modifications to the managed care plan contract and submitted to CMS for approval under § 438.3(a). We do not believe that requiring additional documentation is necessary and believe that our existing processes for the submission of contract modifications is sufficient without adding a new documentation requirement for states.

We confirm that the +/−1.5 percent is to be calculated as a percentage of the certified rate. Section 438.7(c)(3) permits rate adjustments during the contract year by increasing or decreasing the capitation rate certified per rate cell by 1.5 percent without submitting a revised rate certification. This means that the certified rate per rate cell can be adjusted by the +/− 1.5 percent without a revised certification. However, states cannot use both the *de minimis* rate adjustment under § 438.7(c)(3) and the newly proposed 5 percent, or +/− 2.5 percent from the midpoint, rate range under proposed § 438.4(c). As proposed and finalized, § 438.4(c)(2)(ii) prohibits a state that is using a rate range from also modifying capitation rates under § 438.7(c)(3) by +/−1.5 percent (see also section I.B.2.a. of this final rule for a discussion of § 438.4(c)).

*Comment:* Several commenters described the regulation under § 438.7(c)(3) as permitting *de minimis* rate changes during the contract year or during the rating period.

*Response:* While these commenters did not specifically recommend a revision to the regulation, the public comments highlighted a need for CMS to clarify this issue here. In developing our responses to the public comments, we noticed a technical error in the regulatory text in § 438.7(c)(3). In the 2018 proposed rule, we described our proposal by stating that § 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 (83 FR 57275). In the 2016 final rule, when we originally finalized § 438.7(c)(3), we described the final rule as providing the ability for the state to adjust the actuarially sound capitation rate *during the rating period* by +/−1.5 percent (81 FR 27568). However, we noticed that the regulatory text in § 438.7(c)(3) does not actually contain this language, even though the preamble of the 2016 final rule does describe the rate changes under § 438.7(c)(3) as changes made during the rating period or during the contract year. Therefore, we are finalizing a revision to § 438.7(c)(3) to include the language ''during the rating period'' as part of the standard for using the 1.5 percent adjustment. A retroactive adjustment to the capitation rate must meet the requirements in § 438.7(c)(2) as there is no regulatory provision carving *de minimis* rate changes out of the scope of § 438.7(c)(2) and the preamble discussions in the 2016 final rule and 2018 proposed rule limited the *de minimis* rate changes to those changes made during the contract year or rating period.

*Comment:* Several commenters appreciated the proposal to provide annual rate development and documentation guidance for capitation rates, documentation requirements, updates in the rate review process, and demonstrating competitive bidding. Some commenters requested that states be provided the opportunity to give feedback on proposed changes prior to implementation. Some commenters recommended that the following topics be addressed in any subregulatory guidance: value-added benefits, changes to rates with changes in scope of services, the role of states versus CMS in certifying rates, guidelines for documentation, calculation definitions, and information on the appropriateness of withholds. One commenter requested that guidance be issued with sufficient time for managed care plans to negotiate payment rates with providers.

*Response:* We will take these comments under advisement as we develop and publish future subregulatory guidance. As we noted in the 2018 proposed rule, we have published rate review guidance every year since 2014, and we proposed § 438.7(e) to demonstrate our commitment to efficient review and approval processes. We will continue to work with states and managed care plans 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.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.7(c)(3) and (e) as proposed, with a modification in § 438.7(c)(3) to include the language ''during the rating period'' as part of the standard for using the 1.5 percent adjustment.

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

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. 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), and (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. This proposal was never finalized and does not align with the MLR requirements for Medicare Part C or Part D or the private market. We also proposed at that time 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), and (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, will 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, in the 2018 proposed rule, we proposed 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 also proposed 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.

The following summarizes the public comments received on our proposal to amend § 438.8 and our responses to those comments.

*Comment:* Several commenters supported the proposal 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),'' consistent with how § 438.8(e)(4) was finalized in the 2016 final rule. One commenter stated that it was pleased that CMS did not substantially modify the MLR requirements for Medicaid and CHIP managed care plans.

*Response:* We believe that it is critical for our rules to be technically accurate and our proposed revisions correct technical errors from the 2016 final rule.

*Comment:* One commenter requested clarification on what activities CMS expects states to require their MCOs, PIHPs, and PAHPs to report on as a result of the revision to § 438.8(k)(1)(iii). One commenter requested clarification on whether the technical correction to § 438.8(k)(1)(iii) would allow Medicaid and CHIP plans' fraud-related costs to be included in the Quality Improvement Activities (QIAs) portion of the numerator. Several commenters also recommended that CMS align Medicaid policy with Medicare Advantage and permit fraud prevention expenditures as QIAs in the MLR numerator.

*Response:* Our proposed rule did not propose any policy changes for the Medicaid MLR regulation. The technical amendments were proposed to correct errors from the 2016 final rule and ensure that § 438.8 is internally consistent. Section 438.8(e) provides, irrespective of the corrections adopted here, that fraud prevention activities, as defined in paragraph (e)(4), are included in the numerator. With the revision we are finalizing to § 438.8(e)(4), the regulation is clear that MCO, PIHP, or PAHP expenditures on activities related to fraud prevention will be incorporated into the Medicaid MLR calculation, using the same standards for identifying fraud prevention activities in the private market MLR regulations at 45 CFR part 158. We intend that if and when those part 158 regulations defining fraud prevention activities are amended in the future, the updated standards will likewise be used for the Medicaid MLR requirements. The correction to § 438.8(k)(1)(iii) makes the Medicaid MLR requirements consistent by requiring reporting from MCOs, PIHPs, and PAHPs of fraud prevention activities as defined in paragraph (e)(4), which are the activities that are used in the MLR calculation.

We are aware that Medicare Advantage adopted different regulations on the treatment of fraud prevention expenditures and expanded the definition of QIA in §§ 422.2430 and 423.2430 to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. We note that when we finalized the MLR requirements in the 2016 final rule, we specifically aligned Medicaid MLR standards with the regulations for the private market at 45 CFR part 158. As such, the Medicaid MLR rules do not reference the QIAs in Medicare Advantage, and instead we adopted the terminology used in the private market MLR regulations in part 158 related to activities that improve health care quality as specified in § 438.8(e)(3). While we will take commenters' recommendations to align with Medicare Advantage on this point under advisement, we are not finalizing such modifications as part of this final rule. We note, however, that fraud prevention activities, subject to the different definitions and limitations specified for the different programs, are ultimately included in the numerator for the MLR for Medicaid managed care plans, private market insurance, Medicare Advantage plans, and Medicare Part D plans.

*Comment:* Commenters opposed the proposed technical clarification and recommended that CMS reconsider our alignment with regulations in the private market at 45 CFR part 158.

*Response:* We disagree with commenters and believe that it is critical for our rules to be technically accurate. Our proposed revisions only correct technical errors from the 2016 final rule and we did not propose to reconsider our alignment with regulations in the private market. We do not see a reason to reconsider or change that alignment.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the technical amendments to § 438.8(e)(4) and (k)(1)(iii) as proposed.

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. 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 proposed to revise § 438.9(b)(2) by adding ''except § 438.4(b)(9).''

The following summarizes the public comment received on our proposal to amend § 438.9 and our responses to those comments.

*Comment:* One commenter supported the proposal to amend § 438.9(b)(2) to clarify that NEMT PHAPs are not required to comply with the MLR standards.

*Response:* Amending § 438.9(b)(2) will conform the regulation text to our policy for how rates for NEMT PAHPs are developed and ensure that there isn't a Federal requirement for such plans to develop and report an MLR.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendment to § 438.9(b)(2) as proposed.

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) and (3) and (d)(6)(iv), requiring that states and managed care plans include taglines in prevalent non-English languages and in large print on 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).[8] 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 and the managed care plan's member/customer service unit.

We explained in the November 2018 proposed rule how 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 2016 final rule, states and managed care 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 proposed 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 amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010)).[9] 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 explained our rationale 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 noted as well how 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 communication for individuals with disabilities.

Additionally, we proposed 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 would align the documents that require taglines with the documents that must be translated into prevalent non-English languages and would facilitate the use of smaller, more user-friendly documents. We note that states would 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 would be a minimum standard.

In § 438.10(d)(3), we proposed to make the same substantive changes proposed for § 438.10(d)(2), as well as to reorganize the paragraph for clarity. We believed 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 proposed to limit the tagline requirement to materials that are critical to obtaining services, we proposed to delete § 438.10(d)(6)(iv).

The following summarizes the public comments received on our proposal to amend § 438.10 and our responses to those comments.

*Comment:* Many commenters supported the proposal to adopt the ''conspicuously visible'' standard for taglines in place of the ''no smaller than 18-point'' large print definition. Many commenters stated that the proposal would provide greater flexibility for communicating with beneficiaries, increase readability for beneficiaries, reduce costs and logistical efficiencies associated with printing and mailing, and provide greater consistency with overlapping Federal regulations. Many commenters supported the proposal to amend § 438.10(d)(2), (3), and (6) but requested that CMS define ''conspicuously visible.''

*Response:* We continue to believe that a more flexible requirement for taglines will continue to put enrollees and potential enrollees on notice of the availability of written translation, oral interpretation, and auxiliary aids and services for people who have limited English proficiency or a disability while helping to avoid unnecessarily long documents. We decline to include a specific definition or minimum font size in § 438.10, other than as specified in current § 438.10(d)(6)(iii). When adopting 45 CFR 92.8(f)(1), a regulation implementing section 1557 of the PPACA, the Office for Civil Rights (OCR), clarified that assessing the effectiveness of taglines ''is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the

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

[9] Nondiscrimination in Health Programs and Activities final rule (81 FR 31376 (May 18, 2016).

information.'' [10] We believe that definition is appropriate for Medicaid managed care programs, and we will use this in interpreting and enforcing the standards in § 438.10(d)(2) and (3) as revised. Notwithstanding this change in the regulation text, states and managed care plans have continuing obligations under Federal disability rights laws that in some circumstances require the provision of large print materials as an appropriate auxiliary aid or service, including materials in 18-point or larger font size, unless certain exceptions apply.[11] Additionally, we remind states and managed care plans of their obligations to comply with all Federal and state laws as specified at §§ 438.3(f) and 438.100(d) and that enrollment discrimination is expressly prohibited in § 438.3(d). States that elect to change the required font size for taglines should work with their managed care plans and stakeholders and local experts on disabilities to gather input on selecting the most appropriate characteristics of ''conspicuously visible.''

We note that OCR issued a notice of proposed rulemaking on June 14, 2019,[12] that proposed to eliminate § 92.8 and thus the use of the term ''conspicuously visible.'' In doing so, HHS stated that the proposed elimination of § 92.8 was intended in part to reduce redundancies while maintaining enforcement of civil rights statutes (84 FR at 27887). HHS did not intend in that proposed rule to direct the parameters of tagline requirements set forth in regulations such as § 438.10(d), which derive from statutory authorities other than section 1557 of the PPACA. Consequently, the intent of the proposed 1557 rule is not inconsistent with Medicaid's exercise of discretion in amending these regulations. We believe ''conspicuously visible'' reflects an appropriate level of protection for enrollees of Medicaid managed care plans and of the flexibility that we desire to provide to states and managed care plans. Therefore, regardless of whether that proposed rule is finalized, we are finalizing ''conspicuously visible'' in § 438.10(d)(2), (3), and (6) as explained in this final rule.

A typographical error was made in the proposed regulatory text at § 438.10(d)(2). The word ''language'' was erroneously written as singular: ''Written materials that are critical to obtaining services for potential enrollees must include taglines in the prevalent non-English language . . .'' It was not our intention to propose a change along those lines and 'language'' should have remained plural in the 2018 proposed rule. We are correcting this error in this final rule and finalizing the amendment to § 438.10(d)(2) with ''languages.''

*Comment:* Many commenters disagreed with the proposal to adopt the ''conspicuously visible'' standard for tag lines in place of the ''no smaller than 18-point'' large print definition. Commenters stated that this change would result in reduced access to plan information by enrollees and potential enrollees with visual impairment and the harm caused by this result should outweigh any possible benefit to other stakeholders. One commenter suggested that 12-point Times New Roman be adopted as the minimum. Several commenters stated that while aligning requirements across the health system is favorable, the ''conspicuously visible'' requirement adopted under the PPACA is overly vague and requested CMS provide greater clarity to the requirement to eliminate ambiguity. One commenter recommended that CMS include a requirement for states to provide a sample to CMS of what they determine meets the ''conspicuously visible'' standard.

*Response:* We acknowledge that adopting ''conspicuously visible'' is less descriptive and specific than ''no less than 18-point'' but do not believe that states will apply the conspicuously visible standard in a way that will reduce access to information or cause harm to beneficiaries with disabilities. States and managed care plans understand the importance of the information required by § 438.10 and benefit when beneficiaries read and utilize the information. We note that current § 438.10(d)(6)(iii) requires that all written materials for potential enrollees and enrollees use a font size no smaller than 12 point. We do not believe that it will be necessary for us to review a sample of what states determine to be conspicuously visible; we expect states and managed care plans to exercise due diligence in gathering input from experts in disabilities and other stakeholders in developing their materials to comply with the regulation as revised in this final rule.

We note that states and managed care plans were required to comply with § 438.10(d) by the beginning of rating periods that started on or after July 1, 2017 and finalizing the ''conspicuously visible'' standard in place of the 18-point font standard does not require states and managed care plans already in compliance to make changes. Continued use of 18-point font will comply with the regulation as amended here. This revision simply provides states and managed care plans with an option to select and use a different conspicuously visible font size to achieve the desired outcome. We remind states and managed care plans that they will be held accountable for compliance with § 438.10(d)(2) through (6) and with ensuring that all necessary steps are taken to adequately accommodate enrollees and potential enrollees that request information in large print or that request other formats or auxiliary aids and services. States and managed care plans have continuing obligations under Title VI and section 1557 of the PPACA to take reasonable steps to provide meaningful access to programs to individuals who have limited English proficiency. This may require states and managed care plans to provide documents and information in other languages to LEP individuals, including documents and information that are not ''critical to obtaining services''. Further, in assessing whether states and managed care plans have met this obligation, the Department considers whether recipients of Federal financial assistance take steps to identify LEP persons with whom it has contact, by providing notice of the availability of language assistance. HHS, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html.*

*Comment:* Several commenters stated that CMS failed to provide any evidentiary basis for how vision-impaired persons would be able to access plan information under this standard and stated that vision impairment is more common among the Medicaid-eligible population. Some commenters stated that this proposal violates section 1557 of the PPACA, which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability.

*Response:* Persons with disabilities, including vision impairments, make up a significant proportion of the Medicaid population. Under regulations implementing the ADA, section 504 of the Rehabilitation Act of 1973 and section 1557 of the PPACA, states and

[10] 81 FR 31397.

[11] See, for example, 28 CFR 35.104 (defining ''auxiliary aids or services'') and 35.160(a) through (b); 28 CFR part 164; 28 CFR 36.303(a) through (c) and (h); 45 CFR 84.52(d) and 92.202(a).

[12] Docket No.: HHS–OCR–2019–0007 (*https://www.federalregister.gov/documents/2019/06/14/2019-11512/nondiscrimination-in-health-and-health-education-programs-or-activities*).

managed care plans must take appropriate steps to provide effective communication to people with disabilities. This includes providing appropriate auxiliary aids and services to individuals with disabilities ''where necessary to afford individuals with disabilities, . . . [] an equal opportunity to participate in, and enjoy the benefits of, a service, program, or activity of a public entity.'' (28 CFR 35.160(b)(1); see also 28 CFR 36.303; 45 CFR 84.52(d) and 92.202.) ''Auxiliary aids and services'' is defined to include large print, and many other alternative formats used by individuals who are blind and vision-impaired. (28 CFR 35.104; 28 CFR 36.303(b)(1); 45 CFR 92.4.) Thus, separate and apart from these regulations, states and managed care plans have an obligation to make materials and information accessible to blind and visually impaired individuals. Regardless of how states and managed care plans apply the ''conspicuously visible'' standard, they must provide auxiliary aids and services, including large-print type under certain circumstances, to potential enrollees and enrollees upon request and at no cost under § 438.10(d)(3), (d)(5)(ii), and (d)(6)(iii). While we did not provide any empirical studies to address the use of a ''conspicuously visible'' standard, we do not believe that is necessary because it is a qualitative and not a quantitative standard; using a standard that focuses on whether the information is sufficiently conspicuous and visible that enrollees could reasonably be expected to see and be able to read the information avoids the ''one size fits all'' hazard that a quantitative standard that focuses only on font size could raise. We expect that states and managed care plans will be able to use size, font, color and other elements of their printed materials to make information conspicuously visible. It may be that for some materials, the font and color used are as effective, if not more effective, than merely making the font larger for individuals with disabilities to be able to see and read the information.

*Comment:* One commenter expressed concern that the proposed ''conspicuously visible'' standard will result in additional challenges for managed care plans if states create standards that greatly exceed the proposed requirement and as a result, requested that CMS adopt safeguards that would allow managed care plans to work with states to define standards that balance enrollee accessibility with administrative burden.

*Response:* We decline to include further criteria or safeguards in § 438.10. We encourage states to collaborate with their managed care plans, experts in older adults and persons with disabilities, and other stakeholders to determine appropriate characteristics of ''conspicuously visible''. However, we also remind stakeholders that states, under their own authority and state law, may impose higher or more protective standards to ensure enrollee access to information than the minimum imposed by § 438.10(d).

*Comment:* Many commenters agreed with the proposal to only require taglines on materials critical to obtaining services. They agreed that putting taglines on all written materials was unnecessary, impeded the use of certain effective forms of written communication, and created unnecessarily long documents that were not easy for enrollees to use.

*Response:* We agree that requiring taglines only on materials critical to obtaining services will help states and managed care plans create consumer-friendly documents that maximize effectiveness for the enrollee.

*Comment:* Many commenters disagreed with the proposal to replace the requirement to include taglines on ''all written materials'' with the requirement for taglines only on materials for potential enrollees and enrollees that ''are critical to obtaining services.'' Many commenters stated that taglines have proven to be a low-cost and effective means of communicating information to individuals with limited English proficiency (LEP) and people with disabilities and that this change would weaken beneficiary protections and result in reduced access to plan information by some enrollees and potential enrollees. Commenters also stated that the proposed requirement would give managed care plans or state agencies the ability to decide what materials meet this requirement, possibly resulting in important materials failing to be included, thereby reducing access and ability to make well-informed plan decisions for disabled, or LEP individuals. Many commenters further stated that this change is inconsistent with section 1557 of the PPACA and regulations implemented by HHS' OCR that ''covered entities'' must provide taglines on all ''significant'' documents and creates conflicting standards.

*Response:* As noted in this rule, ''conspicuously visible'' will be used to assess the effectiveness of taglines based on whether the content is sufficiently conspicuous and visible that enrollees and potential enrollees in the Medicaid managed care plan could reasonably be expected to see and be able to read the information.

In addition, we expect that states and managed care plans will exercise due diligence in determining which documents are critical to obtaining services. Requiring taglines on less than all written materials is consistent with Medicare Advantage, qualified health plans in the Marketplace, and current implementing regulations for section 1557 of the PPACA as issued by the HHS and OCR. While requiring taglines only on materials that are critical to obtaining services is a change from the 2016 final rule, we do not believe that it will disadvantage certain populations. Further, the availability of other resources for assistance such as a state's beneficiary support system or a managed care plan's phone lines and websites provide additional opportunities for potential enrollees and enrollees to access the information they need or want. We remind states and managed care plans that they have independent obligations under Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, section 1557 of the PPACA, and the ADA that may require them to do more than what 42 CFR part 438 requires.

We do not believe that we are creating a conflicting standard between documents that are ''critical to obtaining services'' versus requiring taglines on ''significant documents'' as used in § 92.8. The standard ''critical to obtaining services'' cuts to the heart of the role of Medicaid managed care plans: The provision of services to enrollees. By adopting a different standard, we preserve for the Medicaid program the ability to make different determinations about which documents must contain taglines. Therefore, we are finalizing the amendments to § 438.10 using the standard ''critical to obtaining services'' to identify the documents that must contain taglines. We believe states are in the best positon to apply the standard since they have the necessary information and familiarity with the documents to analyze the scope and purpose of each document. This standard and the lack of a definitive list provides the means to ensure that the proper documents used in each program and managed care plan contain taglines, based on the use and audience of each document.

*Comment:* A few commenters requested that CMS provide a targeted list of publications that require taglines. Many commenters requested that CMS include additional definitions clarifying which materials are ''critical to obtaining services'' to remove ambiguity to the greatest extent possible; however,

commenters did not provide specific examples. One commenter requested that CMS consider permitting taglines and non-discrimination statements be provided annually on at least one document that is critical to obtaining services, as opposed to on all ''significant'' publications.

*Response:* Section 438.10(d)(3) includes a non-exhaustive list of documents that are critical to obtaining services; we decline to further list documents that are ''critical to obtaining services.'' We do not believe that an exhaustive list can be provided in the § 438.10(d)(3) regulation as each state and managed care plan produces different types of documents and that states and managed care plans must apply the standard in the regulation to determine which documents are critical to obtaining services. Providing a list also runs the risk that regulated entities focus only on the list without conducting the necessary analysis to think through the purpose and scope of each document to identify each document that is critical to obtaining services. We clarify here that including taglines only on documents critical to obtaining services is a minimum standard, and therefore, states and managed care plans have the option to continue requiring (and including) taglines on all written materials. We also decline to adopt the commenter's suggestion that taglines only be required annually on at least one document that is critical to obtaining services. Finalizing the text as proposed provides states and managed care plans with sufficient responsibility and authority to identify the documents that require taglines. Only providing taglines annually and on as few as one document is not sufficient notification to enrollees.

*Comment:* One commenter expressed concern that the proposed changes to § 438.10(d)(2) and (3) seemed to be in conflict. Commenter stated that paragraph (d)(2) requires that written materials that are critical to obtaining services for potential enrollees include taglines 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). The commenter noted that paragraph (d)(3) requires that written materials that are critical to obtaining services include taglines 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. Commenter stated that if the written materials that are critical to obtaining services for potential enrollees overlap with written materials for enrollees, it is unclear what the tagline should say and requested clarification.

*Response:* As the tagline information required in § 438.10(d)(2) and (3) is the same except for the telephone number, we believe the commenter is requesting clarification on that aspect. As such, we clarify that if documents are intended for use with both potential enrollees and enrollees, the documents would need to comply with the requirements in both § 438.10(d)(2) and (3); that is, the document would need to include both the toll-free telephone number of the entity providing choice counseling services and the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit.

*Comment:* Commenters expressed concern that allowing managed care plans to decide which documents are critical to obtaining services has the potential to result in adverse selection, whereby plans would discourage enrollment by persons with significant health needs.

*Response:* States and managed care plans must comply with all applicable laws under § 438.3(f). Enrollment discrimination, including on the basis of health status, as well as on other prohibited bases, is expressly prohibited in § 438.3(d). Section 438.3(f) requires compliance with applicable civil rights laws, which prohibit discrimination more broadly than just with regard to enrollment. We believe that these requirements are sufficient to address this issue and remind stakeholders that nothing in our amendment to § 438.10 changes these other obligations.

*Comment:* One commenter expressed concern that the proposal to delete § 438.10(d)(6)(iv) appeared to delete the requirement that information on how to request auxiliary aids and services be included in a tagline and sought clarification as to whether that was CMS' intent.

*Response:* Our intent was to delete the requirement that the tagline be large print in a font size no smaller than 18-point, not to delete the requirement that a tagline provide information on how to access auxiliary aids and services. Instructions on how to access auxiliary aids and services is important information that should be included in a tagline. To correct this inadvertent error, we are finalizing additional revisions in paragraphs (d)(2) and (3) so that the list of information required to be included in taglines in § 438.10(d)(2) and (3) includes information on how enrollees can request auxiliary aids and services. We believe having all of the tagline elements in one sentence in each paragraph makes the requirements clear and easy to understand. We acknowledge that the availability of auxiliary aids and services is already addressed as a requirement in § 438.10(d)(3), (d)(5)(ii), (d)(6)(iii), and (g)(2)(xiii) but those references do not specifically require that the information be provided in a tagline nor precisely how a potential enrollee or enrollee can make a request. We believe revising the lists in § 438.10(d)(2) and (3) is the most effective way to ensure that the information on how to request auxiliary aids and services is provided as a tagline on all documents critical to obtaining services.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing amendments to § 438.10(d)(2) and (3) and (d)(6)(iv) substantially as proposed with a modification to § 438.10(d)(2) and (3) to add how enrollees can request auxiliary aids and services to the list of information required to be included in taglines and to make ''language'' plural in § 438.10(d)(2).

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 certain specified enrollees of a provider's termination within 15 days of a covered plan's receipt or issuance of the termination notice (67 FR 41015, 41100). 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). Currently, § 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 usually 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, we proposed at § 438.10(f)(1) to 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 require that 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.

The following summarizes the public comments we received on our proposal to amend § 438.10(f) and our responses to those comments.

*Comment:* Many commenters supported the proposal to change the requirement that managed care plans issue termination notices within 15 calendar days after receipt or issuance of the termination notice to the later of 30 calendar days prior to the effective termination date or 15 calendar days after the receipt or issuance of the notice. Many commenters agreed with CMS' rationale that it would reduce beneficiary confusion by reducing the number of unnecessary notices that they receive. Commenters also noted that the proposal aligns with commercial coverage practices and provides additional flexibility for managed care plans to negotiate with providers who are considering terminating their network contract and attempt to resolve the provider's underlying issue. One commenter stated that CMS should work with states to develop, implement, and deploy enforcement measures for this provision. One commenter recommended that CMS should monitor implementation of the new timeline.

*Response:* We believe it is prudent to allow managed care plans time to work with providers to potentially resolve the underlying issue and maintain a provider's network participation to avoid disrupting care for enrollees. To the extent that the new timelines for this notice that we are finalizing in this rule will permit Medicaid managed care plans to align their processes across different lines of business, we believe that is a bonus benefit to our goal of reducing the potential for confusion to enrollees. We do not believe that states nor CMS will need to develop new or unique enforcement mechanisms for this provision. States have existing oversight and monitoring processes which should be updated to reflect these new timeframes.

*Comment:* One commenter suggested that CMS require states or plans to maintain a hotline that enrollees can call to ask questions about and better understand notices of provider terminations to reduce confusion.

*Response:* States are required to have beneficiary support systems under § 438.71 and managed care plans customarily use their member/customer service units to assist enrollees with questions and information to comply with § 438.10(c)(7), which requires plans to have mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan. We do not believe it is necessary to mandate a separate mechanism to address questions about provider termination notices. We encourage plans to be proactive in notifying enrollees about the availability of the call center and other existing resources to deal with a provider's termination from the plan's network.

*Comment:* Many commenters disagreed with the proposal to change the requirement that managed care plans issue termination notices within 15 calendar days after receipt or issuance of the termination notice to the latter of 30 calendar days prior to the effective termination date or 15 calendar days after the receipt or issuance of the notice. Many commenters stated that patients should be given as much notice as possible to find a replacement provider to avoid disruptions in continuity of care which can have negative health outcomes and increase costs, especially with regard to specialists, patients with chronic conditions, disabilities, or linguistic challenges, and patients in rural areas. A few commenters stated that the risk of beneficiary confusion is outweighed by the risk to patients who may experience gaps in care as they seek alternative providers. Another commenter stated that the currently approved timeline is not adequate to maintain continuity of care and should instead be lengthened to at least 90 days. A few commenters provided additional recommendations, including ensuring that authorizations for services and the established timeframe be honored for patients transitioning to new providers.

*Response:* We understand that in some situations, permitting managed care plans to issue notices of certain provider terminations within 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, will result in an enrollee notification period that is shorter than the notification period currently required by § 438.10(f). We clarify here that the new timeframe finalized in § 438.10(f) is a minimum notification period; managed care plans are encouraged to provide enrollees more than the minimum required notification period to reduce the possibility of disruption in care. Additionally, enrollees should be educated and encouraged to utilize the numerous resources that can assist them with locating providers, such as their managed care plans member/customer service units, the state's beneficiary support system, and their managed care plan's provider directory. Some enrollees also have a case manager or care coordinator from whom they can receive assistance in locating a comparable provider. Managed care plans often include the contact information for comparable providers near the enrollee in the notice of termination and some plans utilize proactive outreach calls to assist enrollees in these situations. We encourage all plans to provide customized information and assistance to prevent disruptions in care from occurring. We agree with commenters that managed care plans should review existing authorizations for enrollees affected by a provider termination to ensure that disruptions in care are prevented. We remind states and managed care plans of their obligations under § 438.206 to ensure that all covered services must be available and accessible in a timely manner and that if a provider network is unable to provide necessary services covered under the contract, the managed care plan must timely and adequately provide them out-of-network. States also have program monitoring obligations under § 438.66 that should be used to monitor for access and continuity of care issues that arise from this change in notification time frame and adjust program policies accordingly.

*Comment:* One commenter recommended that notification of provider termination should include information on how the affected beneficiary can disenroll or select a plan

in which his or her provider participates.

*Response:* Section 438.56(c) and (d) list the reasons for which disenrollment from a Medicaid managed plan (including to switch to another plan, if offered) may be requested by an enrollee; termination of a provider from the plan network is not cause for disenrollment except in limited circumstances under that regulation. Aside from those reasons, and subject to certain limitations, states have the authority to determine additional reasons or periods for disenrollment. States and managed care plans have been addressing changes in provider networks based on provider terminations since the beginning of network-based managed care programs. In the absence of significant, systemic problems that need a Federal solution, we do not believe that additional regulation of states and plans in this way is necessary.

After consideration of public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendment to § 438.10(f)(1) as proposed.

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) which does not exist. We proposed in this rule to correct the reference to paragraph (g)(2)(ii)(A), which describes the applicable services to which paragraph (g)(2)(ii)(B) refers.

We received no public comments on this proposal and will finalize § 438.10(g)(2)(ii)(B) as proposed.

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) requiring each managed care plan to include information in its provider directory 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 Cures Act amended section 1902 of the Act,[13] to add requirements for publication of a FFS provider directory.[14] 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 directories 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 a directory include a provider's cultural and linguistic capabilities, including the languages spoken by the provider or by the skilled medical interpreter providing interpretation services at the provider's office. The statute does not require information on whether the provider has completed cultural competence training; therefore, we proposed 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 that information in an electronic directory must be updated no later than 30 calendar days after the managed care plan receives 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 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 proposed to modify the requirements for updating a paper provider directory that would permit less than monthly updates if the managed care plan offers a mobile-enabled, electronic directory.

We noted in the 2018 proposed rule that 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 (83 FR 57278); using updated data, research has shown that 67 percent of U.S. adults living in households with incomes less than $30,000 a year owned smartphones in 2018.[15] We discussed access to information through smartphones in the proposed rule: 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 [16] and recent studies show that the majority of Americans have used their smartphones to access information about their health,[17] and consider online access to health information important.[18] We explained our belief that providing mobile-enabled access to 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 [19] and medical claims on Blue Button [20] to empower enrollees to better manage and coordinate their healthcare. For enrollees that request a paper directory, we opined that quarterly updates would not significantly disadvantage them as other avenues for obtaining provider information are readily available, such as the managed care plan's customer service unit or the state's beneficiary support system.

To reflect this change in access to data and modify the requirements for updating a paper provider directory to permit less than monthly updates if the managed care plan offers a mobile-enabled directory, we proposed several revisions to § 438.10(h)(3). First, we proposed to add paragraphs (h)(3)(i) and (ii) to § 438.10 which would delineate requirements for paper directories from those for electronic directories. Second, we proposed to add paragraphs (h)(3)(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 would be required for plans that do offer a mobile enabled directory. Lastly, we proposed to make ''directories'' singular (''directory'') at

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

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

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

[16] *Id.*

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

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

[19] 2016 Medicare Marketing Guideline 100.6. *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf.*

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

§ 438.10(h)(3)(ii) which would avoid implying that a managed care plan must have more than one directory of providers.

In the proposed rule, we explicitly reminded 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 also encouraged 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.

The following summarizes the public comments we received on our proposal to amend § 438.10(h)(1)(vii) and our responses to those comments.

*Comment:* Several commenters supported the proposal to no longer require provider directories to note whether a provider has completed cultural compliance training and noted that doing so would ease administrative burden on plans and providers by better aligning the Medicaid managed care policy with the amendment to section 1902(a)(83) of the Act, made by the Cures Act. One commenter noted that completion of the cultural competency course was not an indicator of a provider's cultural capabilities for any particular culture and that many beneficiaries do not understand the significance of the notation in the provider directory, thereby reducing its importance.

*Response:* We appreciate the support for no longer requiring managed care plans to include an indication of cultural competence training as a required element in a provider directory. The statute does not require information on whether the provider has completed cultural competence training and we believe it's important to facilitate states aligning the requirements for their FFS directories with those of their managed care plans.

*Comment:* One commenter suggested that provider self-reported data be acceptable to meet the proposed requirement for the directory to report linguistic and cultural capabilities and that, if after solicitation, no capabilities are reported, the directory should list ''none reported'' as the cultural capabilities of that provider.

*Response:* We decline to amend the regulation to specify how to collect cultural competence data, including the degree to which self-reported data is reliable, and how a provider's cultural competencies or lack of cultural competencies should be displayed in a provider directory. We believe states are better suited to determine how to collect this information and how it should be displayed, particularly given that some states may elect to use a consistent format for their FFS and managed care programs.

*Comment:* Several commenters disagreed with the proposal to eliminate the phrase ''and whether the provider has completed cultural competence training'' from provider directories. These commenters stated that the change is unnecessary, removes important information for many beneficiaries seeking new providers and providers seeking to make effective referrals for existing patients, removes the incentive for providers to complete cultural competency training, and may increase health disparities in underserved beneficiary populations by potentially limiting a patient's confidence in choosing a provider that is best suited for them and preventing adequate access to healthcare services. Commenters noted that inclusion of the phrase would help ensure that a provider is sensitive to a patient's beliefs, practices, and culture, thereby strengthening the patient-provider relationship and improving the possibility of better health outcomes.

*Response:* We understand that some commenters consider an indication of cultural competence training in provider directories as useful information for enrollees and providers. However, we do not believe that removing a ''yes'' or ''no'' indicator reflecting the completion of training impacts the usefulness of the other information presented about cultural competencies nor that it necessarily indicates whether a provider is more sensitive to patients' beliefs, practices, and culture. Given that states are required to also display a provider's cultural and linguistic capabilities—which is far more descriptive than a ''yes/no'' indicator about training—in their FFS directories, we believe that they will select clear, consistent, and meaningful ways to display the information and ensure that their managed care plans do so as well.

*Comment:* A few commenters noted that displaying a provider's cultural and linguistic capabilities without also indicating whether the provider took a cultural competence training is not enough to adequately convey whether the individual has the skills or training to effectively communicate or provide language assistance. One commenter suggested that states should be required to maintain a list of providers who have completed cultural competency training.

*Response:* We clarify that displaying whether a provider has completed cultural competence training is not prohibited, it is merely not required under the amendment to § 438.10(h)(1)(vii) that we are finalizing in this rule. If managed care plans determine that displaying the information is useful, they may continue including it in their directory; similarly, states can adopt standards to require the directory to include more information than the Federal minimum adopted in § 438.10(h)(1). Additionally, if enrollees do not find a provider's linguistic competency adequate for effective communication, we encourage them to contact their managed care plan immediately for assistance. Under § 438.206(b)(1) plans are required to ensure adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities. We decline to require states and managed care plans to maintain a list of providers who have completed training and defer to states and managed care plans to decide if doing so would be useful for their enrollees.

After consideration of public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendment to § 438.10(h)(1)(vii) as proposed.

The following summarizes the public comments received on our proposal to amend § 438.10(h)(3) and our responses to those comments.

*Comment:* Many commenters supported the proposal to require only quarterly updates for paper directories for plans that offer a mobile enabled directory in lieu of monthly updates. These commenters stated that the proposal strikes a suitable balance for streamlining access between electronic and print formats, increases consistency with the Medicare Advantage program, reduces administrative burden and environmental impact while having

minimal negative impact to enrollees, and incentivizes plans to invest in mobile enabled features that improve beneficiary experience.

*Response:* We believe enrollees will appreciate the increased ease of access to provider directory information and believe that decreasing the rate of updates to paper directories when there is a mobile-enabled electronic alternative to the paper provider directory is an appropriate way to ensure enrollee access to information about the network of providers.

*Comment:* Several of the commenters cited concerns with potential ambiguity regarding the term ''mobile-enabled'' and requested CMS provide a definition of the term to ensure that states and plans are able to take full advantage of the offered flexibility while reducing administrative burden for plans that may be required to meet different standards across multiple states. Several commenters recommended that CMS not limit rulemaking to mobile ''applications'' and that ability to access an online printable directory, search tool, or provider directory formatted for viewing on a mobile device should be considered compliant with the proposed requirement.

*Response:* We use the term ''mobile-enabled'' to mean a mobile website or a mobile application; we defer to states and managed care plans to determine whether a mobile website or application is most appropriate for each applicable managed care program and managed care plan, provided that the end result is that the provider directory is mobile-enabled as explained here. As we outlined in the proposed rule, we believe that making the provider directory information usable for smartphone or mobile technology users is the key point, not the technology or format used to accomplish that. A mobile-enabled website could include a mobile friendly, mobile optimized, or a responsive design. A true mobile enabled website will automatically detect what environment each visitor is using to access the website, then display it in the format best for that device, whether a smartphone, tablet, or other mobile device is used. With a mobile-enabled website, the navigation and content are reorganized so that the web page fits the browser window for the device used, and the pages are made ''lighter,'' so they download more quickly. Our goal with proposing to reduce the frequency of paper directory updates if a mobile-enabled directory is available is to improve the enrollee's ability to navigate and utilize the directory information when accessing it on a mobile device. We would expect features such as small image sizes to allow for fast loading, simplified navigation that is ''thumb'' friendly, reduced graphics that do not interrupt access to critical information, and text-based phone numbers, physical addresses, or email addresses that can trigger a call, directions, or email message from the mobile device to be included in a mobile-enabled provider directory. Managed care plans may find it helpful to visit HHS' website for Building and Managing websites; it sets out different stages of ''mobile'' that could serve as a useful guide when determining which enhancements would be useful to the end user.[21] HHS guidance notes that when developing exclusively mobile versions of websites, these ''microsites'' should be designed for mobile accessibility. These sites should contain code specific to, and designed for, mobile web tasks and browsing. These microsites often contain pared down information on the same topics covered on the main site. Additionally, content should be written in such a way as to be read easily on a mobile device, usually in small text groupings of about three to four lines of text and provide the most important information at the top of the page, so that the site user has access to the most important information quickly.

By providing guidance on what it means for the provider directory to be mobile-enabled, we aim to establish a base for the characteristics of a mobile-enabled website without restricting website developers. States and managed care plans can determine whether a mobile website or application is most appropriate to provide access that meets the regulatory standard.

We do not consider merely being able to access a managed care plan's provider directory from its website on a mobile device or a printable online directory to be mobile-enabled. A website that is not mobile-enabled, is usually very difficult to read when accessed using a mobile device, often requiring the user to zoom, scroll, and manipulate the image to view it. Additionally, we clarify that § 438.10(c)(6) already requires that required enrollee information, which would include a provider directory, provided electronically by a managed care plan must be in an electronic format which can be retained and printed; the standard for mobile-enabled provider directories, which are only relevant for purposes of identifying the frequency of updates to the paper provider directory, is different than what is required by § 438.10(c)(6).

[21] *https://www.hhs.gov/web/building-and-managing-websites/mobile/index.html.*

*Comment:* Commenters recommended that CMS clarify that the proposed changes apply to duals programs, including Dual Eligible Special Needs Plans (D–SNP) and Medicare-Medicaid Plans (MMP).

*Response:* To the extent Part 438 applies to (1) a D–SNP (if it is also a Medicaid MCO, PIHP, PAHP, and, in some cases, PCCM, or PCCM entity), or (2) a MMP under the capitated financial alignment model demonstrations, § 438.10(h)(3)(i)(B) would also apply.

*Comment:* One commenter recommended that CMS require electronic notification to enrollees and providers of availability of updates and another commenter recommended that CMS work with states to develop, implement and deploy enforcement measures for these provisions.

*Response:* We are not finalizing a new rule to require electronic notification to enrollees and providers of updates to the provider directory. We believe the commenter is referencing updates necessary for mobile applications. If so, the use of a mobile enabled application is at the option of the state and managed care plan as a means to provide a mobile-enabled provider directory as described in § 438.10(h)(3). However, if a software application is used and updates to the application are required, we would expect the necessary notifications to be sent to users of the application. We do not believe that states will need to develop new or unique enforcement mechanisms for this provision.

*Comment:* Several commenters expressed that CMS should only require that printed provider directories be distributed upon request.

*Response:* Managed care plans must provide paper directories upon request per § 438.10(h)(1), which provides that each MCO, PIHP, PAHP, and when appropriate the PCCM entity, must make available in paper form upon request and electronic form. We remind managed care plans that if required information is provided electronically instead of on paper, § 438.10(c)(6) applies. Therefore, use of a mobile-enabled directory will not satisfy the requirement to provide the provider directory in electronic form; use of a mobile-enabled provider directory is relevant only for purposes of identifying the updating schedule with which a managed care plan must comply under § 438.10(h).

*Comment:* A few commenters recommended that CMS require managed care plans that meet the condition for quarterly updates to produce update flyers upon request or a customer support phone line with after-

hours capacity. Some of these commenters also expressed that the customer support phone line should not only provide contact information for providers, but also assist in making appointments and allow for patients and providers to update Medicaid managed care plan network records.

*Response:* We are not incorporating these suggestions into the regulatory requirements for managed care plans as we do not believe that they are necessary to ensure enrollee access to the provider directory. We encourage managed care plans to insert errata sheets into paper directories to reflect the most up-to-date provider information, provide extended customer service hours, offer appointment setting assistance, and utilize effective electronic mechanisms for collecting provider directory information.

*Comment:* One commenter recommended that printed provider directories be provided in a format that permit directories for certain geographic areas—as Medicare permits—rather than by the entire managed care plan's service area. This commenter further noted that in a large state, provider information for the entire state may not be useful to members in a specific region and that member's need provider information on a reasonable service area based on where they access health services. Another commenter recommended that printed directories for an entire service region of a managed care plan should only be required annually.

*Response:* Section 438.10(h) requires that each MCO, PIHP, PAHP, and when appropriate PCCM and PCCM entity make available—in paper form upon request and electronic form—certain specified information about the providers in its network. There is no requirement in § 438.10(h) for a single directory to be printed for a managed care plan's entire service area. States can permit or require their managed care plans to print directories for areas less than the entire service area if the state has determined that best meets the needs of their enrollees given known utilization and travel patterns within the state. This would allow more customized, consumer friendly directories to be sent and is well suited to on-demand printing rather than bulk printing. On-demand printing allows managed care plans to print the directory data from the current on-line version, thus allowing enrollees using printed versions to receive the same information as enrollees using an electronic directory. We remind managed care plans that enrollees must be able to access information on a plan's entire network if they choose to and that all information required by § 438.10 must be provided in paper form upon request, at no cost, and within five business days. Plans subject to this requirement can provide paper versions of directories that cover smaller areas (if permitted by the state) so long as, in aggregate, the paper directories provide the necessary information for the plan's entire service area and entire network.

*Comment:* A few commenters requested that CMS consider alternatives to the proposed requirements for printing provider directories such as providing monthly updates or inserts.

*Response:* We believe the commenter is suggesting that errata sheets alone should be permitted to be sent to enrollees in lieu of an entire directory but the comment is not clear as an errata sheet is merely an update to what is included in the provider directory, so sending only the errata sheet would not seem useful if the paper directory that was being updated with new provider information had not first been provided. If being used to meet the monthly paper director update requirement in § 438.10(h)(3), errata sheets must be inserted into a paper directory. We point the commenter to the response in this final rule which clarifies another option that states may permit; specifically, that the printing of partial directories is permissible when requested by an enrollee and if allowed by the state.

*Comment:* One commenter stated that managed care plans exempted from the requirement to timely update their paper directories should be required to display conspicuously on their paper directories and websites that real-time assistance is available along with the number to call to obtain such assistance.

*Response:* We do not believe that additional revision to paragraph (h)(3) along these lines is necessary. The phone number for assistance is already required in § 438.10(d)(3) which specifies that managed care plans must include a tagline on all provider directories and that taglines must contain the toll-free and TTY/TDY telephone number of the plan's customer/member services unit. This requirement for providing the tagline about the customer/member services unit applies regardless whether the managed care plan makes available a mobile-enabled provider directory and regardless of the updating schedule for the provider directory.

*Comment:* Many commenters disagreed with the proposal to only require quarterly updates to paper provider directories if mobile enabled directories are available. Many commenters stated that there continues to be too high a percentage of people among the Medicaid-eligible population and among people with disabilities that do not have sufficient understanding of or have access to mobile devices or broadband internet service [22] to justify reducing the frequency of updates to paper directories and that this proposal would result in increased difficulty and burden navigating the healthcare system and accessing care. Several commenters cited census data indicating half of households with annual incomes under $25,000 lack a computer, broadband internet access, or both, expressed that the proposed changes are premature given the absence of research on enrollee preferences for print versus mobile/electronic formats, and stated that CMS should engage in active compliance monitoring and enforcement actions when plans fail to meet existing standards. One commenter cited the National Association of Insurance Commissioners' (NAIC) recent update to their network adequacy model act which included provisions requiring plans to update their provider directory at least monthly.

*Response:* We acknowledge that not all Medicaid enrollees have a smartphone or internet access, but studies have shown that 67 percent of U.S. adults living in households with incomes less than $30,000 a year owned smartphones in 2018.[23] We understand that the challenges of paper printing do not diminish a segment of the population's need for paper directories, nor should it diminish plans' efforts to produce accurate paper directories.[24] However, we do not believe those issues lessen the value of increasing access to the directory for those portions of the population that choose to utilize electronic methods. Per § 438.10(h)(3), managed care plans must update paper provider directories at least monthly after the managed care plan receives updated provider information. Managed care plans could take steps to alleviate discrepancies between directory updates such as inserting an errata sheet before mailing, printing on demand a directory that covers less than a plan's entire service area when requested by an enrollee, and ensuring that their customer service, care management, and nurse help line (if applicable) staff have

[22] *https://www.pewresearch.org/fact-tank/2017/04/07/disabled-americans-are-less-likely-to-use-technology/.*

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

[24] *https://www.pewresearch.org/fact-tank/2017/04/07/disabled-americans-are-less-likely-to-use-technology/.*

access to the most updated data and are prepared to assist enrollees with locating network providers. Managed care plans should also ensure that their network primary care providers have easy access to updated provider directory information since primary care providers are frequently the source of specialty referrals for enrollees. Lastly, managed care plans should be sensitive to the disparities in the use of electronic information when providing resources for their telephone hotline, and providing auxiliary aids and services to people with disabilities.

After consideration of public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendments to § 438.10(h)(3) as proposed.

9. Disenrollment: Requirements and Limitations (§ 438.56)

We inadvertently included PCCMs and PCCM entities in § 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 proposed 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.

No public comments were received on this provision. For the reasons outlined in the proposed rule, we are finalizing the amendment to § 438.56(d)(5) as proposed.

10. Network Adequacy Standards (§ 438.68)

Currently, § 438.68(b)(1) requires states to develop time and distance standards for specified provider types if covered under the contract. In the 2016 final rule, we declined to set other national requirements or specific benchmarks for time and distance (for example, 30 miles or 30 minutes) as we believed it best not to be overly prescriptive and we wanted to give states the flexibility to build upon the required time and distance standards as they deemed appropriate and meaningful for their programs and populations. (81 FR 27661). We proposed revisions to § 438.68(b)(1) to require states to use a quantitative standard, rather than only a time and distance standard, for providers. We explained in the proposed rule how as states have worked to comply with the 2016 final rule, they have alerted us to increasing concerns about the appropriateness of uniformly applying time and distance standards to the specified provider types across all programs. 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 the 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. To address states' concerns and facilitate states using the most effective and accurate standards for their programs, we proposed to revise § 438.68(b)(1) and (2) by deleting the requirements for states to set time and distance standards and adding a more flexible requirement that states set a quantitative network adequacy standard for specified provider types. We explained in the proposed rule that 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 encouraged 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.

We stated that this proposed 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, particularly for LTSS programs given the often very limited supply of providers and the potential functional limitations of the LTSS population. We proposed to remove § 438.68(b)(2)(i) and (ii) and reflect all LTSS network adequacy requirements in § 438.68(b)(2). Currently, § 438.68(b)(1) specifies the provider types for which states are required to establish network adequacy standards and § 438.68(b)(1)(iv) requires states to establish time and distance standards for ''specialist, adult and pediatric.'' As noted in the 2016 final rule, we believed 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 believed it was 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 clarified that our proposal would give states 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 proposed 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.

Currently, § 438.68(b)(1)(viii) requires 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). 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 this state input, we proposed to remove § 438.68(b)(1)(viii) to eliminate any uncertainty states may have regarding this requirement.

The following summarizes the public comments received on our proposal to amend § 438.68 and our responses to those comments.

*Comment:* Many commenters supported the proposal to delete the requirement for states to establish time and distance standards and instead require any quantitative standard. Commenters stated that not requiring the use of time and distance increases flexibility to states and will have a positive impact on more accurately assessing access to telemedicine. Many commenters offered recommendations including requiring states to use a combination of data-driven quantitative

and qualitative standards for capacity, availability, and accessibility that have been cooperatively developed with stakeholders to ensure appropriate network access and patient satisfaction that is reasonable and achievable. A few commenters recommended requiring states to establish separate standards for rural and urban areas that align with the Medicare Advantage managed care program. One commenter recommended setting a maximum number of measures that can be implemented by states.

*Response:* While we agree that states should use a combination of data-driven quantitative and qualitative standards that have been developed with stakeholder input to comprehensively assess network adequacy, we do not believe that it is appropriate to include that as a requirement in the regulation. As we noted in the proposed rule, 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. We decline to require states to establish separate standards for rural and urban areas or to align their standards with those used in the Medicare Advantage program, but note that § 438.68(b)(3) permits states to vary network adequacy standards for the same provider type based on geographic areas. We also decline to limit the number of measures a state can implement to assess network adequacy. We believe states are in the best position to determine the most appropriate number and type of quantitative measures to provide them with the information needed to effectively manage their programs, as well as fulfill their obligations under §§ 438.206 and 438.207.

*Comment:* Commenters recommended requiring states and health plans to routinely monitor their standards and network performance for alignment with needs of the enrolled population and that states enforce these standards through corrective action when necessary. Additionally, commenters recommended requiring states to measure network access at the subnetwork level, that is, when a managed care plan restricts its enrollees to using only a portion of the plan's larger network, if managed care plans impose subnetwork access requirements on enrollees. Some commenters recommended requiring adequacy standards for specific specialties and provider types. A few commenters suggested that CMS encourage states to acknowledge differences in provider types, particularly for pharmacies, as patients have multiple options outside of brick-and-mortar establishments to fill prescriptions such as mail order and home delivery, which do not lend themselves easily to inclusion under typical network adequacy standards. Commenters stated CMS should give states the flexibility to set different standards for pharmacies due to their unique features.

*Response:* We expect states and health plans to routinely monitor their network performance against the standards established by the state under § 438.68 as amended in this final rule; we believe that states will set these standards in alignment with, and taking into account, the needs of the covered population. We also expect that states will take corrective action when necessary. The timeframes for submission of network adequacy documentation required by § 438.207(c) is a minimum, and states and managed care plans should use network adequacy measurement as a tool that can be utilized at any time to proactively identify trends and address issues. Under § 438.68, network adequacy standards can be set at whatever level a state deems appropriate; thus, states that have plans utilizing subnetworks, could establish and measure network adequacy at that level. We decline to specify additional provider types as suggested by commenters in § 438.68(b)(1) nor to add more categories or types of ''pharmacies'' in § 438.68(b)(1)(vi), but clarify here that the provider types listed are a minimum. States are free to apply network adequacy standards to additional provider types as they deem appropriate for their programs.

*Comment:* One commenter recommended stipulating that telehealth providers may only be counted toward a managed care plan's network adequacy when that provider is actively providing services to CHIP/Medicaid beneficiaries in that community and the managed care plan has demonstrated that its telehealth coverage policies and practices offer parity to telehealth providers.

*Response:* We defer to each state to determine the criteria to be applied to telehealth providers and how such providers would be taken into account when evaluating network adequacy of the state's Medicaid managed care plans. Section 438.68(b) does not set criteria of this nature that states must use. Under § 438.68(c)(1)(ix), states must consider the availability and use of telemedicine when developing their network adequacy standards. If states elect to include telehealth providers in their network adequacy analysis, we believe that the states will establish criteria that appropriately reflect the unique nature of telehealth, as well as the availability and practical usage of telehealth in their state.

*Comment:* Several commenters stated that CMS should, at minimum, encourage states to consider the following when establishing standards and measuring network adequacy: Regionalization of specialty care; co-located service offerings; enrollee ratios by specialty; geographic accessibility including proximity to state lines; foreseeable road closures; wait times by specialty based on provider hours and availability; volume of technological and specialty services available to serve the needs of covered persons requiring technologically advanced or specialty care; diagnostics or ancillary services; patient experience survey data, and minimum appropriate providers available to meet the needs of children and adults with special health care needs.

*Response:* We believe these factors could be valuable additions to states' network adequacy review process, and therefore, encourage states to consider them, although we decline to mandate their use in § 438.68. We also remind states to be cognizant of the mental health parity provisions applicable to MCOs, PIHPs, and PAHPs in § 438.910(d) when selecting measures of network adequacy. Plans also need to be mindful of their responsibilities for mental health parity under part 438, subpart K, in network development and evaluation. We believe that states are in the best position to determine the most appropriate measures for use in their programs to address the local needs of their populations.

*Comment:* A few commenters recommended baseline or minimum provider time and distance, patient-provider ratios, and timely access standards which could be used to inform state-developed network adequacy standards. A few commenters suggested specific minutes and miles standards while another suggested specific appointment wait time standards. One commenter stated that giving states too much flexibility could result in significant variability across states thereby increasing administrative burden for plans which operate in multiple states.

*Response:* As we stated in the 2016 final rule (81 FR 27661), we decline ''to adopt quantitative standards for time and distance.'' Underlying that 2016 final rule with regard to § 438.68(b) and our 2018 proposed rule is a belief that states should be allowed to set appropriate and meaningful quantitative standards for their respective programs. States are in the best position to set specific quantitative standards that

reflect the scope of their programs, the populations served, and the unique demographics and characteristics of each state.'' We reiterated this position in the proposed rule and continue to believe that we should defer to states and not set Federal standards as prescriptive as the commenters suggest. We understand that providing states this level of flexibility could result in widely varied standards but given the diversity and complexity of Medicaid managed care programs, such variation may be warranted. We encourage states and managed care plans to collaborate on the development of network adequacy standards and for plans that participate in Medicaid in multiple states, to share information with states so that best practices and lessons learned can be leveraged to improve network adequacy measurement in all states. States should consider using technical expert panels and multiple sources of stakeholder input to ensure that they develop robust and appropriate network adequacy measures for their programs.

*Comment:* A few commenters suggested that CMS provide additional clarification and detail regarding ''quantitative network adequacy standards,'' specifically asking if CMS recommends weighing variables a certain way, whether variables will be adjusted for different provider types that might have varying data based on their demands and location, what will be the reporting sources for network adequacy data and if they are self-reported, how will states ensure minimal subjectivity in the data, and how will standards such as ''minimum percentage of contracted providers that are accepting new patients'' be implemented.

*Response:* We decline to include additional specificity in § 438.68 addressing considerations for state development or implementation of network adequacy standards. We believe the list in § 438.68(c) reflects an appropriate level of detail. The commenters' suggestions may be useful to states and we encourage states to consider them as appropriate.

*Comment:* A few commenters recommended that CMS outline possible quantifiable standards that could supplement time and distance standards or provide additional guidance regarding the types of quantitative network adequacy standards that could be adopted by a state. A few commenters suggested that CMS convene a group of stakeholders or experts to address issues regarding network adequacy standards such as clear definition and suggested guidelines of what constitutes network adequacy, including as they relate to populations that access LTSS provided in the home.

*Response:* We decline to adopt or implement these recommendations as we believe that providing states with the flexibility to identify the type of quantitative standard, as well as the standard itself for purposes of establishing and measuring network adequacy in Medicaid managed care programs, is appropriate in light of the traditional role of states in administering Medicaid. We continue to believe that we should defer to states and not set overly prescriptive Federal standards. We note here that we convened a group of states to gather information on their best practices and lessons learned about network adequacy. The resulting document was published in April 2017: *Promoting Access in Medicaid and CHIP Managed Care: A Toolkit for Ensuring Provider Network Adequacy and Service Availability* and is available at *https://www.medicaid.gov/medicaid/managed-care/downloads/guidance/adequacy-and-access-toolkit.pdf.* This toolkit, designed as a resource guide for state Medicaid and CHIP agency staff, is intended to: Assist state Medicaid and CHIP agencies with implementing the requirements of the new Federal rule related to network adequacy and service availability standards; provide an overall framework and suggest metrics for monitoring provider network adequacy and service availability, as well as Medicaid and CHIP managed care enrollees' access to care overall; and highlight effective or promising practices that states currently use to develop and monitor provider network and access standards, and promote access to care. We encourage states and managed care plans to review the Toolkit as they establish standards under § 438.68.

*Comment:* One commenter noted that states should be required to consult with American Indian/Alaskan Native (AI/AN) tribes to determine quantitative network adequacy standards and specialists to which the standards would apply, such that gaps in coverage and limitations in access to care for AI/ANs in tribal communities are minimized.

*Response:* We agree that states should engage in robust stakeholder engagement when developing their network adequacy standards to ensure inclusion of appropriate provider types based on the needs of the covered populations. We remind states of their obligations for tribal consultation as specified in Section 1902(a)(73) of the Act as well as additional guidance issued in State Medicaid Director Letter 10–001 (*https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10001.PDF*).

*Comment:* Many commenters disagreed with the proposal to delete the requirement for states to set time and distance standards and instead require a quantitative minimum access standard. Commenters stated that current requirements already provide states with adequate flexibility in establishing network adequacy standards and are necessary to avoid narrowing of existing networks to ensure plans make every effort to safeguard patient access. Several commenters expressed that not enough time has passed since the associated provisions in the 2016 final rule became effective to form an evidentiary basis from which to determine whether the proposed changes are necessary.

*Response:* We believe that, while useful and appropriate for many plans and areas, time and distance analysis may not always produce results that accurately reflect provider availability within a network. We believe that deleting the requirement to use a time and distance standard for all of the required provider types will enable states to choose from a variety of quantitative network adequacy standards that meet the needs of their respective Medicaid managed care programs in more meaningful and effective ways. We clarify that the proposed change to § 438.68(b)(1) does not require states currently using a time and distance standard to cease using, or make changes to, their standard. The proposed change merely offers states an option to use a different adequacy standard if they believe that time and distance is not the most appropriate standard for their program.

*Comment:* Many commenters noted that removal of current measures may result in additional burden to providers, as well as enrollees residing in rural areas and would increase risk and negatively impact health outcomes for children and underserved populations.

*Response:* We do not believe that providing states with the option to use a different quantitative standard than time and distance will add provider burden or negatively impact health outcomes for children and underserved populations. Our expectation is that if states use a variety of quantitative measures designed to produce the most accurate and comprehensive assessment possible of network adequacy of providers needed for services covered under the contract, providers and enrollees should benefit from that because adequate access to necessary providers will have been ensured.

*Comment:* One commenter stated that the proposed rule fails to meet the statutory requirement that the Medicaid managed care plans provide assurances that it ''maintains a sufficient number, mix, and geographic distribution of providers of services'' as directed in section 1932(b)(5) of the Act and that time and distance standards are the only standards described in the proposed rule which can make these assurances. This commenter further stated that CMS lacks the legal authority to eliminate the statutory requirement that Medicaid managed care plans assure the state and the Secretary that it maintains a sufficient ''geographic distribution of providers of services.''

*Response:* We disagree that time and distance is the only standard that can produce information sufficient to enable a managed care plan to attest that it maintains a sufficient number, mix, and geographic distribution of providers of services. Time and distance standards are one of many quantitative measures that states and managed care plans can use, alone or in combination, to assess provider networks and ensure a sufficient number, mix, and distribution of providers. 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). We clarify that our proposal in no way eliminates the statutory requirement that managed care plans assure the state and the Secretary that it maintains a sufficient geographic distribution of providers of services. That requirement is unaffected by this change and implemented by § 438.207.

*Comment:* Many commenters expressed concern with CMS' rationale for the proposal regarding the impact of telemedicine on the efficacy of time and distance standards (83 FR 57278). Commenters noted that telehealth and telemedicine cannot offer the full array of services that are otherwise available to a patient who is physically present in a provider's office. Commenters stated that states should be required to develop separate network adequacy standards for telemedicine, but maintain standards for traditional service delivery, and noted that in-person access should remain a priority when measuring network access as many situations are not applicable for the use of technology-enabled care.

*Response:* We understand the commenters' concerns but clarify that it was not our intent to imply that telehealth offers the full array of services that are otherwise available to a patient who is physically present in a provider's office. We used telehealth as an example of a situation where measuring access using a time and distance standard may not be optimally effective to evaluate the adequacy of a provider network and the ability of the plan to ensure access to services. We agree that states need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68 that accurately reflect the practical use of both types of care in their state. Under § 438.68(c)(1)(ix), states must consider the availability and use of telemedicine when developing their network adequacy standards.

*Comment:* Some commenters recommended requiring states to establish standards that align with other regulatory provisions (such as those applicable to Qualified Health Plans (QHPs) or Medicare Advantage plans), and the Medicaid statute at section 1932(c) of the Act (cited by the commenter as 42 U.S.C. 1396u–2(c)), which requires states to establish standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity. The commenters stated that alignment with these provisions would ensure reasonable timelines for access to care and continuity of care. A few commenters recommended requiring states, contracted managed care plans, and pharmacy benefit managers to follow Medicare Part D regulatory guidance on access to specialty medications.

*Response:* We decline to require states to align their network adequacy standards with the standards applicable to other programs (such as standards for QHPs, Medicare Advantage or Medicare Part D). We believe that the states establishing and assessing their managed care plans' networks using the standards required in § 438.68 will ensure compliance with the statute. However, we clarify that § 438.68 is consistent with section 1932(c)(1)(A)(i) of the Act, which requires states to develop and implement a quality strategy that includes standards for access to care so that covered services are available within reasonable timeframes and that ensure continuity of care. We believe that the managed care regulations at § 438.206, which requires that states ensure that all services covered under the contract are available and accessible to enrollees, and § 438.68, which requires states to develop network adequacy standards, work together to ensure that states meet their obligations under the Act. We acknowledge that states may find some of those standards to be appropriate for their Medicaid managed care programs and that adopting existing measures may reduce the amount of time states have to spend developing standards, as well as reduce operational burden on managed care plans that also participate in other programs. States should review standards used by other programs and evaluate their potential usefulness in their Medicaid managed care programs. However, we believe that state flexibility on this point is paramount and will not impose alignment as a requirement.

*Comment:* Several commenters supported the proposal to give states the authority to define ''specialist'' in whatever way they deem appropriate for their programs. Some commenters offered suggestions for specific types of specialists that we should require states to include in their definition of ''specialist.'' A few commenters recommended that CMS provide guidance to states on specialties that should be considered or included in each category listed in § 438.68(b)(1) and prioritize provider types to help avoid undue administrative burden on plans due to variability across states.

*Response:* We appreciate the comments in support of our proposal to clarify that states have the authority to designate ''specialists'' to which network adequacy standards will apply under § 438.68(b)(1). We decline to identify additional specific specialties or provider types for states to include in this category. We believe states are best suited to identify the provider types for which specific access standards should be developed in order to reflect the needs of their populations and programs. We note that States' network adequacy standards are included in their quality strategies and are subject to publication and public comment consistent with existing transparency provisions in § 438.340(c)(1).

*Comment:* Many commenters disagreed with the proposal to allow states to define ''specialist'' in whatever way they deem appropriate and recommended that CMS identify specific provider types as specialists. One commenter stated that CMS should define specialists to include providers who focus on a specific area of health and include sub-specialists who have additional training beyond that of a specialist. Some commenters

recommended requiring states to include specific specialists including hematologists, adult and pediatric oncologists, surgical specialists, pulmonologists, allergists, and emergency physicians. One commenter recommended that CMS revise its proposed language to state ''(as designated by the state in a manner that ensures access to all covered services),'' which would reiterate the need for states to ensure that managed care plan's provider networks guarantee full access to all benefits covered under the state plan and are representative of the types of providers that frequently provide services to consumers within their corresponding service areas.

*Response:* We understand commenters' concerns but do not agree CMS should define ''specialist'' in § 438.68(b)(1)(iv). As noted in the 2016 final rule on this topic, we believe that states should set network adequacy standards that are appropriate at the state level and are best suited to designate 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 identify at the Federal level specific specialists for which each state must establish an access standard (81 FR 27661). We expect states to apply network adequacy standards to all provider types and specialties necessary to ensure that all services covered under the contract are available and accessible to all enrollees in a timely manner as required by § 438.206.

*Comment:* Commenters noted that allowing states to define ''specialist'' may inadvertently limit access for enrollees to covered services, result in higher costs if certain categories of specialists are no longer in-network, lead to inconsistent application of the policy when patients see physicians in another state that defines specialists in different ways, and decrease quality of care in states that create standards which allow less qualified providers (for example, nurse practitioners in lieu of doctors) to meet ''specialist'' criteria. One commenter expressed concern that allowing states to define ''specialist'' could negatively affect national quality measures that rely heavily on certain provider types rendering care to count towards numerator compliance.

*Response:* We do not agree that allowing states to designate which specialists are subject to the required network adequacy standards is likely to limit access, increase costs, lead to lower quality of care, promote inconsistent application due to differing designations among states, or affect the accuracy of national quality measures. Network adequacy standards are utilized by managed care plans and states to assess network adequacy at an aggregate level on a periodic basis. Meaning, network adequacy standards are not used to determine the availability of, or authorize care by, a particular type of provider for an individual enrollee. We believe that § 438.206 is sufficiently clear on states' and managed care plans' responsibilities for ensuring that all covered services are available and accessible to enrollees in a timely manner, including specifically addressing situations when an enrollee's managed care plan's network is unable to provide necessary services in § 438.206(b)(4). Managed care plans must necessarily develop their networks in ways that enable them to comply with all of their obligations under §§ 438.206 and 438.207. Lastly, although we do not see a correlation between the specialists a state chooses to include for network adequacy purposes and provider types necessary for calculating quality measures, states can include specialists that are implicated in quality measure calculations if they so choose.

*Comment:* Several commenters suggested that the final rule should instruct states that their designations of specialists for purposes of § 438.68(b), and any network adequacy standards, must be consistent with existing state laws regarding licensure and certification, as well as the Medicaid managed care nondiscrimination regulation which prohibits managed care plans from discriminating against providers based on their licensure or certification.

*Response:* States and managed care plans must comply with all applicable Federal and state laws as specified in §§ 438.3(f) and 438.100(d) and provider discrimination is specifically prohibited in §§ 438.12 and 438.214. Specifically, § 438.12 prohibits managed care plans from discrimination in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable state law, solely on the basis of that license or certification and § 438.214(c) specifies that managed care plans are prohibited from discriminating against providers that serve high-risk populations or specialize in conditions that require costly treatment. We do not believe that the requirement on states to establish network adequacy standards in § 438.68(b) contravenes or limits these other provisions, or that an amendment to § 438.68 to incorporate similar requirements about non-discrimination is necessary or appropriate.

*Comment:* A few commenters agreed with the proposal to eliminate the requirement for states to establish time and distance standards for ''additional provider types'' identified by CMS because it will foster experimentation and innovation to improve care delivery as well as streamline assessment of network adequacy.

*Response:* We believe removing the requirement for states to establish time and distance standards for ''additional provider types'' identified by CMS will enable states to recognize and react more quickly to local needs and developing trends in care.

*Comment:* Several commenters disagreed with the proposal to no longer require states to establish time and distance standards for ''additional provider types when it promotes the objectives of the Medicaid program.'' Commenters stated that the current requirement gives CMS an efficient way to address changes in Medicaid benefits, workforce shortages, or concerns regarding access to care without going through the rulemaking process, which impairs CMS' ability to respond to emergent concerns. Several commenters suggested that rather than eliminating the provision, it could be amended to provide states with advanced notice (specifically one year) before including a new provider type. A few commenters stated that any concerns regarding implementation timelines could be addressed in informal guidance or by allowing states to create implementation standards within certain parameters established through agency instruction.

*Response:* We believe that deleting § 438.68(b)(1)(viii) removes an unnecessary level of administrative burden and makes it clear that designating additional provider types that are subject to network adequacy analysis is a state responsibility. This revision is consistent with the other revisions proposed at § 438.68(b) introductory text and (b)(1)(iv). We considered proposing a specific timeline for advance notice instead of deleting § 438.68(b)(1)(viii) completely, but ultimately concluded that that approach was not consistent with the overall goal and purpose of § 438.68(b).

*Comment:* Several commenters supported the proposed network adequacy requirements allowing states to use any quantitative standard when developing network adequacy standards for long term services and supports programs, specifically noting appreciation for flexibility in determining how networks are developed and stated that CMS'

emphasis on states developing standards that ensure beneficiary access and provider availability rather than just time and distance is appropriate.

*Response:* We appreciate the comments in support of our revisions to reorganize § 438.68(b)(2) to reflect consistency with the requirement in § 438.68(b)(1) for states to develop network adequacy standards for specified provider types.

*Comment:* Commenters suggested that CMS develop meaningful and appropriate network adequacy standards (including national standards) for LTSS providers that recognize the realities of various settings and locations in which these services are delivered as well different provider types (agency employees versus independent personal care workers). One commenter also stated that any national standards developed by CMS should be subject to a stakeholder notice and comment period and ensure that standards support consumer choice of providers and community living. One commenter encouraged CMS to provide states with increased guidance rather than less, including, network adequacy metrics based on choice standards, service fulfillment standards, and provider ratios. The commenter continued that guidance should ensure that networks for LTSS services in which the provider travels to the enrollee are just as robust as those in which the enrollee travels to the provider.

*Response:* We decline to set national network adequacy standards. We believe it is particularly important that states have flexibility to set network adequacy standards customized for their LTSS programs given the wide variation in program design, the often very limited supply of providers, the provision of services outside of an office setting, and the potential functional limitations of the LTSS population. We encourage states to solicit stakeholder input in the development of their LTSS network standards to ensure that they adequately address situations when enrollees travel to the provider as well as when the provider travels to the enrollee. CMS issued guidance on setting network adequacy standards in April 2017: *Promoting Access in Medicaid and CHIP Managed Care: A Toolkit for Ensuring Provider Network Adequacy and Service Availability* and is available at *https://www.medicaid.gov/medicaid/managed-care/downloads/guidance/adequacy-and-access-toolkit.pdf.* This toolkit, designed as a resource guide for state Medicaid and CHIP agency staff, includes a specific chapter on LTSS. See Chapter V ''Network and Access Standards and Monitoring for Special Provider and Service Types.''

*Comment:* Several commenters disagreed with the proposal to delete the requirement for states to set time and distance standards for LTSS providers and stated that such standards are highly beneficial to guiding how LTSS network adequacy standards are developed and judged, and that these standards are particularly relevant for LTSS given the provider shortages for direct-care staff in many areas. Commenters further stated that time and distance standards help ensure that there are providers available in a given area and provide home care agencies, managed care plans, and state agencies with a standard that is easy to use and understand to assess whether provider shortages are due to long travel times that require additional compensation. Another commenter stated that for nursing facility and other institutional-type LTSS providers, time and distance standards also ensure that enrollees are able to maintain their relationships with their community and family during their time in a facility and that if an enrollee has to enter a facility far way (either in time or distance), the enrollee is less likely to be able to maintain the support networks they will ultimately need to successfully transition back into the community.

*Response:* We agree that time and distance may be useful network adequacy standards for certain provider types and we clarify that our proposed revisions do not prohibit nor discourage the use of time and distance as a network adequacy standard. Our proposed revisions merely remove the requirement that time and distance standards be used as the standard for all provider types. States and managed care plans can continue using time and distance—alone or in conjunction with other standards such as enrollee-to-provider ratios—for any provider types that they deem appropriate. Nursing facilities and other institutional-type facilities that provide LTSS are not specifically included in § 438.68(b)(1); as such, the development and application of network adequacy standards to these provider types is at state discretion because we do not designate the LTSS provider types for which specific evaluation standards must be developed and used in paragraph (b)(2); identifying specific provider types at the Federal level is unnecessary as states have the requisite knowledge and expertise about the services covered under their managed care plans to know which provider types should be individually evaluated for access. We agree that facilitating the maintenance of the support networks that will help enrollees transition back to and stay in the community after an institutional stay is important and we urge states and managed care plans to consider this in the development of their network adequacy standards.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.68 as proposed.

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 proposed to remove the words ''contracting health care professionals'' and insert ''network providers'' in § 438.236(b)(3).

The following summarizes the public comments received on our proposal to amend § 438.236 and our responses to those comments.

*Comment:* One commenter supported the proposed language change to remove the words ''contracting health care professionals'' and insert ''network providers'' in § 438.236(b)(3).

*Response:* We thank the commenter for the support. Consistent Use of ''network provider,'' which is a defined term in § 438.2 promotes clarity in the regulations.

After consideration of public comments and for the reasons articulated in the proposed rule and our responses to comments, we will finalize § 438.236(b)(3) as proposed.

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 by the managed care plan of all enrollee encounter data that the state is required to submit to us 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. Some managed care plans consider this information to be proprietary and inappropriate for public disclosure. We explained in the proposed rule that we understand their 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 proposed to revise § 438.242(c)(3) to explicitly include ''allowed amount and paid amount.'' We explained in the proposed rule 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 (EOBs) or other disclosures to enrollees about their coverage.

In the proposed rule, we noted that the health insurance industry has consistently stated that the contractual payment terms between managed care plans and providers are 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 also stated that we would treat data as trade secret when the requirements for such a classification are met. We stated that we recognize the significance of the volume of data collected in the T–MSIS and take our 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 affirmed our commitment to safeguarding data protected by Federal law from inappropriate use and disclosure.

The following summarizes the public comments received on our proposal to amend § 438.242(c) and our responses to those comments.

*Comment:* Many commenters supported the proposed revision to § 438.242(c)(3) and agreed that more accurate and complete Medicaid data and transparency are needed and that data on allowed and paid amounts are critical to monitoring and administering the Medicaid program. Commenters noted that this clarification will strengthen the ability of state and Federal officials to monitor managed care plan payments to network providers for their effect on access to care, is consistent with statutory provisions regarding reporting of encounter data established in the Patient Protection and Affordable Care Act of 2010 (PPACA) (Pub. L. 111–148, enacted March 23, 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010)) (''Affordable Care Act''),[25] and will help to identify potential fraud, waste, and abuse. A few commenters supported this proposal because they believe that managed care plans erroneously state that this information is trade secret. Several commenters stated that the proposed revision to § 438.242(c) will improve the accuracy, transparency, and accountability of encounter data.

*Response:* We agree that it is important for states and us to have complete and accurate encounter data for proper program administration. We appreciate the support and recognition of this important program policy from commenters.

*Comment:* Several commenters requested clarifications about the proposed changes to § 438.242(c). A few commenters requested more guidance on the definitions of ''allowed amount'' and ''paid amount'', and one commenter recommended that CMS seek input from managed care plans and other stakeholders on the proposed definitions. A few commenters requested clarification on how the requirement to report allowed and paid amounts will apply to subcapitated arrangements with providers that do not have clear payments for individual services and do not use a per service payment structure. Specifically, a few commenters requested clarification regarding whether the allowed and paid amounts that the state is required to report to CMS are the amounts the MCO, PIHP, or PAHP or subcontractor allowed and paid to the direct healthcare provider.

*Response:* We understand the request for additional clarification on how the allowed and paid amount fields should be populated in T–MSIS submissions. For provider claims paid by the managed care plan or subcontractor on a FFS basis, ''allowed amount'' and ''paid amount'' have the same meaning as used for completing EOBs sent to enrollees; that is, the allowed amount reflects the amount the managed care plan or subcontractor expects to pay for a service based on its contract with the provider and the paid amount reflects the amount the managed care plan or subcontractor actually sends to the provider after adjudicating the claim. This would be the same for claims paid by the state Medicaid agency or a managed care plan.

We acknowledge that there are many types of payment arrangements including other than a per service payment arrangement, used in Medicaid managed care and that data fields in T–MSIS may need to be populated in different ways to accurately capture the data associated with the different arrangements. It is critical that Transformed Medicaid Statistical Information System (T–MSIS) data reflect all data associated to services provided to managed care enrollees, including services provided by subcontractors. For example, comprehensive data on pharmacy services subcontracted to a pharmacy benefit manager must be submitted to T–MSIS with the same level of accuracy and completeness as data for claims paid by the managed care plan directly. The requirements for populating fields in T–MSIS are documented in a data dictionary and accompanying guidance issued by CMS. We also have technical assistance available for states that have questions about submitting T–MSIS data. For more information, visit: *https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/index.html.* The dynamic nature of health care payment arrangements necessitates that we use flexible and rapid methods for distributing T–MSIS information to states in the most efficient and effective manner. As such, including overly specific details to address every type of payment arrangement in a regulation is not prudent nor feasible. States should consult T–MSIS requirements and guidance documents and request technical assistance as needed to ensure that their T–MSIS submissions meet current standards.

*Comment:* One commenter stated that the allowed amount is not needed for administering the Medicaid program because it is not necessary for invoicing Federal rebates or capturing Federal reimbursement for Medicaid expenditures. Another commenter stated that the capitation rates should be set based on the paid amount, not the allowed amount, and that if CMS has concerns about amounts paid, it should look towards addressing policies that drive up costs, such as state-mandated formularies or any willing provider provisions, and adopt proven benefit design tools used in the commercial market to keep costs down.

*Response:* We disagree with the commenter that the information about

[25] Sections 6402(c)(3) and 6504(b)(1) of the Affordable Care Act reorganize, amend, and add to sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act by adding provisions related to routine reporting of encounter data as a condition for receiving Federal matching payments for medical assistance.

the allowed amount should not be collected. While allowed amount data submitted by managed care plans to states may not be utilized as routinely as paid amount data in setting capitation rates or oversight activities, it nonetheless provides states and CMS insight into important aspects of a managed care plan's network, namely, its fee schedule and contractually negotiated rates. Analyzing allowed amount data can facilitate plan comparisons that are not possible with paid amounts as well as provide insight into possible causes for access issues within a plan's network. We clarify here that we did not intend to convey in our proposal that we had ''concerns with paid amounts,'' but rather to clarify the meaning of ''all enrollee encounter data'' in § 438.242(c)(3) as finalized in the 2016 final rule by explicitly stating the mandatory submission of encounter data includes allowed amount and paid amount data. Under § 438.818, states must submit all enrollee encounter data to CMS; § 438.242(c) requires states to require Medicaid managed care plans to submit to the state the same encounter data that must be submitted in their T–MSIS submissions to us. As explained in the 2016 final rule, Sections 6402(c)(3) and 6504(b)(1) of the Affordable Care Act reorganize, amend, and add to the provisions of sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act by adding provisions related to routine reporting of encounter data as a condition for receiving Federal matching payments for medical assistance. Section 1903(i)(25) of the Act mandates that, effective March 23, 2010, Federal matching payments to the states must not be made for individuals for whom the state does not report enrollee encounter data to us. The PPACA amendment to section 1903(m)(2)(A)(xi) of the Act specifies that the obligation for an MCO to report ''patient encounter data'' was, for contract years after January 1, 2010, to the state in a timeframe and level of detail specified by the Secretary. The data that must be collected and reported under these provisions is the same, but the population covered by section 1903(i)(25) of the Act, compared to the population covered by section 1903(m)(2)(A)(xi) of the Act, included enrollees of PIHPs and PAHP. (81 FR 27737). These statutory changes or the data required from Medicaid managed care plans were reflected in §§ 438.242 and 438.818 of the 2016 final rule.

*Comment:* Several commenters appreciated CMS' commitment to safeguarding data protected by Federal law from inappropriate use and disclosure but recommended that CMS reinforce this assurance in regulatory language by including an affirmative statement in § 438.242(c) that would make the submissions subject to applicable Federal and state confidentiality laws and regulations. A few commenters stated that they appreciate CMS' recognition that contractual payment terms between managed care plans and providers may be confidential and trade secret information, the disclosure of which could potentially harm competition among managed care plans and providers.

*Response:* We decline to include additional regulatory text indicating the applicability of Federal and state laws and regulations to the collection of enrollee encounter data that states are required to submit to T–MSIS. We exercise due diligence to comply with all applicable laws and regulations with respect to all data in T–MSIS. We do not believe that this final rule is the appropriate place to discuss fully the scope and applicability of various confidentiality and data protection laws to encounter data that must be submitted under sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act. If, and when, there is a request for disclosure of this data (or if we seek to disclose without a request), we will evaluate the applicable law and whether encounter data submissions are protected from release or disclosure under Federal law. The facts of each situation, including the age and scope of the data, are necessarily key components in any such analysis.

*Comment:* A few commenters disagreed that the allowed amount is already in the public domain in the form of EOBs because EOBs are not public documents. Several commenters stated that the allowed amount is considered proprietary information by most plans and is not appropriate for public disclosure.

*Response:* We understand commenters' concern; however, there are no restrictions on an enrollee's use or disclosure of their EOBs. We recognize the significance of managed care plans' concerns and commit to treating these data as confidential under applicable law *when the requirements for such treatment are met.* We also acknowledge the significance of the large volume of data collected in T–MSIS as opposed to the very limited amount of data available from individual EOBs, and the potential uses the quantity would enable. We take our obligations seriously to safeguard information that is protected under Federal law from inappropriate use and disclosure.

*Comment:* One commenter urged CMS to not only ensure that contractual payment terms are safeguarded from disclosure, but also stated that aggregated data that could be used to reverse engineer contractual payment terms is safeguarded. Another commenter requested additional information about the measures CMS uses or proposes to use to safeguard the allowed and paid amount data and recommended that CMS apply stringent safeguards in how this information is used to ensure that this data is only used for its intended purposes and not in manners that have the potential to adversely impact competition for plans and providers. One commenter requested that the final rule clarify that any additional disclosure of allowed and paid amounts, beyond that made to the state and CMS, is at the discretion of the managed care plan. One commenter stated that they discourage requiring submission of allowed and paid amounts, and that at a minimum, managed care plans need to better understand the purpose of this data collection and CMS' intended use for this data.

*Response:* We understand the concern that the large quantity of data maintained in T–MSIS could be used to reverse engineer payment terms and fee schedules. Safeguarding information that is protected under Federal law from inappropriate use and disclosure is a priority for us. However, there are adequate protections in other Federal law (for example, exemption 4 in the Freedom of Information Act, 5 U.S.C. 552(b)(4), the Trade Secrets Act, 18 U.S.C. 1905) so adding a new regulatory protection here is not appropriate. Further, we decline to include regulatory text giving plans discretion over the use and distribution of T–MSIS data. CMS will comply with all applicable Federal requirements associated with use and disclosure of data. As we stated in the proposed rule, we consider encounter data invaluable for proper monitoring and administration of the Medicaid program, particularly for capitation rate setting and review, financial management, program integrity, and utilization analysis. As we explained in SMD 13–004 (*https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-004.pdf*), our goal is for T–MSIS data to be used for initiatives such as to study encounters, claims, and enrollment data by claim and beneficiary attributes; analyze expenditures by medical assistance and administration categories; monitor expenditures within

delivery systems and assess the impact of different types of delivery system models on beneficiary outcomes; examine the enrollment, service provision, and expenditure experience of providers who participate in our programs; and observe trends or patterns indicating potential fraud, waste, and abuse in the programs so we can prevent or mitigate the impact of these activities. We are committed to collecting accurate and comprehensive data, meeting our obligations to safeguard that data, and using it to reach our goals to improve the Medicaid program and the health outcomes of its beneficiaries.

*Comment:* A few commenters expressed concerns about the impact of reporting the allowed amount on costs associated with modifying encounter data collection and IT systems for states and health plans. One commenter stated that the allowed amount is not currently an available field in either the National Council for Prescription Drug Programs (NCPDP) standard reporting layouts frequently used by states as the basis for capturing their pharmacy encounters, or in the 837 ASC[26] X12 standards used to report professional claims. One commenter recommended that instead of requiring the allowed amount to be reported with enrollee encounter data, CMS should use the approach taken by the 837 ASC X12 workgroup that permits calculation of the allowed amount from the fields needed to calculate it in the data already captured in the current layout. Commenter stated that calculating allowed amount in this manner would promote greater consistency in reporting and allow CMS to achieve its goal of more accurately identifying administrative costs.

*Response:* We believe the commenter is referring to the pre-adjudicated allowed amount field. If so, we understand that the allowed amount is no longer a required field in 837 ASC X12 for pre-adjudicated claims. However, Loop 2400 HCP02 (Priced/Repriced Allowed Amount) data element does still exist in the 5010 format and is applicable to post-adjudicated claims. The allowed amount added by the managed care plan or subcontractor during adjudication is the data that should be submitted to T–MSIS. We clarify here that we are not requiring the creation of new fields in any of the standardized transaction formats referenced in § 438.242(c)(4); existing fields should be populated consistent with the T–MSIS data dictionary. As such, we do not believe states nor managed care plans will need to invest significant, if any, IT resources to comply. We decline to adopt a requirement for a calculated allowed amount over one populated when the claim is adjudicated.

*Comment:* A few commenters recommended ways to implement the proposed change to § 438.242. Commenters stated that, given the variety of contracting and subcontracting arrangements, consultation should occur between Medicaid plans, states, and CMS on how best to define and implement this provision to ensure that all appropriate costs are captured for rate development. A few commenters recommended that there be sufficient time for implementation because the use of new fields in the encounter system will require considerable programming for point of service claims, and one commenter requested a future effective date for these changes.

One commenter recommended making reporting the allowed amount optional. One commenter recommended that CMS work with healthcare stakeholders to create industry standard formats for encounter file submissions and seek public input through future formal rulemaking. Commenters also recommended that CMS finalize any such industry standard formats with sufficient time and definitive guidance in advance of required use.

*Response:* The size and scope of today's Medicaid programs need robust, timely, and accurate data to ensure the highest financial and program performance, support policy analyses, and maintain ongoing improvement that enables data-driven decision making. Encounter data are the basis for any number of required or voluntary activities, including rate setting, risk adjustment, quality measurement, value-based purchasing, program integrity, and policy development. Since 1999, states have been required to electronically submit data files to MSIS, including eligibility and paid claims files. The paid claims files have always required the same fields of data that are present on a claim form or standardized electronic format. Submitting allowed and paid amounts for encounter data to CMS is not a new requirement for states, although their compliance rates of completeness and accuracy have varied widely. Congress enacted sections 6402(c)(3) and 6504(b)(1) of the PPACA which reorganized, amended, and added to the provisions of sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act by adding provisions related to routine reporting of encounter data as a condition for receiving Federal matching payments for medical assistance. Section 1903(i)(25) of the Act mandates that, effective March 23, 2010, Federal matching payments to the states must not be made for individuals for whom the state does not report enrollee encounter data to us. Further, section 1903(m)(2)(A)(xi) of the Act specifies that an MCO must report ''patient encounter data'' for contract years after January 1, 2010, to the state in a timeframe and level of detail specified by the Secretary. We do not believe that the clarification we are adding to the regulation (by incorporating explicit wording that the allowed amount and paid amount are part of the required encounter data reporting) for the purpose of emphasizing the importance of accurate and complete submission by Medicaid managed care plans necessitates additional consultation or significant implementation efforts. We do not believe there is a need for one industry standard reporting format solely for encounter data submissions. We addressed data standardization and file formats for submission of encounter data in the 2016 final rule in § 438.242(c)(4), which specifies submission of encounter data to the state in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate. As noted previously in our responses to comment on the proposal to amend § 438.242(c)(3), we believe that populating the existing field in the X12N 837 and NCPDP formats, and the ASC X12N 835 format will not entail significant burden.

Generally, all regulations have future effective dates, and we do not believe we need to set an additionally delayed or unique compliance date for § 438.242(c)(3) as revised in this final rule given the lengthy history of this requirement.

After consideration of the public comments and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing § 438.242(c) as proposed.

13. Medicaid Managed Care Quality Rating System (MAC 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). That regulation provides that we, in consultation with states and other stakeholders, and after providing public notice and opportunity to comment, will identify performance measures and a methodology for a Medicaid and CHIP managed care quality rating system. That regulation

[26] Accredited Standards Committee.

also provides that states will have the option to use the CMS-developed QRS or establish an alternative state-specific QRS (''state alternative QRS''), provided that the state alternative QRS produces substantially comparable information about plan performance. Under the regulation, any state alternative QRS is subject to CMS approval.

In the 2016 final rule, we used the acronym Medicaid Managed Care Quality Rating System QRS (MMC QRS). In this final rule, we refer to the Medicaid and CHIP Managed Care Quality Rating System (''MAC QRS''), as both Medicaid and CHIP are subject to the QRS regulations.

In the November 14, 2018 proposed rule, we proposed to make several revisions to the QRS regulations at § 438.334. These proposed revisions were intended to better balance the goal of facilitating inter-state comparisons of plan performance and reducing plan burden through standardization with the need for state flexibility and the practical challenges inherent in producing comparable ratings across heterogeneous states. We proposed no changes to § 457.1240(d), therefore all proposed changes to § 438.334 would be incorporated by § 457.1240(d)'s cross-reference and apply equally to both a state's Medicaid and CHIP programs.

Specifically, we proposed to revise the requirement in § 438.334(c)(1)(i) (redesignated at paragraph (c)(1)(ii) in this final rule) to make explicit our intention to take feasibility into account when requiring that the information yielded by a state alternative QRS be substantially comparable to the information yielded by the CMS-developed QRS, by taking into account differences in state programs that may complicate comparability. We also proposed to add a new paragraph (c)(4) to explicitly provide that we would engage with states and other stakeholders in developing sub regulatory guidance on what it means for an alternative QRS to yield substantially comparable information, and how a state would demonstrate it meets that standard.

Current § 438.334(b) provides that CMS ''will identify performance measures and a methodology'' for the MAC QRS. We proposed to revise paragraph (b) to provide that CMS will develop a MAC QRS framework, including the identification of a set of mandatory performance measures and a methodology.

We proposed to redesignate § 438.334(c)(1)(i) and (ii) as paragraphs (c)(1)(ii) and (iii), respectively, and proposed to add new paragraph (c)(1)(i) to require a state alternative QRS to include the mandatory measures identified in the framework. We noted that states will retain flexibility to include additional measures important to serving their quality goals and meeting the needs of their beneficiaries and stakeholder communities. The purpose of the proposed change is to facilitate comparable ratings while continuing to provide flexibility for states to include additional measures important to serving their beneficiaries and achieving their quality goals. We also noted that, as the MAC QRS and our recently launched Medicaid and CHIP Scorecard serve related goals, we expect to coordinate the measures selected for the Scorecard and those selected for the CMS-developed QRS. The Scorecard includes measures from the Child and Adult Core Sets that CMS identifies and publishes pursuant to sections 1139A and 1139B of the Act and that are voluntarily reported by states, as well as federally-reported measures in three areas: State health system performance, state administrative accountability, and Federal administrative accountability. Both the Child and Adult Core Sets and the Scorecard are reviewed annually and are expected to continue to evolve. More information about the Scorecard is available at *https://www.medicaid.gov/state-overviews/scorecard/index.html.*

We proposed to revise § 438.334(b) to provide that the CMS-developed QRS will align where appropriate with the Qualified Health Plan (QHP) 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. We noted that alignment would be determined as part of the ongoing development of the proposed measures and methodologies and would be addressed in the MAC QRS-specific rulemaking.

Finally, we proposed to revise the current introductory language in § 438.334(c)(1) introductory text and (c)(1)(ii) to eliminate the requirement that states obtain prior approval from CMS before implementing a state alternative QRS to reduce the upfront administrative burden on states and speed time to implementation. Instead of prior CMS approval, we proposed at § 438.334(c)(3) that states would, upon CMS request, submit the following information to CMS to demonstrate compliance with § 438.334(c): The state's 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 the rationale for comments not accepted; and other information specified by CMS. We noted that as part of our general oversight responsibilities, we would still review states' alternative QRS and work with states on any identified deficiencies. We described the proposed approach as similar to the oversight process we use for states' Medicaid eligibility verification plans (§ 435.945(j)), and CHIP eligibility verification plans (§ 457.380(i)), which require states to submit eligibility verification plans to CMS upon request, in a manner and format prescribed by CMS. However, our proposal for the state alternative QRS would not have required prior approval.

The following summarizes the public comments received on our proposal to amend § 438.334 and our responses to those comments.

*Comment:* We received many comments supporting the establishment of a minimum mandatory measure set that would be applicable across both the CMS-developed QRS and state alternative QRS. A number of commenters stated that this proposal will reduce administrative burden on plans and providers and allow for more easily comparable data across states. Several commenters supported the proposal to apply the minimum mandatory measure set across the CMS-developed QRS and state alternative QRS, noting this will establish a level of consistency across states but continue to give states additional flexibility to add measures important to the state. One commenter supported coordinating the minimum set with Scorecard and offered to work with CMS on exploring how the QRS and Scorecard can support one another.

*Response:* We thank commenters for their support and are finalizing the proposed policies for (1) adoption by CMS of a minimum mandatory measure set within the full MAC QRS measure set and of a methodology developed in accordance with § 438.334(b) with some modifications as discussed in this section of this final rule; and (2) application of the minimum mandatory measure set to state alternative QRS in § 438.334(c)(1)(i).

*Comment:* A number of commenters recommended that the minimum set of mandatory measures should include measures that are focused on outcomes; are clinically credible; address potentially avoidable outcomes; are comprehensive in scope; have

quantifiable financial impact; use standard data; and are comparable across states.

*Response:* We will take commenters' suggestions under advisement as we continue the stakeholder engagement and MAC QRS development process leading to a future MAC QRS-specific rulemaking.

*Comment:* One commenter sought confirmation that health plans will not be responsible for reporting measures that are specific to types of services not included in their benefit packages, in situations where states have provided carve-outs for those services such as pharmacy, behavioral health or dental.

*Response:* While the reporting requirements for plans associated with the MAC QRS are beyond the scope of this rule, we agree that it would not be reasonable to hold plans accountable for services that are not included in their contracts and which they do not provide. We intend to take this and other considerations related to service carve-outs and limited benefit plans into account as part of the stakeholder engagement process, in development of the proposed MAC QRS-specific rulemaking.

*Comment:* Many commenters expressed concern with aligning the MAC QRS with other CMS quality rating approaches and/or with the proposals to develop the minimum set of mandatory measures and to coordinate that minimum set with the Scorecard initiative. Several commenters noted deficiencies or gaps in the current QHP and Medicare Advantage 5-Star Quality Rating System methodologies, and pointed out that the Medicaid/CHIP programs serve different populations than Medicare and QHP programs and cover different services. As such, these commenters believed that alignment with the Medicare Advantage 5-Star Quality Rating System may not provide an accurate picture of the care being provided. A few commenters expressed concern with the proposed alignment because Medicaid and CHIP serve a significant number of children and recommended that CMS ensure pediatric specific ratings are available and that the measure set include measures relevant to children and their caregivers.

Some commenters noted that the current version of Scorecard contains only 16 quality measures and expressed concern that a measure set comprised only of Scorecard measures would leave large measurement gaps for key Medicaid populations, such as adults and children with disabilities, pregnant women and newborns, persons receiving long term services and supports, and aging populations. A few commenters noted that a mandatory measure set may not be applicable across disparate managed care programs within a state that serves unique populations. One commenter did not support the proposal to require mandatory measures, because the mandatory measures may be in clinical domains in which their state already excels. The commenter also noted that a mandatory measure set would not consider the resources states with an existing QRS may have already spent to gain support for the measures already contained in such an existing QRS.

*Response:* We are finalizing the authority and requirements for (1) a framework for the MAC QRS, including the identification of the performance measures, a minimum mandatory measure set within the full MAC QRS measure set, methodology, and (2) an alignment where appropriate with the qualified health plan (QHP) 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 in the amendment to § 438.334(b), which we are redesignating as paragraph (b)(1). We use the term framework to encompass all of the critical components of a QRS, which include, but are not necessarily limited to, the selected performance measures and methodology. Although alignment, where appropriate, with other CMS quality rating systems and approaches is required under the rule we are finalizing, the regulation, as proposed and finalized, does not limit MAC QRS measures only to those included in the Scorecard, the listed rating systems, or other CMS quality rating systems. For example, measures not currently included in Scorecard but important to beneficiaries and pertinent to specialty services and specific populations (for example, MLTSS measures) will also be considered for the full MAC QRS measure set. Moreover, states will continue to have the flexibility to add measures for services, programs and populations that are important to each state, should the full MAC QRS measure set (including the minimum mandatory subset) not include specific measures important to a particular state for its quality improvement goals. Therefore, we are finalizing the amendments to § 438.334(b), redesignated as paragraph (b)(1), with modification to clarify that the MAC QRS framework includes the identification of the performance measures, as well as a subset of mandatory performance measures, and a methodology. Per § 438.334(b)(1), we will consult with states and other stakeholders in developing the framework including the MAC QRS measure set and subset of minimum mandatory measures, which then will be subject to formal public notice and comment so we expect that stakeholders and the public will have ample opportunity to provide comment on the measures identified by us, including the mandatory measures.

Further, while the proposed and final rule call for the MAC QRS to be aligned with the QHP QRS, the Medicare Advantage 5-Star rating system and other related CMS quality rating approaches (such as Scorecard) where appropriate, this does not mean alignment in all aspects. Differences would be appropriate, for example, to address the different populations and services covered in the Medicaid and CHIP programs.

*Comment:* Many commenters supported our proposal to align the CMS-developed MAC QRS with other CMS rating approaches where appropriate. Several commenters agreed that alignment across programs will reduce administrative burden and promote high-quality care.

*Response:* As we noted in the proposed rule, we proposed to expand the requirement to align the MAC QRS, where appropriate, with other CMS-developed quality rating approaches, based on feedback gathered through early stages of the stakeholder engagement process that a more expansive approach to alignment would reduce reporting burden on plans that operate across multiple markets, such as Medicare Advantage and the Marketplace. We are finalizing the amendment to include alignment with the Medicare Advantage 5-Star rating system and other CMS quality rating approaches in addition to the QHP QRS at § 438.334(b)(1). In the final regulation text, we are making a technical modification to the citation of the Medicare Advantage 5-Star rating system to indicate that it is described in 42 CFR part 422, subpart D.

*Comment:* A few commenters requested clarification on the process CMS will use to develop the MAC QRS framework including measures and methodology and requested that CMS provide a timeline for development of the MAC QRS framework.

*Response:* As we noted in the proposed rule, we have begun the early stages of a stakeholder engagement process needed for the MAC QRS 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 us on the framework, objectives, measures, and methodologies for the MAC QRS. The TEP includes representatives from state Medicaid and CHIP agencies, plans, beneficiary advocates, and quality measurement experts. We intend to continue this type of stakeholder engagement to develop the MAC QRS, culminating in the publication of a MAC QRS-specific proposed rule in the **Federal Register**, consistent with at the requirements in § 438.334(b), which we are redesignating as paragraph (b)(1). We also intend to provide technical assistance and guidance to states to assist them with implementation of the MAC QRS.

As we explained in both the 2015 Medicaid managed care proposed rule (80 FR 31153) and the 2016 final rule response to comments (81 FR 27688), after finalizing the initial CMS-developed QRS, we may periodically review it to determine the need for modifications, such as refining the methodology and updating the measures to ensure continuing alignment. However, we realize that the current regulations do not clearly reflect the policy described in the preambles; therefore, we are adding a new paragraph at § 438.334(b)(2) to make clear that CMS would follow the same stakeholder engagement and rulemaking process prior to updating the CMS-developed QRS, including consulting with States and other stakeholders and then providing public notice and opportunity to comment, in accordance with paragraph (b)(1) of § 438.334.

*Comment:* Several commenters supported the proposed language change that clarified and reinforced our intention to include stakeholders in developing the MAC QRS framework, including a set of performance measures, a subset of mandatory measures, and methodology for determining a rating based on reported measures. A few commenters recommended working with the Core Measures Quality Collaborative. A few commenters recommended including beneficiaries, providers and researchers in the process. One commenter recommended that Medicaid MCOs have an opportunity to participate in the development of the QRS framework. A few commenters supported CMS' proposal to work with stakeholders to develop sub regulatory guidance on what it means for an alternative QRS to yield substantially comparable information. A few commenters requested that health plans be included in the process. One commenter suggested that CMS should seek input from The Partnership for Medicaid.

*Response:* We appreciate commenters' interest and willingness to participate in the development of the MAC QRS. We are committed to a stakeholder engagement process that captures the diverse viewpoints of the Medicaid and CHIP community. Our current regulation at § 438.334(b), redesignated as § 438.334(b)(1) in this final rule, provides for CMS consultation with states and other stakeholders in the development of the CMS-developed QRS. Our proposal at § 438.334(c)(4) (for the Secretary to issue guidance in consultation with states and other stakeholders) was intended to codify our intention similarly to actively engage with states and other stakeholders in the development of the ''substantially comparable'' guidance for state alternative QRSs as well. We are retaining the policy to require consultation in development of the CMS-developed QRS in § 438.334(b)(1) of the final rule and finalizing proposed paragraph (c)(4), with a technical modification in both paragraphs to clarify that issuance of the MAC QRS-specific rulemaking and the subregulatory guidance on substantial comparability will be ''after consulting,'' rather than ''in consultation,'' with states and other stakeholders. We believe this technical change eliminates potential confusion about the timing of stakeholder consultation and clarifies that it is a distinct engagement process that will happen before the rulemaking used to adopt or revise the framework for the CMS-developed QRS. We recognize the broad range of stakeholders interested in the development of the MAC QRS and are committed to working with them in the development of both the MAC QRS and subregulatory guidance related to alternative QRS.

*Comment:* Several commenters supported our proposal, in § 438.334(c)(1)(ii), to take feasibility into account when applying the substantial comparability requirements to a state alternative QRS. A few commenters appreciated CMS's effort to clarify the considerations that will be taken into account in applying the standard and providing additional flexibility to states, but continued to question how the substantially comparable standard will be implemented. Many other commenters expressed concerns that this proposal would create too much flexibility, limiting comparability and allowing states to implement inadequate rating systems with measures that are not useful for Medicaid populations, especially vulnerable populations within their state.

*Response:* We agree that comparability is an important goal and that utilization of meaningful measures is key, but we also believe feasibility is an important consideration because states' covered populations and program design, as well as their information technology, data collection and reporting capacity, differ. We are finalizing paragraph (c)(1)(ii) as proposed. We will engage with states and other stakeholders in developing the sub regulatory guidance specifying the criteria and process for determining the substantially comparability standard, as required under § 438.334(c)(4). We look forward to working with states and other stakeholders to strike the right balance between comparability and flexibility under the standard for state alternative QRSs, set forth in § 438.334(c)(1)(ii) of the final rule, while producing ratings that are meaningful and useful for beneficiaries, plans, and states. As § 438.334(c)(4) requires that we consult with states and other stakeholders before issuing the guidance on the substantial comparability standard, it would be premature to provide specific guidance on that point here. We also expect that the MAC QRS will evolve, and with continued CMS support and technical assistance to states, what may not be initially feasible may become more feasible over time.

*Comment:* Many commenters recommended additional measures and measure sets for alignment with and inclusion in the MAC QRS. Several commenters recommended including the Medicaid and CHIP Core Measure Sets. Several commenters recommended aligning the MAC QRS measures with the ''Meaningful Measures'' initiative by CMS for use across CMS programs. A few commenters encouraged CMS to utilize standard, nationally developed and consensus-based measures. A few commenters encouraged CMS to use reliable and valid measures that reflect quality of care and plan performance. A few commenters recommended that any mandatory measures should be relevant to long-term care and LTSS programs and one commenter recommended that the CMS-developed QRS and any state alternative QRS be required to include at least the domains listed in § 438.330(c)(1)(ii) on quality of life, rebalancing, and community integration. Several commenters requested that the mandatory measure set include sufficient measures for pharmacy, cancer care, screenings and preventive care. One commenter urged

CMS to recognize the importance of access to care as a summary indicator when developing a standardized Medicaid QRS.

A few commenters suggested including Healthcare Effectiveness Data and Information Set (HEDIS) measures. A few commenters also encouraged the use of medication use-related metrics and aligning with the Pharmacy Quality Alliance (PQA) measures. A few commenters requested that CMS define pharmacy quality within the QRS and urged that measures related to pharmacy performance be standardized, achievable, and have proven criteria that measure individual pharmacy performance. One commenter recommended including the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. Another commenter recommended aligning with the Medicare Part D star rating program. One commenter encouraged aligning with the Dental Quality Alliance for oral health. A few commenters encouraged CMS to ensure that states have a dental-specific QRS domain rather than a single measure within a broader set. One commenter suggested that measures related to cancer care should be included and that these measures should focus on the specifics of cancer treatment, be meaningful to patients and relevant to all oncology specialties. One commenter suggested using existing summary indicators for the qualified health plans (QHPs).

*Response:* We did not propose specific measures or measure sets in this rule, which is focused on the overarching authority for the MAC QRS. Consideration of specific measures and measure sets is being addressed in the ongoing engagement CMS is having with stakeholders in developing the MAC QRS framework. The regulation we are finalizing at § 438.334(b)(1) requires the MAC QRS that CMS develops to align where appropriate with CMS quality rating approaches, but does not preclude our consideration of other quality rating systems. We will consider them as we continue the stakeholder engagement and development of the MAC QRS within the authority of § 438.334.

We provide here for readers some information about some of the CMS initiatives noted by the commenters. Section 1139A of the Act requires HHS to identify and publish a core measure set of children's health care quality measures for voluntary use by state Medicaid and CHIP programs. In addition, section 1139B of the Act similarly requires HHS to identify and publish a core set of health care quality measures for adult Medicaid enrollees. For more information on the Medicaid and CHIP Core Measure Sets see *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/index.html.* CMS's comprehensive initiative ''Meaningful Measures'' was launched in 2017 and identifies high priority areas for quality measurement and improvement across our programs. Its purpose is to improve outcomes for patients, their families and providers while also reducing burden on clinicians and providers. More information about this initiative may be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

*Comment:* A few commenters supported the proposal to eliminate the prior-approval requirement in § 438.334(c)(1) of the current regulations for states opting to develop a state alternative QRS, noting this will reduce delays in implementing a state alternative QRS and will allow for greater state flexibility. One commenter supported the proposal but expressed concern that too much flexibility for states could create too much variation among QRS requirements across states. Many other commenters opposed removing the prior-approval requirement. Some commenters perceived this change could undermine CMS's oversight authority, or reduce plan accountability by allowing states to choose only those measures on which the state and/or their contracted health plans already perform well and for which there is little room for improvement. Some commenters perceived this change could reduce the ability to share and collect meaningful data, and create additional reporting requirements and burdens on physicians. A few commenters were concerned that states could receive feedback from CMS requiring a change in their state alternative QRS late in its implementation, after states had already expended significant time and resources in developing and building their alternative QRS. These commenters requested that CMS allow states the option to submit their alternative QRS for some level of CMS review and approval prior to implementation.

*Response:* The proposal was intended to provide states with upfront administrative flexibility and avoid potential delay in implementation. However, we also understand the concerns of commenters regarding this risk to states in expending time and resources on an alternative QRS which CMS might subsequently determine does not meet the substantial comparability standard. We also agree with commenters' concerns about the risks to ensuring that all state alternative QRS's meet the substantial comparability standard. Therefore, we are not finalizing our proposal to remove the requirement that states submit alternative QRS to CMS for approval prior to implementation. As discussed in this rule, the prior approval requirement currently codified at § 438.334(c)(1)(ii) is being redesignated as paragraph (c)(1)(iii) in this final rule with one grammatical correction as to the word ''receives''. In addition, our proposal to amend § 438.334(c)(2), which was to revise the introductory text solely to be consistent with the proposal to eliminate the prior approval requirement, is not being finalized.

*Comment:* One commenter requested clarification whether updates to a state's alternative QRS would trigger a CMS review or additional stakeholder outreach. One commenter suggested that CMS review states' alternative QRS on at least an annual basis to address any deficiencies.

*Response:* As explained in this rule, we are not finalizing the change to the current requirement that states receive prior-approval from CMS of an alternative QRS prior to its implementation. For the same reasons, we agree with the commenters that prior approval of modifications is necessary to ensure that the standards for use of an alternative QRS continue to be met and that states do not make significant investment in modifications that CMS then determines do not comply with the substantially comparable standard. Prior approval from CMS of a state alternative QRS, including modifications to a state alternative QRS, is required under the current regulations at § 438.334(c)(1)(ii), and we are not substantively modifying this requirement in light of our decision not to finalize the proposal to eliminate the prior approval requirement. This requirement is redesignated as § 438.334(c)(1)(iii), in this final rule. Further, we note that § 438.334(c)(2), which we are not amending, requires that both implementation of a state alternative QRS and modification of an approved state alternative QRS require Medical Care Advisory Committee input and a state public notice and comment process prior to submission to us for approval. These stakeholder engagement requirements, which apply whether a state is implementing an initial state alternative QRS or making modifications to an existing state alternative QRS, continue to apply. We believe that CMS review and approval of the state alternative QRS prior to

implementation and prior to a modification would be substantively similar in terms of the standards applied and the information considered. We do not believe adding a specific requirement for annual CMS review of an approved alternative QRS is necessary given that CMS approval of the initial state alternative QRS and any modifications are already addressed in the regulation text. As noted in this rule, we are codifying at § 438.334(b)(2) the authority to periodically update and modify the MAC QRS framework including a continued process for stakeholder engagement and public notice and opportunity for comment. When we make changes, we will explain in those future rulemakings and guidance what it means for states implementing the CMS-developed MAC QRS, as well as how the changes affect the substantial comparability analysis of any state alternative QRS. We expect to work with all states to implement future MAC QRS modifications.

*Comment:* Several commenters expressed concern that the removal of CMS prior-approval of alternative QRS also changed the timing of the state-level public stakeholder process from prior to submitting an alternative QRS proposal to CMS to prior to a state implementing an alternative QRS. Commenters expressed concern that this could limit the impact stakeholders have with states developing an alternative QRS. One commenter suggested that CMS should reinforce the importance of the public comment process in developing an alternative QRS and several recommended that CMS model the state-level public comment process on the section 1115(a) demonstration public engagement requirements.

*Response:* As noted, we are not finalizing the proposed removal of CMS prior-approval. In addition, we remind readers that § 438.334(c)(2), which we did not propose to amend, requires states to obtain input from their Medical Care Advisory Committee and to provide an opportunity for public comment of at least 30-days prior to the state submitting to CMS a request for or modification of a state alternative QRS. Also, current § 438.334(c)(3), as amended and redesignated at paragraph (c)(3)(ii), requires states to include documentation of the public comment process in the request to CMS, including discussion of the issues raised by the MCAC and the public as well as documentation of any policy revisions or modifications made in response to the comments and rationale for comments accepted.

*Comment:* One commenter requested that CMS clarify the proposal to redesignate § 438.334(c)(1)(ii) of the current text (that requires states to receive CMS prior approval) to § 438.334(c)(1)(iii) because it conflicts with CMS's proposal to eliminate the prior approval requirement.

*Response:* While we agree this was a technical error in the amendatory instructions for the proposed changes (see 83 FR 57296), we are not finalizing the removal of the prior-approval requirement. We are redesignating revised paragraph (c)(1)(i) (relating to the substantial comparability standard for alternative QRS) as paragraph (c)(1)(ii); adding a new paragraph (c)(1)(i) (applying the minimum mandatory measure set to alternative QRS); and redesignating paragraph (c)(1)(ii) (requiring CMS prior-approval of alternative QRS) as paragraph (c)(1)(iii). We are also finalizing the proposed amendment to paragraph (c)(1) so that it provides that ''a state may implement'' a state alternative QRS. The proposed text eliminates a redundancy in the current regulation text, paragraph (c)(1), which provides that a state ''may submit a request to CMS for approval''. This language is redundant with the requirement in redesignated paragraph (c)(1)(iii) requiring that states receive CMS approval prior to implementing an alternative QRS.

After consideration of all the comments received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the changes to the MAC QRS regulations at § 438.334 as proposed with some modifications for clarity and with the exception of the proposal to eliminate the requirement for CMS prior approval of a state's use of an alternative QRS. We are finalizing amendments to § 438.334 as follows:

- We are finalizing amendments to proposed paragraph (b), redesignated it as paragraph (b)(1), with minor modifications. As finalized, paragraph (b)(1) includes clarifications about the MAC QRS framework, including performance measures, a subset of minimum mandatory measures, and methodology; timing of CMS's consultation with states and other stakeholders; clarifications to the listed examples of the content of the MAC QRS; and a technical correction to the citation to the Medicare Advantage 5-Star Quality Rating System.
- We are finalizing a new paragraph at § 438.334(b)(2) to make clear that CMS, after consulting with States and other stakeholders and providing public notice and opportunity to comment, may periodically update the MAC QRS framework developed in accordance with paragraph (b)(1).
- We are finalizing proposed revisions to eliminate duplicative language in the introductory language in paragraph (c)(1).
- We are finalizing, as proposed, revisions to current paragraph (c)(1)(i) (relating to feasibility factors for the substantial comparability standard for a state alternative QRS) and redesignating this as paragraph (c)(1)(ii); finalizing a new paragraph (c)(1)(i) (applying the minimum mandatory measure set to state alternative QRS); and redesignating current paragraph (c)(1)(ii) (requiring CMS prior-approval of state alternative QRS) as paragraph (c)(1)(iii)).
- We received no comments on the several proposed changes to § 438.334(c)(3), regarding the information about their alternative QRS that states would need to provide to CMS. We proposed that states would provide, in addition to the information about stakeholder engagement already required by § 438.334(c)(3), a copy of the alternative QRS framework, including the performance measures and methodology to be used in generating plan ratings, and other information specified by CMS to demonstrate compliance with the substantial comparability standard. We are finalizing these proposed changes with modification to correct several grammatical errors, to enumerate the additional information to be provided in separate paragraphs (c)(3)(i) through (iii) and to more clearly identify the scope of the information we may request by using a cross-reference to paragraph (c)(1).
- We are finalizing the proposed addition of paragraph (c)(4) related to a stakeholder engagement requirement and issuance of guidance on the substantial comparability of alternative QRS, with one modification to change the phrase ''in consultation'' to ''after consultation.''

14. Managed Care State Quality Strategy (§ 438.340)

In the November 2018 proposed rule, we proposed to make some technical changes to § 438.340 to clarify the inclusion of PCCM entities, as described in § 438.310(c)(2), as one of the managed care entities to be included in the state managed care quality strategy. Specifically, because § 438.340(b)(8) did not make clear how PCCM entities should be incorporated into the other elements of the quality strategy, we proposed to delete § 438.340(b)(8) and to add PCCM entities to the list of managed care plans identified in the

quality strategy elements described at § 438.340(b)(2), (b)(3)(i), (b)(6), and (c)(1)(ii). We then proposed to redesignate paragraphs (b)(9), (10), and (11) as paragraphs (b)(8), (9), and (10), respectively, and to make a conforming revision to the cross reference in § 438.340(c)(3)(ii) to refer to redesignated paragraph (b)(10). We explained in the 2018 proposed rule why additional revision to add references to PCCM entities to other paragraphs in § 438.340(b) was not necessary.

Additionally, we proposed to amend § 438.340(b)(6) which, for the purposes of the states' plan to reduce health disparities within the quality strategy, defines ''disability status'' based on whether the individual qualified for Medicaid on the basis of a disability. Specifically, we proposed to remove this definition of disability status because we were concerned that it may be unintentionally narrow, leading to under-recognition of individuals with disabilities. Because disability status can change over the course of an individual's lifetime, qualifying for Medicaid on the basis of disability will only be one source of information to determine a beneficiary's disability status, and not necessarily the only source or the most accurate source of this information. In addition, there is no consensus definition of ''disability status,'' and the definition applied for purposes of Medicaid eligibility is not necessarily the only definition appropriate for evaluating health disparities. We also noted that providing this demographic information for each Medicaid enrollee to the managed care plan at the time of enrollment is a minimum standard under the current regulation and encouraged states to send updated demographic information to an enrollee's managed care plan whenever updated demographic information is available to the state.

As we considered the comments on these proposed changes, discussed in this rule, we realized that the regulation on the state managed care quality strategy is not the most appropriate place for the requirement to transmit certain information to managed care plans to be located. Since the requirement to transmit this information is tied to the enrollment of the individual beneficiary in the managed care plan, we believe it would be best to include this requirement as part of the standards for enrollment. Therefore, we are moving this requirement from § 438.340(b)(6) to § 438.54(b) (relating to state managed care enrollment systems) by adding a new paragraph (b)(3) in § 438.54, requiring states to provide the demographic information listed in § 438.340(b)(6) for each Medicaid enrollee to the individual's managed care plan at the time of enrollment. The movement of this requirement from § 438.340(b)(6) to § 438.54(b) is a non-substantive, technical change.

The following summarizes the public comments received on our proposal to amend § 438.340 and our responses to those comments.

*Comment:* A few commenters supported the technical correction related to PCCM entities to delete § 438.340(b)(8) and to add references to PCCM entities in each regulatory paragraph regarding the applicable quality strategy elements.

*Response:* We are finalizing the proposed changes to delete paragraph (b)(8) and to add reference to PCCM entities to paragraphs (b)(2), (b)(3)(i), and (c)(1)(ii) as proposed. We also had proposed to add reference to PCCM entities in paragraph (b)(6) and are finalizing the substance of that change. In conjunction with moving the sentence in § 438.340(b)(6) (requiring the State to provide its plans with certain demographic information), to which that change was proposed, to § 438.54(b)(3), we are including reference to PCCM entities in § 438.54(b)(3) as revised in this final rule. With the deletion of paragraph (b)(8) in § 438.340, we also are finalizing the proposed redesignation of paragraphs (b)(9), (10), and (11) as paragraphs (b)(8), (9), and (10), respectively. We note that we are finalizing a conforming technical change to paragraph (c)(3)(ii) to change the internal reference from paragraph (b)(11) to its new designation of paragraph (b)(10).

*Comment:* Several commenters supported the proposal to remove the definition of disability status from § 438.340(b)(6). Several commenters agreed that the current definition of disability status in this regulation is too narrow but expressed concern that removing the definition would make it difficult to compare health disparity data across states without a common definition. A few commenters recommended that there should be a common or standard approach to defining disability status, noting the variation in how it is defined across HHS, as well as other Federal agencies. The commenters stated that the lack of a standardized, routine approach for defining and identifying the population with disabilities impedes efforts to monitor the population, target care appropriately, or develop quality measures that could be used to improve understanding of gaps and how effective interventions are in closing those gaps. One commenter suggested using the HHS definition of disability status currently used in population health surveys. One commenter suggested including voluntary disability status questions in the Medicaid eligibility application. One commenter recommended that CMS issue guidance on how best to collect and share data on disability status. One commenter recommended that states adopt a definition of disability status that will allow plans to identify individuals who may need LTSS or individuals with disabilities that may need reasonable accommodations.

*Response:* While we agree that standardization and comparability are important considerations, we are not able to define disability status for the purposes of other programs. We also recognize that not all states have the same data systems or access to all of the same sources of data on disability status. The only uniform definition of disability status for purposes of these regulations would be to limit designation of disability status to beneficiaries who are eligible for Medicaid on the basis of disability, which we agree with commenters is too narrow. Thus, we have determined it best not to establish a uniform definition of disability. At the same time, we agree with commenters who are concerned that having no definition will impede identification of individuals with disabling conditions, provision of appropriate services and utilization of robust quality measurement to drive improvements in care. Therefore, we are neither finalizing the proposal to remove the definition of disability status from § 438.340(b)(6) entirely nor adopting a single definition at the Federal level for this regulation. Instead, we are revising § 438.340(b)(6) to provide states with flexibility to define in their quality strategy ''disability status.'' Further, we are requiring in § 438.340(b)(6) that the state's quality strategy include how the state will make the determination that a Medicaid enrollee meets the state's definition, including a description of the data source(s) that the state will use to identify disability status. To assure some uniformity, we are adopting a requirement that, at a minimum, states' definition of ''disability status'' include individuals who qualify for Medicaid on the basis of disability. We appreciate commenters' requests for guidance on how best to collect and share data on disability status and will consider developing such guidance in the future.

With regard to states' efforts to identify enrollees who may need LTSS or reasonable accommodations, we note that the standards for coordination and continuity of care located at § 438.208(c) already require states to implement mechanisms to identify persons who need LTSS or have special health care needs, as defined by the state, to MCOs, PIHPs and PAHPs. Additionally, § 438.208(c)(1) requires states to specify this plan in the state's managed care quality strategy. The mandatory elements of the managed care quality strategy are identified in § 438.340(b), and the requirement to describe the state's plan for identifying persons who need LTSS or who have special health care needs is codified at redesignated § 438.340(b)(9) in this final rule). We also note that qualified individuals with a disability, including those who do not need LTSS may be entitled to reasonable accommodation under Federal disability rights law. The provisions we are finalizing here do not change or limit application and obligations arising under Federal disability rights law so we remind states and managed care plans to ensure that their obligations are met.

*Comment:* Several commenters recommended that if CMS finalizes this proposal, CMS should require states to include in their quality strategy how they define disability and the sources of information they used to make the determination. Commenters stated that doing so would foster greater transparency and aid in comparability.

*Response:* We agree that transparency and comparability of health data are important considerations. We are finalizing § 438.340(b)(6) with a modification to address the definition of ''disability status.'' We are retaining the requirement in the current regulation that disability status means whether the individual qualified for Medicaid on the basis of disability, but that is a minimum standard for identifying disability status rather than the only permitted definition. We are also finalizing regulation text to require that states include in their quality strategy how the state is defining ''disability status'' and how the state will make the determination that a Medicaid enrollee meets the standard, including which data sources the state is using to identify these individuals.

*Comment:* A few commenters did not support the proposed change to the definition of disability status, claiming that states do not have access to other data sources to determine disability status and requiring them to use other data sources would create confusion in the eligibility system and add undue reporting burden.

*Response:* We disagree that states do not have other data sources to determine disability status. In fact, several state Medicaid agencies supported our proposal because they would prefer to use other and more accurate data sources than to rely solely on the information used to establish eligibility. For example, states may use Title II data, which would indicate whether the Social Security Administration has found that the person has a disability. Further, we did not propose and are not finalizing a requirement that states are required to use other data sources to ascertain beneficiaries' disability status for purposes of meeting the requirements in § 438.340(b)(6). However, if states have other, more accurate sources of information of disability status or any other demographic factors, we believe it is appropriate that states be permitted to use such information as part of their plan to identify, evaluate, and reduce, to the extent practicable, health disparities. As finalized, § 438.340(b)(6) enables states to do so.

*Comment:* One commenter expressed concern about states obtaining demographic information from additional sources and whether the methods of gathering and using the information would respect patient health information privacy.

*Response:* We appreciate the commenter's concern. However, the ability to use information obtained from other available sources of information on disability status does not create new authority for states to obtain such information. Rather, § 438.340(b)(6) of the final rule simply provides states with flexibility to use other third party information which the state already is permitted to access for a purpose directly connected to administration of the state plan, that is, to improve the health outcomes of individuals living with disabilities or falling into demographic groups associated with poorer health outcomes. Such use is consistent with the privacy and confidentiality protections afforded beneficiaries under section 1902(a)(7) of the Act and the HIPAA Privacy Rule, 45 CFR part 160 and subparts A and E of part 164. If a data source is not available to the state or the state is not authorized to use a particular data source, our regulation at § 438.340(b)(6) does not change that or create authorization for access by the state.

*Comment:* Several commenters agreed with CMS' encouragement that states should send updated demographic information to managed care plans whenever available.

*Response:* We appreciate commenters' support.

After consideration of all comments received, and for the reasons outlined in the proposed rule and our responses to the comments received, we are finalizing the technical changes related to references to PCCM entities, as proposed, in § 438.340(b)(2), (b)(3)(i), and (c)(1)(ii). In paragraph (b)(3)(i), we are also finalizing a minor grammatical correction to use ''will'' in place of ''would'' in the last sentence. We are not finalizing the proposed addition of the term ''PCCM entity'' to paragraph (b)(6) as proposed, but are finalizing the requirement that the state provide the demographic information listed in § 438.340(b)(6) for each Medicaid enrollee to the individual's MCO, PIHP, PAHP, or PCCM entity at the time of enrollment at § 438.54(b)(3). We are finalizing the deletion of paragraph (b)(8) and the redesignation of paragraphs (b)(9), (10), and (11) as paragraphs (b)(8), (9), and (10), respectively. We are finalizing a conforming technical change to paragraph (c)(3)(ii) to change the internal reference from paragraph (b)(11) to its new designation of paragraph (b)(10).

Further, we are not finalizing the deletion of the definition of disability status in § 438.340(b)(6), but instead are modifying the current regulation to indicate that ''disability status'' means, at a minimum, whether the individual qualified for Medicaid on the basis of a disability and to require that states include in their quality strategy how the state defines disability status and how the state determines whether a Medicaid enrollee meets the standard, including any data sources the state will use to identify disability status.

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

In the 2018 proposed rule, we proposed a technical correction to amend the cross references listed in § 438.358(b)(1)(iii), which requires that a review be conducted within the previous 3-year period to determine MCO, PIHP, and PAHP compliance with certain managed care standards. Specifically, we proposed a technical correction to § 438.358(b)(1)(iii) to insert cross-references to several standards which this review must address but which had been inadvertently omitted from the 2016 final rule, including §§ 438.56 (Disenrollment requirements and limitations), 438.100 (Enrollee rights) and 438.114 (Emergency and post-stabilization services). The

requirements in these regulations 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. It was not our intent to change the scope of EQR or to delete these cross-references in the 2016 rule. Indeed, we noted in both the 2015 proposed rule (80 FR 31156) and the 2016 final rule (81 FR 27706) that we did not intend to make substantive changes to eliminate any elements of the compliance review EQR activity.

The following summarizes the public comments received on our proposal to amend § 438.358 and our responses to those comments.

*Comment:* All the commenters on this topic supported the technical correction to add the references to § 438.358(b)(1)(iii) to match the scope of the regulation and the EQR protocols prior to the 2016 final rule.

*Response:* We thank the commenters for their support. Adding these references to certain requirements for access standards, structure and operations, and quality measurement and performance ensures that § 438.358(b)(1)(iii) provides for the same scope of EQR as it required prior to amendment by the 2016 final rule.

After consideration of all comments received and for the reasons outlined in the proposed rule and our responses to those comments, we are finalizing the amendments to § 438.358(b)(1)(iii) as proposed.

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 must have been subject to the Medicaid EQR during those 2 years and been found to have performed acceptably with respect to 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; however, this is explicitly provided as an option for states. States have discretion to require all their managed care plans to undergo EQR, even those MCOs that could be exempted under § 438.362. To increase transparency regarding state use of the exemption from the Medicaid EQR for certain MCOs, we proposed to add a new § 438.362(c) to require that states annually identify on their website, in the same location as where EQR technical reports are posted, the names of the MCOs it has exempted from EQR, and when the current exemption period began.

We sought comment on whether instead to revise § 438.364(a) to require that states identify the exempted plans and the beginning date of the plan's current exemption period in their annual EQR technical reports, either in addition, or as an alternative, to posting this information directly on the state's website. We also solicited comments on how states are currently using the exemption provision and how states currently make that information publicly available.

The following summarizes the public comments received on our proposal to amend § 438.362 and our responses to those comments.

*Comment:* Several commenters supported the proposal to require states to publicly identify any exempted plans along with the beginning date of their current exemption period on their website or in the annual EQR technical support. Commenters stated that this proposal represents little burden to plans or states but improves transparency and accountability. Other commenters noted that without this exemption information posted on the website, the annual EQR technical report may be misinterpreted as a comprehensive account of the quality of all managed care plans in a state, when in actuality there may be plans omitted from the report.

*Response:* We thank commenters for their support and agree that acknowledging the exemptions provided to certain MCOs from the EQR provides greater transparency with minimal burden on states. We are finalizing with modification the proposed revision to § 438.362 to make minor grammatical changes and to add a new paragraph (c) to require identification of MCOs exempt from Medicaid EQR, or that no MCOs are exempt, as appropriate, on the state agency website required under § 438.10(c)(3).

*Comment:* Several commenters supported the alternative suggestion that states identify MCOs exempt from Medicaid EQR activities in the EQR technical report, noting that this would allow for historical trending of exemption information whereas the information states post on their website may only include current exemption information. Several commenters stated that CMS should require the information to be both included in the EQR technical report as well as displayed on the website. These commenters noted that posting this information in more than one place will not present a burden to the states since they already make exemption determinations, inform their EQRO of which plans are exempted from EQR, and maintain EQR information on their websites. Finally, several commenters noted that if CMS does not require both methods, CMS should prioritize sharing the information on the state's website, as this is more accessible to beneficiaries, providers, and other stakeholders.

*Response:* We agree with commenters that both alternatives are useful. Because they are not mutually exclusive, we are also finalizing new regulation text at § 438.364(a)(7) that states also include in their EQR technical reports the names of the MCOs exempt from EQR by the state, including the beginning date of the current exemption period or that no MCOs are exempt, as appropriate.

*Comment:* Some commenters sought clarification with regard to what would be required of states that do not exempt managed care plans from EQR due to a Medicare review.

*Response:* We had intended that if no MCOs are exempt from the Medicaid EQR, the state would indicate this fact on the state's website consistent with the new transparency requirement. Requiring an explicit statement that no MCOs have been exempted from the requirement ensures that this information is clearly communicated on the state's website. To make this clear, we are finalizing the proposed revisions to § 438.362 and the additional revision to § 438.364(a)(7) with additional text to make this requirement explicit.

*Comment:* A few commenters recommended that CMS require states to provide direct links to the most current Medicare performance review for the MCOs they have exempted from EQR to allow consumers and advocates to easily find relevant performance data on exempted plans. They stated this would improve transparency without adding any burden to plans or states in terms of redundant reporting.

*Response:* We do not currently publish all information about Medicare performance reviews for every plan. At this time, we annually provide summary information on Medicare Parts C and D plan performance, compliance, audits

and enforcement actions on *CMS.gov*. Moreover, we did not propose to require states to make public the most current Medicare performance review. Therefore, we are not adopting the recommendation made by these commenters. We agree that directing consumers to information about Medicare performance reviews would support our transparency goals, and encourage states to provide links to any publicly available information, but we do not think a requirement for that is necessary or appropriate to finalize here.

After consideration of all comments received on this topic and for the reasons outlined in the proposed rule and our responses to those comments, we are finalizing the revision to § 438.362 with an additional requirement for states to indicate that no MCOs are exempt from EQR if that is the case and technical modifications to improve the clarity of the text. We are also finalizing a new paragraph (a)(7) in § 438.364 of the final rule to require that information on state exemption of MCOs be included as an element of the annual EQR technical reports or that no MCOs are exempt, as appropriate.

17. External Quality Review Results (§ 438.364)

In the 2018 proposed rule, we explained how in § 438.364(d), we had inadvertently referenced paragraph (b) instead of referencing paragraph (c). We proposed to revise § 438.364(d) to amend the incorrect reference.

We did not receive comments on this technical correction to § 438.364(d) and, for the reasons noted here and in the proposed rule, are finalizing it as proposed.

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

We proposed to revise the definition of ''adverse benefit determination'' in § 438.400(b) to clarify treatment of denials of claims on the basis that they are not clean claims. In the 2016 final rule at § 438.400(b)(3), we finalized 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 proposed to revise § 438.400(b)(3), to specify 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) is not an adverse benefit determination. Under the proposal, the notice requirements in § 438.404 would not be triggered if the denial is solely because the claim is not a clean claim as defined at § 447.45(b). Section 447.45(b) defines ''clean claim'' as one that can be processed without obtaining additional information from the provider of the service or from a third party, and includes a claim with errors originating in a State's claims 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. We explained that this amendment would eliminate burden on plans to send unnecessary notices and avoid anxiety for enrollees receiving such notices and that the proposed change was not expected to expose enrollees to financial liability without notice, or jeopardize their access to care or rights to appeal.

We also provided guidance on how we would interpret the proposed change to the definition of adverse benefit determination. 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 must be determined for each claim individually, regardless of whether notices were required for previously submitted claims.

The following summarizes the public comments received on our proposal to amend § 438.400 and our responses to those comments.

*Comment:* Many commenters supported the proposed change to eliminate the enrollee notice requirement for claims denied for not meeting the definition of a clean claim. Commenters noted that Medicaid enrollees are inundated with communications from providers and insurers, adding to the stress and confusion they experience when navigating the health care system. Accordingly, they should not be notified when a denial is based on a technical error that providers and managed care plans can resolve without enrollee input. Commenters noted that this proposed change would reduce beneficiary anxiety and confusion.

*Response:* We appreciate the supportive comments and believe enrollees and managed care plans will benefit from the reduction in unnecessary notices.

*Comment:* Commenters recommended that the proposed clean claim language could cause confusion among managed care plans and states as they attempt to determine how to apply notice requirements in cases where a claim falls under the technical definition a clean claim, but the claim denial does not impact the enrollee.

*Response:* In cases where a claim meets the technical definition of a clean claim and payment is denied in whole or in part, that denial does meet the definition of adverse benefit determination and the managed care plan must send the notice required in § 438.404. The revision to § 438.400(b)(3), as proposed and as finalized, only addresses claims that do not meet the definition of clean claim in § 447.45(b). Whether a claim denial ''impacts the enrollee'' is not part of the definition of an adverse benefit determination and does not affect a managed care plan's responsibility for sending the notice required in § 438.404. To make our intent clear, we will add ''solely'' in the final text of § 438.400(b)(3) to clarify that the only claim denials for all or part of the payment that do not trigger the notification requirements are those denials that result solely from the claim not meeting the definition of clean claim in § 447.45(b).

*Comment:* Several commenters requested that CMS not finalize the proposed clean claim language and instead specify more directly that notice requirements are not triggered in situations where a member will be held harmless or is not financially responsible despite a full or partial denial of a payment for service. Alternatively, commenters noted that CMS could provide additional context for the definition of ''clean claim'' by including guidance and a range of practical examples. The examples should make clear that the notices are not triggered in the denial cases mentioned in the preamble such as missing data or duplicate submissions, nor are they triggered in other similar cases such as clear billing errors or practices involving waste or abuse. Commenters stated that either change would still provide for independent determinations on the need for notices at a later point, for example, after a resubmitted claim, if an enrollee could then be subject to financial liability.

*Response:* We decline to adopt the commenters' suggestion to exempt all claims that do not result in enrollee liability from the definition of adverse benefit determination. While this may seem a minor expansion of the types of claims our revision targets, it actually would, in some states, increase the number of eliminated notices exponentially. These notices are an important beneficiary protection as they may be the only notification an enrollee receives alerting them that a claim has been submitted on their behalf. If the enrollee then begins to receive bills from the provider, they are already aware of the situation and have the information needed to appeal or obtain information from the managed care plan about their cost sharing rights and responsibilities. Further, the provision of these notices when there is a denial of coverage (or payment), is consistent with the principle that enrollees are entitled to be active participants in their health care; without full understanding of what is covered, enrollees are not able to make knowledgeable decisions about their health care coverage and their use of health care.

From a program integrity perspective, another benefit of these notices is the opportunity it provides the enrollee to detect potential fraudulent claims. For example, if a provider is billing for services that were never rendered, the adverse benefit determination notice is likely the enrollee's first alert to the situation. Enrollees can play an important role in the detection and reporting of potential fraud, waste, and abuse, and it was not our intent in this provision to undermine that. By limiting the carve out from the definition of adverse benefits determination to situations where the denial is because the claim does not meet the definition of clean claim, we believe we struck the appropriate balance between reducing burden and confusion for enrollees and maintaining an important enrollee protection.

With regard to the request for additional context, we do not believe we can, or should, develop a list of examples for the regulation text. The potential number of reasons for denying a claim because it does not meet the definition of clean claim is unlimited and any attempt to create an exhaustive list of examples would likely cause ambiguity and confusion. The obligation to determine if a claim meets the definition in § 447.45(b), that is, is a claim that can be processed without obtaining additional information from the provider of the service or from a third party rests with the managed care plan and must be determined for each claim, regardless of whether notices were required for previously submitted claims. Plans must apply the definition in § 447.45(b) consistently and reasonably and have an obligation to comply with their responsibilities in connection with adverse benefit determinations, as that term is defined in § 438.400 as finalized here. The concept of a ''clean claim,'' including as defined in § 447.45(b), is ubiquitous in the health care system and we do not believe that this is a difficult standard to apply.

*Comment:* Several commenters opposed the proposed change and stated that these types of denials should continue to be treated as adverse benefit determinations that trigger notice requirements. Commenters stated that it is important to err on the side of providing more transparency and information to enrollees so they can be as fully engaged in their care as possible. One commenter noted that if a consumer is not aware of a denied claim, the provider may send a bill if Medicaid is secondary to private insurance. Another commenter recommended the continuation of the requirement to send notices for these types of denials but allow for a process for enrollees to opt out of receiving the notices about these specific types of denials if they so choose.

*Response:* We agree that adverse benefit determination notices do improve transparency and provide claim information to enrollees that they may find useful. However, we do not generally believe receiving a notice on claim denials that are related solely to whether the claim was submitted with all necessary information, and therefore, generate no financial liability or reason to appeal for the enrollee, is advantageous to enrollees nor facilitates engagement in their care. A claim denied solely for not being a clean claim does not impact any future adjudication of that same claim based on program benefit level and medical necessity, which would be subject to the adverse benefit determination notice provision in § 438.400(b)(3). As we stated in the 2018 proposed rule, whether an adverse benefit determination notice is required must be determined for each claim, regardless of whether notices were required for previously submitted claims. Adverse benefit determination notices are a valuable and important beneficiary protection and we believe that finalizing this provision strikes a reasonable balance. We appreciate the commenter's suggestion to retain the current definition and allow enrollees to opt-out, but we decline to implement that suggestion.

After consideration of the public comments received and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the revision to the definition of adverse benefit determination in § 438.400(b) substantially as proposed with the addition of ''solely'' for clarity.

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

We proposed changes to §§ 438.402(c)(3)(ii) and 438.406(b)(3) to eliminate the requirements that an oral appeal be submitted in writing to be effective. 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). 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 stated in the 2018 proposed rule that 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 enrollees who wait for extended periods of time for a resolution and 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) when the

enrollee never submits the written, signed appeal.

We proposed to eliminate the requirement for enrollees to submit a written, signed appeal after an oral appeal is submitted in §§ 438.402(c)(3)(ii) and 438.406(b)(3). We explained our belief that the removal of the requirement would reduce barriers for enrollees who would not have to write, sign, and submit the appeal, would enable plans to resolve appeals more quickly, and would decrease the economic and administrative burden on plans. This proposed change would also harmonize the managed care appeal process with the state fair hearing process because § 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. Although we proposed to eliminate the requirement in § 438.406(b)(3) that an oral appeal must be followed by a written, signed appeal, we did not propose to change the current regulatory language there that specifies that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

The following summarizes the public comments received on our proposal to revise §§ 438.402(c)(3)(ii) and 438.406(b)(3) and our responses to those comments.

*Comment:* Many commenters supported the elimination of the requirement for a written, signed appeal after an oral appeal is submitted. Commenters stated an oral appeal should be sufficient to begin the appeals process alone, and subsequent written, signed requirements add an unnecessary barrier to enrollees filing an appeal with the managed care plan. Commenters stated that the elimination of the written requirement benefits all parties involved, as it reduces the additional administrative burdens for both the enrollee and the plan.

*Response:* We continue to believe eliminating the requirement for enrollees to submit a written appeal after filing an oral appeal will facilitate enrollees receiving resolutions to their appeals much more quickly.

*Comment:* Several commenters expressed concern that no longer requiring a written request will harm enrollees by removing the evidence of an appeal request. Commenters stated that this type of change may inadvertently cause states to no longer be able to hold plans accountable for the overall grievance and appeal system, including following up on appeal requests in a timely manner, processing requests and initiating the appeals process. The filing of the written appeal helps to ensure that data are available on appeals filed and processed, as well as data on the disposition of appeals. Commenters urged CMS to create a way to incorporate a written record that is less burdensome on the enrollee, perhaps assigning a confirmation number to the oral transaction, to ensure that the appeal is received and documented for the appeals process.

*Response:* We clarify that finalizing this provision does not eliminate the option for enrollees to submit appeals in writing; any enrollee that is not comfortable filing their appeal orally due to concerns that the appeal may not be documented or tracked appropriately, can file it in writing. Further, the regulation change we are finalizing in §§ 438.402(c)(3)(ii) and 438.406(b)(3) does not change any reporting, tracking, documentation or other requirements on the managed care plan. To the extent that the managed care plan needs to assign a tracking number, make written (or electronic) records summarizing the oral request made by the enrollee, or take other steps to comply with the requirements for the appeal and grievance system, those have not changed. All that this final rule changes is whether the enrollee must follow up in writing after making an oral request for an appeal. We believe there are adequate regulatory requirements supporting the appeal process; specifically, § 438.228 requires states' contracts with MCOs, PIHPs, and PAHPs to have a grievance and appeal system that meets the requirements of subpart F and § 438.416 specifies the recordkeeping requirements for grievances and appeals. We believe that data collected on appeals may actually improve because excluding oral appeals that were not followed up in writing or not followed up in a timely fashion based on review of a plan's performance, would have inappropriately skewed the resolution timeframes. Without these delays, appeal resolution data should more accurately reflect a managed care plan's performance. Managed care plans may find a method such as a confirmation number useful and we encourage them to consider it along with any other method that they find efficient and effective to accurately track oral appeals and to ensure that the plan is compliant with the appeal and grievance system requirements in part 438, Subpart F.

*Comment:* A few commenters stated that requiring a written request may make it easier for certain populations to file an appeal, such as individuals with disabilities, individuals who are incapacitated, individuals with limited English proficiency and individuals with health aids, health care proxies, powers of attorney and translators, because they would be able to request an appeal in a manner and at a time that is most convenient for them.

*Response:* Finalizing the elimination of the requirement for a written appeal to be submitted in follow up to an oral appeal in §§ 438.402(c)(3) and 438.406(b)(3), does not eliminate the option for enrollees to submit appeals in writing. Enrollees can submit an appeal orally or in writing; the choice of method is a decision left to the enrollee. We expect that enrollees (or their representatives) who believe that a written request is better suited to their own needs will file written appeals.

*Comment:* Several commenters supported the elimination of the requirement for a written, signed appeal but recommended that CMS require states to create redundancy protection to ensure that oral requests for appeals are fully and accurately recorded. Commenters stated that managed care entities may fail to acknowledge and document oral requests, raising concern that the lack of a written record would create a ''he said, she said'' situation between the appealing enrollee and the managed care plan.

*Response:* We agree that oral appeals need to be accurately documented but we decline to require a specific method or impose specific requirements along those lines. Managed care plans should use whatever means they deem most appropriate and that comply with § 438.416, which requires that each grievance or appeal record must contain, at a minimum: A general description of the reason for the appeal or grievance; the date received; the date of each review or, if applicable, review meeting; resolution at each level of the appeal or grievance, if applicable; date of resolution at each level, if applicable; and the name of the covered person for whom the appeal or grievance was filed. Additionally, the record must be accurately maintained in a manner accessible to the state and available upon request to CMS. Given that managed care plans may have to defend their appeal decisions at a state fair hearing if one is requested by the enrollee, we believe managed care plans will select an appropriate documentation method that accurately captures the appeal in sufficient detail. Finally, states have the ability to specify a specific documentation method in a managed care plan's contract if they

wish to do so and this final rule does not change that.

*Comment:* One commenter recommended CMS clarify in the regulation language how a state or managed care plan can make a determination that a verbal contact from a member constitutes an oral appeal. Commenter requested that CMS include the language that a member would need to specifically use or questions that the managed care plan needs to ask to ensure that there is understanding that an appeal is being requested orally. Commenter noted that for the purposes of tracking of appeals and response times, a date of when the appeal process officially starts is necessary, as any lack of clarity as to what constitutes an oral appeal will negatively impact the setting of an official appeal start date.

*Response:* We do not believe it is necessary for us to provide a script for either enrollees or managed care plans. Section 431.221(a) has allowed states to permit oral filings for state hearing requests since 1979. As such, we believe enrollees have a sufficient level of understanding of, and experience in, using an oral appeal filing process and will benefit from the consistency between the process described in § 431.221(a)(1)(i) and the amendment being finalized in this rule. As noted in this rule, enrollees retain the right to file a written appeal if they prefer that method. We note that states have the flexibility to mandate specific processes for their managed care plans to follow for handling oral appeals if they elect to do so.

After consideration of the public comments received and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing §§ 438.402(c)(3)(ii) and 438.406(b)(3) as proposed.

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

We proposed a revision to § 438.408(f)(2) to require the timeframe for an enrollee to request a state fair hearing after receiving an adverse decision from a managed care plan would be 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; under this proposal, the state would set the specific deadline within these limits. Previously, in the 2016 final rule, we revised the timeframe for managed care enrollees to request a state fair hearing to 120 calendar days from a plan's decision; this was codified 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)).[27] It was not our intent to burden states with additional tracking of the fair hearing process in multiple systems, on multiple timeframes. Nor do we want to confuse enrollees in states where some services are provided through FFS and others through managed care.

Therefore, we proposed to revise § 438.408(f)(2) to stipulate that the timeframe for enrollees to request a state fair hearing will 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 stated the proposed revision would allow states that wished to align managed care with the FFS filing timeframe to do so without 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.

The following summarizes the public comments received on our proposal to amend § 438.408(f)(2) and our responses to those comments.

*Comment:* Many commenters supported the proposal to move from a fixed 120 calendar days to a more flexible range of 90–120 calendar days. Commenters noted that this would improve consistency and reduce member confusion by avoiding two different timelines depending on the service delivery model (that is, managed care or FFS), as well as provide consistency for stakeholders. Commenters noted that benefits of such alignment, including minimizing confusion and administrative costs, and encouraging more timely resolution of cases.

*Response:* We agree that finalizing this provision as proposed can benefit enrollees and states.

*Comment:* Several commenters opposed the proposed 90–120 day range. These commenters stated providing enrollees with as much time as possible to prepare for a hearing is substantially more important than providing states with the ability to align their managed care and FFS delivery system timeframes for filing requests for a state fair hearing. Commenters noted that it takes time to collect evidence, gather proper documentation and seek legal help, and noted that it is essential that beneficiaries have every opportunity to make their case.

*Response:* We understand the commenters' concerns but do not believe that enrollees will be disadvantaged in states that elect to limit their managed care enrollees to the minimum 90 calendar days to file for a state fair hearing. We believe 90 calendar days is sufficient time for enrollees to gather documentation and seek legal assistance if desired. We remind commenters that the compliance date for § 438.408(f)(2) was the rating period for contracts starting on or after July 1, 2017, and therefore, states should already be in compliance with the 120 calendar day filing limit. Finalizing this change does not require states to change their filing limit, it simply provides states with an option if they elect to exercise it.

*Comment:* Commenters expressed concern that many beneficiaries are medically fragile, frail, or actively ill or injured and that CMS should be proposing steps to ensure state Medicaid programs fully educate their beneficiaries about the steps required and timing of internal appeals and Medicaid state fair hearings.

*Response:* We do not believe that a change in the managed care regulations is necessary for this purpose. Managed care plans are required to provide information on appeal and state fair hearing rights and processes under §§ 438.10(g)(2)(xi) and 438.408(e)(2)(i). Section 438.10(g)(2)(xi) requires enrollee handbooks to contain grievance, appeal, and state fair hearing procedures and timeframes, in a state-developed or state-approved description and § 438.408(e)(2)(i) requires a notice of appeal resolution to include the right to request a state fair hearing and how to do so. We believe this provides sufficient and appropriate means of conveying this information to enrollees.

*Comment:* One commenter recommended that CMS reduce the timeframe to 60 days because the longer timeline exposes enrollees and plans to increased financial risk since the beneficiary can be held financially responsible for the services rendered during the time the appeal is proceeding as specified in § 438.420(d).

[27] 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.

*Response:* We understand the commenter's concern about enrollee exposure to financial liability but decline to adopt a 60-day filing timeframe. As we stated in the 2016 final rule, because the continuation of benefits option includes the active participation of the enrollee (that is, the enrollee can elect the extent and duration of the services that they wish to continue receiving), the enrollee has some ability to control the amount of liability they are willing to assume in certain situations. (81 FR 27637). We also clarify that regardless of the upper limit on the filing timeframe, enrollees are free to request a state fair hearing immediately upon receiving the managed care plan's notice of adverse appeal resolution. There is no required ''wait time'' between receiving a plan's notice of adverse appeal resolution and making the request for a state fair hearing. We believe that this ability for an enrollee to promptly file for a state fair hearing, plus the protection available in the context of continuation of benefits under § 438.420, provides ample protection against this particular harm and are therefore not revising the appeal timeframe for requesting a state fair hearing for this reason.

After consideration of the public comments received and for the reasons articulated in the proposed rule and our responses to comments, we are finalizing the amendment to § 438.408(f)(2) as proposed.

## 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 managed care requirements do not apply to CHIP. These changes were included in the November 14, 2018 proposed rule. The public comments received on the proposed CHIP provisions in the 2018 proposed rule and our responses are described in this final rule.

### *B. CHIP Managed Care Provisions of the Rule and Analysis of and Responses to Public Comments*

The following sections, arranged by subject area, are a summary of the comments we received regarding specific CHIP proposals. Some of the comments raise issues that are beyond the scope of the proposed rule. We are not summarizing or responding to those comments.

#### 1. Compliance Dates for Part 457 Managed Care Provisions

The 2016 final rule provides that unless otherwise noted, states will not be held out of compliance with new requirements in part 457 adopted in the 2016 final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as the states (and applicable CHIP managed care contracts) complied with the previously applicable regulations (that is, the regulations in place before the 2016 final rule) (81 FR 27499). Since the 2016 final rule was published, some stakeholders expressed that they believed that the preamble was not clear about when states need to comply with the CHIP managed care regulations. We clarified in the 2018 proposed rule that, except as otherwise noted, compliance with the revisions to the CHIP managed care regulations in part 457 of 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.

*Comment:* Several commenters supported the clarification provided regarding CHIP's compliance date.

*Response:* We thank commenters for their support.

#### 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, by cross-reference, the Medicaid requirements in § 438.10. We addressed in the 2018 proposed rule three cross references that should not apply to CHIP and that we inadvertently included in the CHIP regulatory text.

Section 438.10(c)(2) requires state Medicaid agencies to use the state's beneficiary support system as specified in § 438.71. We did not intend to adopt the Medicaid beneficiary support system requirements for CHIP in the 2016 final rule; therefore, we proposed to modify the language in § 457.1207 to exclude § 438.10(c)(2) from the cross-reference used to incorporate the Medicaid requirements into the CHIP regulations.

Section 438.10(g)(2)(xi)(E) requires that the enrollee handbook of Medicaid managed care entities notify Medicaid enrollees that, when requested, benefits will continue when the enrollee files an appeal or state fair hearing (also known as ''aid paid pending''). Because CHIP enrollees are not entitled to continuation of benefits pending an appeal, we intended to exclude the requirement to notify CHIP enrollees of this requirement from the handbook of CHIP plans. Because § 457.1207 of the 2016 final rule inadvertently included a cross reference applying this handbook requirement in CHIP, we proposed to modify the language in § 457.1207 to exclude § 438.10(g)(2)(xi)(E) from the cross-reference used to incorporate the Medicaid requirements into the CHIP regulations.

Additionally, § 438.10(g)(2)(xii) requires that the enrollee handbooks for Medicaid MCOs, PIHPs, PAHPs, and PCCM entities must provide information on how to exercise an advance directive, as set forth in § 438.3(j). CHIP regulations do not include advanced directive requirements, and therefore, we did not intend that managed care plans be required to notify CHIP enrollees on how to exercise advanced directives. As a result, we proposed to modify the language in § 457.1207 to eliminate an erroneous reference applying the Medicaid information requirement regarding advance directives to CHIP.

The following is a summary of the public comments we received on our

proposal to amend § 457.1207 and our responses to them.

*Comment:* Several commenters supported the proposed clarifications and technical corrections.

*Response:* We are finalizing our proposal to amend § 457.1207 as proposed.

*Comment:* One commenter recommended CMS provide an explanation of its position regarding ''aid paid pending''.

*Response:* As we explain in this final rule and as we noted in our response to comments received in the 2016 final rule (81 FR 27768), the right to benefits pending the outcome of a grievance or appeal does not derive from section 1932(b)(4) of the Act, but from the constitutional due process protections afforded to beneficiaries of an entitlement program under *Goldberg* v. *Kelly,* 397 U.S. 254 (1970) and its progeny, including provision of benefits to beneficiaries who are being terminated from or denied coverage pending appeal. Unlike Medicaid, CHIP is not an entitlement program, and therefore the right to benefits pending appeal is not available to CHIP beneficiaries.

*Comment:* One commenter recommended affording states the discretion to apply beneficiary support provisions to CHIP enrollees and to make FFP available for states doing so.

*Response:* The Medicaid provision to provide beneficiary support in § 438.71 and cross-referenced under the beneficiary information requirements in § 438.10(c)(2) requires states to provide counseling to Medicaid enrollees regarding choice of managed care plans and assistance with LTSS, among other requirements. While CHIP does not adopt Medicaid's requirements to ensure beneficiary choice of managed care plans at enrollment in § 438.52 and states are not required to cover LTSS under CHIP, states are required by § 457.110 to provide information to all CHIP applicants and enrollees in order for these families to make informed decisions about their choice of health plans and providers. Under § 457.110, states must provide information to CHIP applicants and enrollees about covered benefits, cost sharing requirements, names and locations of participating providers, and other information related to CHIP. A state is permitted to use its Medicaid beneficiary support system to fulfill the CHIP enrollment assistance and information requirements; states simply are not required to do so. We note also that our revisions to § 457.1207 do not remove application to CHIP of any of the numerous other requirements in § 438.10 that require managed care entities to provide important information to enrollees and potential enrollees about the entity's provision of services through, for example, enrollee handbooks and provider directories. Section 2105(a)(1)(D)(v) allows for claiming of ''other reasonable costs incurred by the state to administer the plan'' as a CHIP administrative expense, subject to the state's 10 percent cap on administrative expenditures under section 2105(a)(2) of the Act. If the state chooses to provide the information to CHIP enrollees through the beneficiary support system established for Medicaid enrollees, the state may claim that expenditure as a CHIP administrative expense.

For the requirements in § 438.71 (relating to LTSS), as we discussed in our response to comments received in the 2016 rule (81 FR 27757), states are not required to cover home and community-based services (that is, LTSS) in their separate CHIPs. Therefore, LTSS beneficiary support is not usually applicable to states with a separate CHIP. States that choose to cover LTSS have flexibility to determine the role the MCOs and other entities have in authorizing LTSS.

*Comment:* One commenter recommended that CMS allow states to provide information regarding advance directives to CHIP enrollees and that FFP be available to states that do so.

*Response:* As we noted in our response to comments received in the 2016 final rule (81 FR 27760), the mandatory Medicaid standards regarding advance directives described in §§ 438.3(j) and 422.128 do not apply to CHIP and we do not believe that they should. We believe that the Medicaid advance directives provisions would create a significant burden on states and MCOs, PIHPs, and PAHPs in the CHIP context, with correspondingly little benefit for beneficiaries, as there are very few adult beneficiaries in CHIP and very few children need an advance directive. States may choose to require a managed care entity to provide information about advance directives to managed care enrollees since the requirements in § 457.1207 (cross-referencing § 438.10, including § 438.10(g)) represent the minimum amount of information that must be provided to enrollees in an enrollee handbook. A state could also choose to require its CHIP managed care entities to provide certain CHIP enrollees (for example, pregnant women) with information about how to execute an advance directive, similar to the requirement for Medicaid set out at § 438.3(j), and may receive FFP as a CHIP administrative expenditure for doing so, subject to the state's 10 percent cap on administrative expenditures under section 2105(a)(2) of the Act. However, because the underlying Medicaid advance directive requirement does not apply in the context of CHIP, we decline to adopt a requirement for states to require their CHIP managed care entities make this information available.

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed the amendment to § 457.1207 to exclude paragraphs (c)(2), (g)(2)(xi)(E), and (g)(2)(xii) of § 438.10 the cross-reference used to incorporate the Medicaid requirements into the CHIP regulations.

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 proposed to revise § 457.1233(b) 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 proposed to revise § 457.1233 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 and discussed in section II.B.1 of this final rule. Therefore, we also proposed to revise § 457.1233(d) to make this technical correction.

The following is a summary of the public comments we received on our proposals to amend § 457.1233.

*Comment:* Several commenters supported the technical corrections and clarification about collection of enrollee

encounter data in the CHIP structure and operations standards regulatory sections.

*Response:* We thank the commenters for their support.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing as proposed the amendments to paragraphs (b) and (d) of § 457.1233.

4. Quality Measurement and Improvement (§ 457.1240)

In the 2016 final rule, we aligned the quality assessment and performance improvement program standards for CHIP MCOs, PIHPs and PAHPs (with minor exceptions) with the Medicaid standards at § 438.330 by adopting references to § 438.330 in § 457.1240(b). Where appropriate, § 457.1240, as finalized in the 2016 final rule, also applied these Medicaid standards to PCCM entities. However, we inadvertently failed to include a cross-reference to one of the Medicaid standards at § 438.330(b)(2), relating to the collection and submission of quality performance measurement data, which we intended to apply to PCCM entities in CHIP. We proposed revisions to § 457.1240(b) to correct this omission and reflect application of § 438.330(b)(2) to PCCM entities in CHIP.

Additionally, we inadvertently failed to exclude references to consultation with the State's Medical Care Advisory Committee as a state requirement when the state drafts or revises the state's quality strategy in § 438.340(c)(1)(i) (which we incorrectly identified as § 438.330(c)(1)(i) in the 2018 proposed rule) and when the state requests, or modifies the use of an alternative managed care QRS under § 438.334(c)(2)(i) and (c)(3). Establishment of a Medical Care Advisory Committee (MCAC) is required for Medicaid programs under § 431.12. Regulations at §§ 438.334(c)(2)(i) and (c)(3) and 438.340(c)(1)(i) require that the state seek input from the MCAC in developing a state alternative QRS and managed care quality strategy. However, there is no requirement that states establish a MCAC for CHIP similar to that in § 431.12, and therefore, the consultation requirements with the state's MCAC in §§ 438.340(c)(1)(i) and 438.334(c)(2)(i) and (c)(3) are not applicable to CHIP. We proposed to revise § 457.1240 to eliminate the MCAC consultation requirements from the incorporation of the Medicaid requirements relating to adoption of a QRS and managed care quality strategy for CHIP.

We noted in the November 2018 proposed rule how changes proposed to § 438.340 (regarding the managed care state quality strategy) were addressed as technical, conforming changes to the CHIP regulation (§ 457.1240(e)) that incorporates § 438.340. Comments on the proposed changes in § 438.340 (relating to the managed care state quality strategy), are discussed in the preamble at section I.B.14 of this final rule while comments received specific to CHIP, which adopts the Medicaid requirements for the state quality strategy, are addressed in section II.B.8 of this final rule.

The following is a summary of the public comments we received on our proposal to amend § 457.1240 and our responses.

*Comment:* Several commenters supported the clarifications and technical corrections of the requirements to collect and submit quality performance measurement data to PCCM entities.

*Response:* We thank commenters for their support and are finalizing the proposed correction.

*Comment:* One commenter noted that proposed § 457.1240 included a reference to ''§ 438.330(c)(1)(i)'' even though this reference does not address consultation with the Medical Care Advisory Committee, which is the requirement that we proposed to remove for CHIP.

*Response:* We appreciate the commenter bringing this error to our attention. We agree that the correct reference should be to § 438.340(c)(1)(i). We are making the proposed correction in the final rule by finalizing an amendment to § 457.1240(e), which cross-references § 438.340 to incorporate requirements for a written quality strategy for assessing and improving the quality of health care and services furnished to CHIP enrollees. As finalized in this rule, § 457.1240(e) excludes the reference to consultation with the MCAC (described in § 438.340(c)(1)(i)) from the incorporation of Medicaid managed care requirements into CHIP. In addition, we have noted that § 457.1240(d), which cross-references § 438.334 and incorporates the requirement for a managed care quality rating system, also fails to exclude from the CHIP regulation the requirement that the state consult with the MCAC. We are also finalizing an amendment to § 457.1240(d) to exclude § 438.334(c)(2)(i) and (c)(3) from application to CHIP. These items were proposed in § 457.1240(b) of the proposed rule but we have determined that they would be more appropriately placed in §§ 457.1240(d) and (e).

*Comment:* Several commenters opposed the proposal to remove consultation with the MCACs regarding the state's quality strategy as a requirement for CHIP and suggested that states be required, or encouraged, by CMS to seek and respond to MCACs, other advocacy groups, and key stakeholder groups involved in CHIP quality measurement and improvement activities to provide their perspective and expertise.

*Response:* We appreciate the commenters' recognition of the important role stakeholder groups play in advising states on CHIP quality strategies and agree with the commenters about the importance of this involvement. Because we agree that stakeholder input is important, § 457.1240(e) generally incorporates those components from the Medicaid managed care rule at § 438.340 by cross-referencing § 438.340 with, as finalized here, only an exclusion for the MCAC consultation in § 438.340(c)(1)(i). Thus, CHIP adopts the Medicaid requirement to make the quality strategy available for public comment before submitting the strategy to CMS (at § 438.340(c)(1)) and to make the review of the effectiveness of the quality strategy conducted by the state at least every 3 years available to the public (at § 438.340(c)(2)). Further, states must ensure ongoing public involvement in the state's CHIP state plan under § 457.120(b). However, the regulations at § 431.12, which require each state to establish an MCAC, specify that the MCAC advise the *Medicaid* agency about health and medical care services (emphasis added). While states have the flexibility to consult their MCAC for purposes of their CHIP quality strategy, and we encourage them to do so, the CHIP regulations do not require establishment of a similar advisory committee for CHIP. Consultation with the MCAC has never been a regulatory requirement for CHIP agencies, and we did not intend to create a mandate for them to do so implicitly through a cross reference in the 2016 managed care regulation. In addition, to require consultation with the Medicaid MCAC would require that the MCAC exceed its regulatory mandate. Therefore, we decline to adopt a requirement for consultation with the MCAC in connection with CHIP managed care programs and the comprehensive quality assessment and performance improvement programs that managed care entities must be required to establish and implement under § 457.1240(d) and (e).

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal to reflect application of § 438.330(b)(2) to PCCM entities in CHIP with some minor non-substantive revisions to § 457.1240(b). We are reformatting and revising the text in two ways. First, we are redesignating most of the current regulation text in § 457.1240(b) as § 457.1240(b)(1) and designating a separate paragraph (b)(2) for the regulation text providing that, in the case of a CHIP contract with a PCCM entity, the requirements of § 438.330(b)(2) and (3), (c), and (e) apply. Second, we are revising the text to improve the readability of the regulation.

We inadvertently proposed to codify exceptions to the applicability of §§ 438.334 and 438.340 (regarding consultation with the MCAC) in § 457.1240(b). In the final rule, we are finalizing these exceptions in the appropriate paragraphs of § 457.1240. In § 457.1240(d), we state that § 438.334(c)(2)(i) and (c)(3) related to consultation with the MCAC do not apply to the requirements related to the managed care quality rating system for CHIP. In § 457.1240(e) we state that § 438.340(c)(1)(i) related to the MCAC does not apply to the requirements related to the managed care quality strategy for CHIP. This is substantively consistent with our proposal to exclude references to consultation with the MCAC from the CHIP requirements.

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 them into § 457.1260, with two substantive exceptions. First, § 457.1260 provides that references to ''state fair hearings'' in part 438 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. Following publication of the 2016 final rule, we became aware of a number of concerns related to how § 457.1260 currently incorporates the requirements applicable to Medicaid managed care plans, including the following:

• *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) would incorporate the definitions adopted in § 438.400, other than this one provision from the definition of adverse benefit determination.

• *General requirements for appeals and grievances (§ 438.402):* In the 2016 final rule, in § 457.1260 we adopted all of § 438.402 into CHIP. This included an optional external medical review at § 438.402(c)(1)(i)(B). However, at § 457.1120(a), CHIP already provides states with two options to conduct an external review of a health services matter. The additional optional external medical review was superfluous. We proposed to effectively eliminate this additional, optional external medical review from the CHIP managed care appeal process by excluding the language of § 438.402(c)(1)(i)(B) in the list of appeal and grievance provisions that were incorporated from the Medicaid managed care appeals requirements in proposed § 457.1260(b).

In addition, we proposed provisions in § 457.1260(b)(2) through (4) that would apply in place of the provisions in § 438.402(c)(1)(i)(A), (c)(1)(ii), and (c)(2), respectively, by substituting references to ''state fair hearings'' from the Medicaid rules with references to part 457, subpart K (which provides for certain CHIP applicant and enrollee protections, including external review) in proposed regulation text that otherwise generally mirrored text in § 438.402. This approach is substantively consistent with the current rule. Our proposed regulation text, at § 457.1260(b), would continue to incorporate Medicaid grievance and appeals system establishment and operation rules in § 438.402(a), (b), and (c)(2) and (3).

• *Timing of notice of adverse benefit determinations (§ 438.404):* We 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 in § 457.1180. We proposed to clarify that we did not intend to incorporate the requirements of part 431, subpart E into CHIP from § 438.404(c)(1). We proposed, at § 457.1260(c)(1), that states must ensure that the CHIP managed care entities comply with the provisions in §§ 438.404(a), (b)(1), (2), and (4) through (6) and (c)(2) through (6). In addition, we proposed at § 457.1260(c)(2) language that would effectively replicate the requirements in § 438.404(b)(3) but substitute the reference to ''state fair hearings'' with the reference to part 457, subpart K. We also proposed, at § 457.1260(c)(3), that states 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.

• *Handling of grievances and appeals (§ 438.406):* We proposed at § 457.1260(d) that the state must ensure that the CHIP managed care entities comply with the provisions in § 438.406.

• *Resolution and notification (§ 438.408):* We proposed revisions in § 457.1260(e) to address the concerns about references to state fair hearings and external medical reviews discussed in this rule. Proposed § 457.1260(e)(2) mirrored the language of § 438.408(a) but we proposed to restate the text (rather than cross-reference Medicaid managed care regulation) so that the use of ''this section'' in the text referred to the language in § 457.1260 instead of § 438.408. In addition, proposed § 457.1260(e)(3) through (7) effectively restated the requirements imposed § 438.408(b)(3), (e)(2), (f)(1) introductory text, (f)(1)(i), and (f)(2), respectively, with references to part 457, subpart K, instead of referring to ''state fair hearings'' as the Medicaid managed care regulation does. We did not include the Medicaid external medical review provisions (§ 438.408(f)(1)(ii)) from the list of appeal and grievance provisions that we proposed to incorporate in proposed § 457.1260. However, our proposed regulation text at § 457.1260(e) incorporated the resolution and notification requirements of Medicaid grievance and appeals rules as set out at § 438.408(b), (c)(1) and (2), (d), (e)(1), and (f)(3).

• *Services not furnished (§ 438.424):* The current regulation inadvertently incorporated and applied 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 does not apply to 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 disputed services furnished while the appeal is pending if the decision to deny authorization of the services is reversed. Therefore, we did not propose to incorporate § 438.420 or § 438.424(b)

in proposed § 457.1260. Proposed § 457.1260(i) mirrored § 438.424(a), except for substituting the reference to ''state fair hearings'' with the reference to part 457, subpart K. in requiring CHIP managed care entities to provide denied services as expeditiously as the enrollee's health requires, but no later than 72 hours, from the date the managed care entity receives notice reversing its denial.

In sum, we proposed revisions to the regulation text in § 457.1260 that adopted some provisions of the Medicaid appeals and grievances requirements in total (such as in §§ 438.406, 438.410, 438.414 or 438.416) and some only in part (such as in §§ 438.400, 438.402, 438.404, 438.408, and 438.424). We solicited comments on whether our more detailed regulation text, which incorporates specific provisions of subpart F of part 438, was sufficiently clear and detailed for the appropriate administration of grievances and appeals in the CHIP context.

The following is a summary of the public comments we received on our proposal to amend § 457.1260 and our responses to those comments.

*Comment:* A few commenters supported the proposed changes to the CHIP grievance system to require the state to require MCOs, PIHPs and PAHPs to comply with incorporated provisions (in §§ 438.402, 438.404, 438.406, 438.408, and 438.414) and noted that these changes would expedite the grievance process.

*Response:* We appreciate the support for our proposal at § 457.1260 regarding the grievance system.

*Comment:* One commenter requests that states be able to use the Medicaid definition of ''adverse benefit determination'' in § 438.400(b) and receive FFP for doing so, even though CHIP is not adopting § 438.400(b)(6). That section includes in the definition of ''adverse benefit determination'' any denial of an enrollee's request to exercise his or her choice to obtain services outside the network under § 438.52 as a result of Medicaid choice at enrollment requirements and certain exceptions to this rule for rural areas.

*Response:* We previously did not adopt § 438.52 in CHIP in the 2016 final rule because CHIP does not require choice of plans at enrollment, and therefore, this should not have been included in the definition of adverse benefit determination for CHIP. However, if a state optionally provided for choice of plan at enrollment, created a rural exception that, like § 438.52(b)(2)(ii), allowed for an enrollee to obtain services outside the network and established that a denial of that rural exception would constitute an adverse benefit determination, FFP would be available. We do not believe that additional regulation text is necessary for § 457.1260 to address the ability of a state to expand the definition of ''adverse benefit determination'' to include denials of optional benefits that the state may adopt for its CHIP. We are finalizing § 457.1260(a)(2) as proposed.

*Comment:* One commenter requested that states be able to adopt the Medicaid state fair hearing process for CHIP and receive FFP for using the Medicaid state hearing process.

*Response:* States are already permitted to use the Medicaid fair hearing process for CHIP pursuant to § 457.1120. Section 457.1120(a) provides that a state must have one of two review processes: (1) A process that meets the requirements of §§ 457.1130 through 457.1180, which set forth specific standards about the matters subject to review, core elements of the review process, impartiality, time frames, continuation of enrollment, and notices; or (2) a process that complies with State review requirements currently in effect for all health insurance issuers (as defined in section 2791 of the Public Health Service Act) in the State. The Medicaid state fair hearing process is compliant with the standards outlined in §§ 457.1130 through 457.1180 (66 FR 2635–2640). Many states already use the Medicaid fair hearing process for this purpose.

The proposed clarifying amendments to § 457.1260 to remove references to the Medicaid state fair hearing process would not eliminate states' option to utilize the Medicaid state fair hearing process to satisfy the CHIP requirements in § 457.1120(a)(1). The proposed revisions, which we are finalizing with modifications in this final rule, simply clarify how the appeals and grievances process under part 438, subpart F relate to the state CHIP review requirements in § 457.1120.

*Comment:* One commenter requested clarification regarding the applicable timelines for adverse benefit notifications for CHIP in proposed § 457.1260(c). The commenter suggested that we had proposed conflicting requirements in proposed § 457.1260(c)(3) and proposed § 457.1260(c)(1), which cross-references § 438.404(c)(3). Further, the commenter suggested that § 438.404(c)(3) addressed the timing of appeals and grievances but not the timing of notices for denials and limitations of services.

*Response:* We agree with the commenter that the timelines as proposed were confusing. The CHIP standard in § 457.1180 simply requires that states provide enrollees and applicants of ''timely written notice'' of any adverse determination. Rather than aligning the standard for CHIP plans to provide notice to enrollees with the standards for Medicaid plans, we agree that alignment with the timeliness standards for states to notify CHIP beneficiaries of other adverse benefit determinations is appropriate. Therefore, in the final rule we state in § 457.1260(c)(3) that CHIP plans must provide the enrollee with timely written notice of adverse benefit determinations, which is consistent with the timeliness standard in 457.1180, except for expedited service authorization decisions. This makes the timeframes for notice consistent across §§ 457.1260 and 457.1180. CHIP does not address expedited service authorization decisions in § 457.1180. Therefore, for these types of decisions, we are finalizing at § 457.1260(c)(3) the use of the Medicaid notice timing requirement in § 438.404(c)(6) (which cross references § 438.210(d)(2)).

*Comment:* Several commenters sought clarification on the continued inclusion (in § 457.1260) of references to continuation of benefits despite the fact that CHIP beneficiaries are not entitled to continued benefits pending appeal. One commenter specifically suggested that we remove the reference to § 438.404(b)(6) in proposed § 457.1260(c)(1) and the proposed language at § 457.1260(e)(4)(ii) and (iii) because each of these relate to the continuation of benefits during an appeal even though CHIP does not adopt the Medicaid continuation of benefits requirements in § 438.420. In addition, several commenters suggested that we include the right to continue to receive benefits pending an appeal in § 438.420 and the related requirement for payment for reversed adverse benefit determinations when benefits were provided pending appeal § 438.424(b) because preservation of enrollee health and due process require that enrollees retain access to services during the resolution of any dispute regarding their entitlement to them. Alternatively, several commenters suggested that CMS at least permit states to continue benefits while pending appeal and require states to notify enrollees of this option.

*Response:* First, we thank commenters for pointing out where our proposed regulation text for § 457.1260 included cross-references to requirements from part 438 that are relevant to the aid pending appeal policy. As there is no continuation of benefits/aid pending appeal requirement in CHIP, we are not

finalizing any of the related references in § 457.1260.

Second, we are not finalizing references to any right or policy regarding the continuation of benefits pending appeal in § 457.1260(c)(2) or (3), (e)(4)(ii) and (iii), or (i). As we have previously explained (83 FR 57284), the right to benefits pending the outcome of a CHIP review does not derive from section 1932(b)(4) of the Act, but from the constitutional due process protections afforded to beneficiaries of an entitlement program under *Goldberg* v. *Kelly,* 397 U.S. 254 (1970) and its progeny, including provision of benefits to beneficiaries who are being terminated from or denied coverage pending appeal. Unlike Medicaid, CHIP is not an entitlement program and therefore the right to benefits pending appeal is not available to CHIP beneficiaries. Therefore, in summary, to address these clarifications and respond to these comments, we are:

- Finalizing § 457.1260(c)(2) and (3), with revisions;
- Not finalizing § 457.1260(e)(4)(ii) and (iii); and
- Finalizing § 457.1260(i) with revisions to eliminate references to aid pending appeal.

*Comment:* One commenter suggested that the language proposed at § 457.1260(e)(3) and (6) was duplicative, as both deemed exhaustion of the plan's appeal process and permitted an enrollee to seek State external review in accordance with part 457, subpart K, if an MCO, PIHP or PAHP failed to comply with the notice and timing requirements for an adverse decision outlined in § 457.1260.

*Response:* We agree, and therefore, are not finalizing the regulation text at proposed § 457.1260(e)(6). We are finalizing the deemed exhaustion provision at § 457.1260(e)(3) and including there a statement that the enrollee may initiate a state external review in accordance with part 457, subpart K, in such cases. We also note an additional duplication of this deemed exhaustion requirement in the proposed language at § 457.1260(b)(3) so we are not finalizing that duplicative provision either. Proposed § 457.1260(b)(4) is redesignated as paragraph (b)(3) in the final rule.

*Comment:* Several commenters stated that they appreciated Medicaid aligning in § 438.408(f)(2) the timeframes for enrollees to request a state fair hearing across the managed care and fee for service delivery systems by giving states the flexibility to choose a time period between 90 and 120 days. The CHIP proposal at § 457.1260(e)(6) maintained the requirement that enrollees have 120 days to request a state review, which is out of alignment with Medicaid.

*Response:* We agree that timeframes should be aligned across delivery systems and programs and appreciate commenters bringing to our attention our inadvertent failure to align the timeframe in proposed § 457.1260(e)(7) with the revisions for Medicaid in proposed § 438.408(f)(2). We are modifying the regulation text in proposed § 457.1260(e)(7), redesignated as paragraph (e)(5), to achieve the intended alignment. Under § 457.1260(e)(5) of the final rule, states have the same flexibility they have in Medicaid to provide enrollees with between 90 and 120 calendar days to request a state external review of a plan's adverse benefit determination.

*Comment:* One commenter questioned why CHIP MCOs have to comply with § 438.408(f)(3) (proposed at § 457.1260(e)(1)) when there is no state fair hearing requirement for CHIP.

*Response:* Although we proposed that the substance of the Medicaid regulations at § 438.408(f)(3) (regarding the parties to be included in a fair hearing) apply to CHIP, we agree that the proposed application of all of § 438.408(f)(3) to CHIP was an error, because § 438.408(f)(3) is explicitly about the parties to be at the State fair hearing. CHIP has separate regulations, found in subpart K of part 457 of the regulations, governing the review process for CHIP beneficiaries. Therefore, we are not finalizing at § 457.1260(e)(1) the proposal that CHIP managed care entities comply with § 438.408(f)(3)).

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, with several modifications, the regulation text proposed at § 457.1260 regarding the appeal and grievance systems. A summary of the changes is as follows:

- Throughout § 457.1260, we are finalizing parenthetical text to identify the scope and nature of the requirements from part 438 that we are incorporating to apply to CHIP MCOs, PIHPs, and PAHPs. In addition, we have corrected cross-references throughout § 457.1260 as needed to refer to the sections within § 457.1260 in lieu of the Medicaid cross-references.
- *Statutory basis and definitions.* We are finalizing § 457.1260(a)(1) and (2) as proposed. Paragraph (a)(1) identifies the applicable statutory provisions regarding CHIP managed care entities having an appeals and grievance system. Paragraph (a)(2) incorporates the definitions of the following terms from § 438.400(b): ''adverse benefit determination,'' except for paragraph (6); ''appeal,'' ''grievance,'' and ''grievance and appeal system.''
- *General requirements.* We are finalizing as proposed § 457.1260(b)(1). We are finalizing paragraph (b)(2) with a minor modification to cite to § 457.1260(e) instead of § 438.408. We are not finalizing the proposal at § 457.1260(b)(3) because it is duplicative of what we are finalizing at paragraph (e)(3). We are finalizing what was proposed at paragraph (b)(4) as § 457.1260(b)(3) regarding the ability of a provider or authorized representative to file a grievance, request an appeal, or request state external review for an enrollee.
- *Notice of Adverse Benefit Determination.* We are finalizing § 457.1260(c) to address the content and timing requirements for notices of adverse benefit determinations, with substantial revisions to the timeframes for these notices. We are finalizing § 457.1260(c)(1) to require that the state ensure that its CHIP managed care entities comply with the provisions at § 438.404(a) and (b)(1), (2), and (5) regarding the content of the notice of an adverse benefit determination. We are also finalizing additional content requirements for these notices in paragraph (c)(2). Taken together, § 457.1260(c)(1) and (2) mean that the following information must be provided to an enrollee as part of a notice of adverse benefit determinations:

++ The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

++ The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

++ The circumstances under which an appeal process can be expedited and how to request it.

++ 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 and the right to request a State external review in accordance with the terms of subpart K of part 457;

++ The procedures for the enrollee to exercise his or her rights to an appeal.

We are finalizing provisions regarding the timing of the notice at § 457.1260(c)(3). As explained in our

response to comments about the timing of notices of adverse benefit determinations, CHIP managed care entities will have to comply with a standard that notices be ''timely,'' consistent with the requirement in § 457.1180, rather than within a specific timeframe for notices of adverse benefit determination, except in cases of expedited service authorizations. In the circumstances of expedited service authorization decisions, the terms of § 438.404(c)(6) (incorporating § 438.210(d)(2) by cross reference) apply. Section 438.210(d)(2) sets out timeframes for expedited authorization determinations.

• *Handling of grievances and appeals.* We are finalizing § 457.1260(d) as proposed, to require states to ensure that CHIP managed care entities comply with the provisions at § 438.406 with regard to the handling of grievances and appeals.

• *Resolution and notification.* We are finalizing § 457.1260(e) with revisions.

++ In paragraph (e)(1), we are finalizing as proposed the requirement that states ensure CHIP managed care entities comply with the provisions at § 438.408(b) (relating to the timeframe for resolution of grievances and appeals), (c)(1) and (2) (relating to the extension of timeframes for resolution of grievances and appeals), (d) (relating to the format of the notice of resolution for grievances and appeals), and (e)(1) (relating to the content of the notice of resolution for grievances and appeals). However, we are not finalizing the proposal to require compliance with § 438.408(f)(3) because the parties to an appeal in the CHIP managed care contexts are set forth at part 457, subpart K.

++ We are finalizing paragraph (e)(2) as proposed with a clarification that the state-established timeframes for resolution of each grievance and appeal must not exceed the timeframes identified in paragraph (e)(1) of § 457.1260, which incorporates the timeframes in § 438.408(b) and (c)(1) and (2).

++ We are finalizing § 457.1260(e)(3) with additional text specifying that an enrollee may seek state external review in accordance with part 457, subpart K, after the plan's appeal process is exhausted.

++ We are finalizing paragraph (e)(4) regarding the content of the notice of appeal resolution with only the proposal that such notice include the enrollee's right to seek state external review in accordance with the terms of part 457, subpart K, and how to do so. We are not finalizing the proposal to require that the notice include the right to request and receive benefits while the review is pending and that the enrollee may be held liable for the costs of those benefits if the adverse benefit determination was upheld.

++ We are finalizing paragraph (e)(5) with modifications. We are finalizing as proposed in paragraph (e)(5) that an enrollee may request a state external review only upon exhausting the CHIP managed care entity's appeal process. We are adding to paragraph (e)(5) the timeframe for requesting a state external review, which was proposed in paragraph (e)(7).

++ We are modifying that proposal to align with § 438.408(f)(2), by requiring that enrollees must have no less than 90 days and no more than 120 days after the plan's date of resolution to request a review.

6. Sanctions (§ 457.1270)

In the 2016 final rule, CHIP adopted, at § 457.1270, the Medicaid requirements related to sanctions in the managed care context in part 438, subpart I. 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 proposed to revise the language of § 457.1270 to reflect these technical changes.

The following is a summary of the public comments we received on our proposals to amend § 457.1270.

*Comment:* A few commenters supported the clarifications and technical corrections to the regulatory sanctions applicable in § 457.1270.

*Response:* We are finalizing the amendments to § 438.1270.

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendments to § 457.1270 as proposed with slight modification. We are adding parentheticals in the regulation text to help readers understand what general subject is addressed in the Medicaid cross-references in § 457.1270(b) and (c).

7. Program Integrity Safeguards (§ 457.1285)

Section 457.1285 sets forth the CHIP requirements for program integrity safeguards for 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. These cross-referenced standards include, among other things, requirements related to provider enrollment, auditing, implementation and maintenance of arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. In the 2016 final rule, we inadvertently failed to exclude from our cross-reference to the Medicaid managed care program integrity provisions a regulation that should not apply to CHIP. Specifically, 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 in Medicaid; we proposed to modify the language of § 457.1285 to reflect this technical correction.

The following is a summary of the public comments we received on our proposal to amend § 457.1285.

*Comment:* A few commenters supported the proposed clarifications and technical corrections to program integrity safeguards.

*Response:* We thank commenters for their support.

*Comment:* One commenter noted that the proposed regulatory text at § 457.1285 included a typographical error in failing to include a reference to § 438.608(d)(4) as proposed. The rule text states, ''except that the terms of § 438.604(a)(2) and (d)(4) of this chapter do not apply;'' however, the text should read ''except that the terms of §§ 438.604(a)(2) and 438.608(d)(4) of this chapter do not apply.''

*Response:* Section 438.608(d)(4) is the correct cross-reference as we explained in the preamble of the 2018 proposed rule, and we make that correction in the final rule.

*Comment:* One commenter requested that CHIP adopt the Medicaid state monitoring requirements in § 438.66.

*Response:* This comment is outside the scope of this rule. We did not propose to incorporate § 438.66 into the CHIP regulations and therefore cannot do so in the final rule as such a substantive change in the responsibilities of a state with regard to its CHIP and the managed care entities with which the state contracts should be subject to public notice and comment. We also refer the commenter to § 457.204, which authorizes CMS compliance actions when a state fails to comply with its oversight responsibilities under these regulations for a managed care contract.

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the

regulation text at § 457.1285 as proposed with one modification. We are modifying the regulatory text at § 457.1285 to exclude §§ 438.604(a)(2) and 438.608(d)(4), rather than § 438.604(a)(2) and (d)(4), from being applied in CHIP.

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 proposed to revise some of these Medicaid regulations. The cross-references to these revised regulations are unchanged in this final rule. We explained in the proposed rule that the changes made to the following Medicaid regulations in this final rule would also apply, by existing cross-reference, to CHIP. We welcomed comments on the proposed changes specifically as they apply to CHIP:

- *MLR standards (§ 438.8(k)):* As discussed in section I.B.6. of this final 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 final 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 final 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 final rule, we proposed 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 final 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 final rule, we proposed 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 final rule, we proposed revisions to § 438.334(b), (c)(1) introductory text, and (c)(1)(ii), redesignating current paragraphs (c)(1)(i) and (ii) as paragraphs (c)(1)(ii) and (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 final 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), (10), and (11) as paragraphs (b)(8), (9), and (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 final 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 final 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 final 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 final 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.

The following is a summary of the public comments we received on our proposal to CHIP conforming changes to reflect Medicaid managed care proposals.

*Comment:* We received several comments supporting CHIP's proposals to align with the Medicaid requirements where appropriate.

*Response:* We thank commenters for their support.

*Comment:* We received several comments that did not include specific comments on the CHIP proposal to incorporate these Medicaid proposals but referred us to their comments on the Medicaid proposals.

*Response:* Because CHIP proposed to adopt, by cross-reference, the proposed changes to §§ 438.8(k), 438.10, 438.56, 438.68, 438.236, 438.242, 438.334, 438.340, 438.358, 438.364(d), 438.400, 438.402, and 438.406, we direct commenters to the responses to their comments on the Medicaid proposals adopted by CHIP.

*Comment:* Several commenters disagreed with the proposal revisions in § 438.68(b), adopted by cross-reference to CHIP through § 457.1218, to eliminate the requirement for states to establish time and distance standards for the list of specified provider types and to eliminate the requirement for standards to be developed for ''additional provider types'' identified by CMS. Alternatively, these commenters requested that CMS establish specific minimum quantitative standards for the specified provider types, including for pediatricians, pediatric specialists, and pediatric dentists, and to also identify additional types of pediatric provider types to be included in network adequacy standards, including pediatric medical subspecialties, providers at FQHCs and pediatric dental specialties.

*Response:* We refer commenters to section I.B.10 of the preamble and the responses provided therein to address comments received for these proposed revisions to § 438.68. As we stated there, we believe removing the requirement for states to establish time and distance standards for specified providers and removing authority for CMS to add additional provider types will enable states to recognize and react more quickly to local needs and developing trends in care. The list of providers for which states must develop quantitative network adequacy standards includes pediatric primary care, pediatric specialists, pediatric behavioral health, and pediatric dental. We believe this list provides the appropriate balance between assuring that states maintain appropriate networks for the child population, and providing flexibility to states to react to the specific needs of their population and provider landscape in their state. States already have the authority to add additional provider types to their network adequacy standards to meet the needs of their CHIP programs and enrollees.

*Comment:* One commenter expressed concern with CMS retaining the general requirement for actuarial soundness in CHIP rates at § 457.1203. The commenter stated that CMS should apply the Medicaid actuarial soundness requirements to CHIP and reconsider its position.

*Response:* We agree that states must develop payment rates for MCOs, PIHPs, and PAHPs for CHIP using actuarially sound principles, as required under

§ 457.1203(a) of the 2016 final rule. However, as we stated in the 2016 final rule, Title XXI does not provide the same specificity about rate development standards as Title XIX, and while we agree that we have authority under section 2101 of the Act to establish additional standards, we have determined it would not be appropriate to impose all of the Medicaid rate-setting standards on separate CHIPs at this time, including those cited by commenters. Under § 457.1201 of the 2016 final rule, states are required to include payment rates in their managed care contracts submitted to CMS upon request of the Secretary. As we stated in the 2016 final rule, as we continue to gain additional experience with rate setting in CHIP, we may consider developing additional standards for CHIP in the future.

After consideration of the public comments, we are finalizing application to CHIP of the changes to the Medicaid managed care requirements in §§ 438.8(k), 438.10, 438.56, 438.68, 438.236, 438.242, 438.334, 438.340, 438.358, 438.364(d), 438.400, 438.402, and 438.406 as finalized in this final rule.

## III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the preamble, ''collection of information'' is defined under 5 CFR 1320.3 of the PRA's implementing regulations. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

In our November 14, 2018 (83 FR 57264) proposed rule, we solicited public comment on each of the aforementioned issues for the following sections of the rule that contained information collection requirements (ICRs).

We did not receive any PRA-related public comments and are finalizing all provisions as proposed.

### *A. Wage Estimates*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

| Occupation title | Occupation code | Mean hourly wage ($/hr) | Fringe benefits and overhead ($/hr) | Adjusted hourly wage ($/hr) |
|---|---|---|---|---|
| Business Operations Specialist | 13–1000 | 35.52 | 35.52 | 71.04 |
| Computer Programmer | 15–1131 | 43.07 | 43.07 | 86.14 |
| Actuary | 15–2011 | 55.89 | 55.89 | 111.78 |
| Office and Administrative Support Worker | 43–9000 | 17.28 | 17.28 | 34.56 |

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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

### *B. Information Collection Requirements (ICRs)*

To estimate the burden for the requirements in part 438, we utilized state submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 55,601,033 enrollees in MCOs, 17,702,565 enrollees in PIHPs or PAHPs, and 5,462,769 enrollees in PCCMs, for a total of 80,242,585 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, 16 states that contract with 21 non-emergency transportation PAHPs, 16 states with 26 PCCM or PCCM entities, and 20 states that contract with one or more managed care plans for managed LTSS).

To estimate the burden for these requirements 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.

#### 1. ICRs Regarding Standard Contract Requirements (§ 438.3(t))

The following requirements and burden will be submitted to OMB for approval under control number 0938–0920 (CMS–10108). Subject to renewal, it was last approved on December 16, 2016, and remains active.

Amendments to § 438.3(t) will 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, and PAHP receives all appropriate crossover claims. If the state elects to use an alternative methodology the 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 will take 1 hour at $86.14/hr for a computer programmer to implement the message on the remittance advice. Given that 23 of the 33 states with duals in managed care have already required their plans to obtain COBAs, we estimate that half of the remaining states (5 states) will elect to pursue an alternative method. In aggregate, we estimate a one-time burden of 5 hours (5 states × 1 hr at a cost of $430.70 (5 hr × $86.14/hr)). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 1.33 hours (5 hr/3 years) at a cost of $143.57 ($430.70/3 years). We are annualizing the one-time burden

estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Additionally, for the 5 states that elect to require an alternative method, the amendments to § 438.3(t) will alleviate the 25 managed care plans that are operating within those states of the one-time requirement to obtain a COBA. In aggregate, we estimate a one time savings of −100 hr (25 plans × −4 hr for a business operations specialist) and −$7,104 (100 hr × $71.04/hr). As this will be a one-time savings, we annualize this amount to –33.33 hr (100 hr/3 years) and −$2,368 (−$7,104/3 years).

For the 5 states that elect to require that their plans obtain a COBA, in aggregate we estimate a one-time burden of 100 hrs (25 plans × 4 hr for a business operations specialist) at a cost of $7,104 (100 hrs × $71.04/hr specialist). As this will be a one-time burden, we annualize this amount to 33.33 hr (100 hr/3 years) and $2,368 ($7,104/3 years). We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

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

The following requirements and burden will be submitted to OMB for approval under control number 0938–1148 (CMS–10398 #52). Subject to renewal, it was last approved on March 1, 2018, and remains active.

Amendments to § 438.6(c) will remove the requirement for states to obtain prior approval for directed payment arrangements that utilize state plan approved rates. To obtain prior approval, states submit a preprint to CMS. Based on our experience, 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 would save 1 hour at $71.04/hr for a business operations specialist per directed payment arrangement. In aggregate, we estimate an annual savings of −40 hours (20 states × −2 preprints/year × 1 hr per preprint) and −$2,842 (−40 hr × $71.04/hr).

3. ICRs Regarding Rate Certification Submission (§ 438.7(c)(3))

Amendments to § 438.7(c)(3) will permit CMS to require states to submit documentation attesting that +/− 1.5% modifications to a capitation rate comply with specified regulatory requirements. We estimate that CMS will require documentation from no more than 3 states annually and that it will take a state's actuary 1 hour to prepare the documentation. For the 3 states that may be required to submit documentation, in aggregate we estimate an annual burden of 3 hrs (3 plans × 1 hr for an actuary) at a cost of $335.34 (3 hrs × $111.78/hr specialist).

4. ICRs Regarding Information Requirements (§ 438.10(d)(2) and (3))

Amendments to § 438.10(d)(2) and (d)(3) will 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 will 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 provision will likely reduce paper, toner, and postage costs for some states and managed care plans. Assuming that this change saves one sheet of paper (average price $25 per 5000 sheet carton or $0.005 per sheet), toner (average price $125 for 25,000 pages or $0.005 per sheet), and postage ($0.38 bulk postage per ounce) per enrollee, we estimate a savings of −$2,542,513 ([−$0.005 per sheet of paper × 74,779,816 enrollees or sheets of paper] + [−$0.005 toner per sheet of paper × 74,779,816 enrollees or sheets of paper] + [−$.024 ($0.38/bulk postage × 0.16 oz per sheet of paper) × 74,779,816 enrollees or sheets of paper]). The estimates are based on commonly available prices for bulk paper, toner, and bulk postage rate. We estimate the −$2,542,513 will be shared equally between the states and managed care plans given that they each provide written materials to enrollees and potential enrollees.

5. ICRs Regarding Information Requirements § 438.10(h)(3)(i)(B)

Amendments to § 438.10(h)(3) will permit states that elect to offer a mobile enabled provider directory to update the hardcopy provider directory quarterly instead of monthly. We are unable to estimate with any accuracy the cost of creating a mobile enabled provider directory; however, we assume it is substantially more than the savings that may be recognized from reducing the frequency of updating the directory since many of the data elements that are in the directory must be maintained accurately for other purposes, such as claims payment. We are not estimating a burden for this provision at this time.

6. ICRs Regarding Network Adequacy Standards (§ 438.68(a))

The following requirements and burden will be submitted to OMB for approval under control number 0938–0920 (CMS–10108). Subject to renewal, it was last approved on December 16, 2016, and remains active.

Amendments to § 438.68(a) will 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 provision replaces the requirement to adopt time and distance standards with a requirement to adopt a quantitative standard to evaluate network adequacy. We estimated in the May 6, 2016 final rule (81 FR 27777) a burden of $12,892 (20 states × 10 hrs at $64.46/hr for a business operations specialist) during the first year of developing the time and distance network adequacy standards for the provider types specified in § 438.68(b)(1). We further estimated a one-time state burden of $10,313.60 (16 states × 10 additional hours at $64.46/hr for a business operations specialist) to develop LTSS standards (81 FR 27777). In each case we did not estimate additional burden for states after the first year.

Since time and distance is one of many quantitative network adequacy standards, for states that used time and distance prior to the 2016 final rule or for those that have adopted time and distance to comply with the 2016 final rule, discontinuing the use of time and distance is merely an option that they may elect if they believe another measure better reflects the needs of their program. 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 change increases flexibility for states without affecting burden on states since it does not require states to take any action.

7. ICRs Regarding Grievance and Appeal System: General Requirements (§§ 438.402(c)(3)(ii) and 438.406(b)(3)).

The following requirements and burden will be submitted to OMB for approval under control number 0938–0920 (CMS–10108). Subject to renewal, it was last approved on December 16, 2016, and remains active.

Amendments to §§ 438.402(c)(3)(ii) and 438.406(b)(3) will no longer require enrollees to follow up an oral appeal with a written appeal. This change will

alleviate the burden on plans to follow up with enrollees that do not submit the written appeal. We estimate it will take up to 2 hours at $34.56/hr for an Office and Administrative Support Worker to call or send 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. In aggregate, we estimate an annual private sector savings of −120,000 hours (300 plans × 200 appeals × 2 hr) and −$4,147,200 (−120,000 hr × $34.56/hr).

8. ICRs Regarding Information Requirements (§ 457.1207)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0920 (CMS–10108). Subject to renewal, it was last approved on December 16, 2016, and remains active.

Section 438.10(d)(2) and (3) are adopted by cross-reference in the CHIP regulations at § 457.1207. As discussed in section II.B.2 of this final rule, amendments to § 438.10(d)(2) and (3) will 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 will 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 and an increase in postage costs as a result of these requirements, we believe that the provision will likely reduce paper, toner, and postage costs for some states. Assuming that, the change saves one sheet of paper (average price $25 per 5,000 sheet carton or $0.005 per sheet), toner (average price $125 per 25,000 pages or $0.005 per sheet), and postage ($0.38 bulk purchase per ounce) per enrollee, we estimate a savings of −$1,983,013.15 [$.005 per sheet of paper × 9,013,687 sheets of paper] + $.005 toner per sheet of paper × 9,013,687 sheets of paper] + (−$1,892,874.27= [$0.21/oz bulk postage × 9,013,687 sheets of paper]). The estimates are based on commonly available prices for bulk paper and toner.

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

The following requirements and burden will be submitted to OMB for approval under control number 0938–0920 (CMS–10108). Subject to renewal, it was last approved on December 16, 2016, and remains active.

Section 438.400(b) is adopted by cross-reference in the CHIP regulations at § 457.1260. As discussed in this final rule, the amendments to § 438.400(b) will 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 provision could reduce paper, toner, and postage costs for some states. Assuming that the change saves one sheet of paper (average price $25 per 5,000 sheet carton or $0.005 per sheet), toner (average price $125 for 25,000 pages or $0.005 per sheet), and postage ($0.38 bulk postage per ounce) per enrollee, we estimate a savings of −$1,757,669.16 [ $.005 per sheet of paper × −4,506,844 adverse benefit notices] + [$.005 toner × −4,506,844 adverse benefit notices] + [ $0.38/oz bulk postage × −4,506,844 adverse benefit notices]. The estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates.

*C. Summary of Added Burden and Burden Reduction Estimates*

Tables 2 and 3 set out our annual burden and burden reduction estimates.

TABLE 2—SUMMARY OF ANNUAL PRA-RELATED REQUIREMENTS AND BURDEN UNDER 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) | 5 | 5 | 1 | 5 | 86.14 | 86.14 | 430 | Once | 0.333 | 143 |
| § 438.3(t) | 5 | 25 | −4 | −100 | 71.04 | −284 | −7,104 | Once | −33.333 | −2,368 |
| § 438.3(t) | 5 | 25 | 4 | 100 | 71.04 | 284 | 7,104 | Once | 33.333 | 2,368 |
| § 438.6(c) | 20 | 2 | −1 | −40 | 71.04 | −71.04 | −2,842 | Annual | −40 | −2,841 |
| § 438.7(c)(3) | 3 | 3 | 1 | 3 | 111.78 | 111.78 | 335.34 | Annual | 3 | 335.34 |
| § 438.10(d)(2) and (3) | 42 | 74,779,816 | n/a | n/a | n/a | −0.005 | −373,899.08 | Annual | n/a | −373,899.08 |
| § 438.10(d)(2) and (3) | 42 | 74,779,816 | n/a | n/a | n/a | −0.005 | −373,899.08 | Annual | n/a | −373,899.08 |
| § 438.10(d)(2) and (3) | 42 | 74,779,816 | n/a | n/a | n/a | −0.024 | −1,794,715.58 | Annual | n/a | −1,794,715.58 |
| § 438.10(h) | | | | | | | | | | |
| § 438.402(c)(3)(i) | 300 | 60,000 | −2 | −120,000 | 34.56 | −69.12 | −4,147,200 | Annual | −120,000 | −4,147,200 |
| Total | 342 | 74,779,818 | varies | −120,032 | varies | varies | −6,691,789 | n/a | −120,040 | −6,692,746 |

TABLE 3—SUMMARY OF ANNUAL PRA-RELATED REQUIREMENTS AND BURDEN UNDER 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 | −1,892,874.27 | Annual | n/a | −1,892,874.27 |
| § 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 | 192 | 40,561,593 | n/a | n/a | n/a | 0.61 | −3,740,680.31 | Annual | n/a | −3,740,680.31 |

## IV. Regulatory Impact Analysis

### *A. Statement of Need*

As described in detail in section I.B. of this final rule, many of the revisions to part 438 outlined in this final 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 final rule streamlines 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 final 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). Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of lnformation and Regulatory Affairs designated this rule as not a ''major rule'', as defined by 5 U.S.C. 804(2).''

We did not receive any public comments on our assumptions or analysis.

We have examined the provisions in this final rule and determined that most of the revisions to part 438 outlined in this final rule are expected to reduce administrative burden as we noted in the Collection of Information (COI) section (see section III. of this final rule). Aside from our analysis on burden reduction in the COI section, we believe that the only provision in this final rule that may have an economic impact is the provision with revisions 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 will 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 will 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 will 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 will 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 in this RIA. Under § 438.6(d)(6), we are finalizing our proposal 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 final rule are met. One of the requirements in the final 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 will 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 final 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 requirements in this final 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 the final rule 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 the transition period, we believe that existing Federal pass-through payment requirements could incentivize states to retain some Medicaid populations 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 this final rule, we wanted 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 final 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 this final rule, states will 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 will 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 will verify that the pass-through payment amounts are permissible under this final rule, 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 this provision to be budget neutral. We requested public comments on our assumptions and analysis as part of the proposed rule.

We did not receive any public comments on our assumptions or analysis.

We are setting out savings based on amendments being finalized in this rule to § 438.400(b) which will 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 per § 438.404(a). While we have no data on the number of adverse benefit notices that are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees (37,389,908); thus, this proposal could reduce paper, toner, and postage costs for some managed care plans. If we assume that in the aggregate, this change saves one sheet of paper (average price $25 per 5,000 sheet carton or $0.005 per sheet), toner (average price $125 for 25,000 pages or $0.005 per sheet), and $0.024 bulk postage ($.038/per ounce × 0.16 oz per sheet of paper) per enrollee, we estimate an annual savings of $1,084,307.30

Based on the calculations in the Collection of Information (COI) section (see section III. of this final rule, Tables 2 and 3), and the additional cost savings identified for § 438.400(b) described above, we are estimating that this final rule will result in an annual cost savings of $12,071,068.

*C. Anticipated Effects*

The Regulatory Flexibility Act (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 final rule will have a significant economic impact on a substantial number of small businesses. We sought comment on this belief.

We did not receive any public comments on our assumptions or analysis. Therefore, we are not preparing an analysis because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small businesses.

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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The 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 sought 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We did not receive any public comments on our assumptions or analysis.

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 2020, that is approximately $156 million. We believe that this final rule will have no consequential effect on state, local, or tribal governments or on the private sector.

We did not receive any public comments on our assumptions or analysis.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirements costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule does not impose any substantial direct costs on state or local governments; however, the provision at § 438.4(b)(1) may preempt state law if the differences among capitation rates for covered populations are not based on valid rate development standards and instead are based solely on network provider reimbursement requirements for covered populations that are mandated by state statute.

We did not receive any public comments on our assumptions or analysis.

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 final rule are expected to reduce administrative burden; therefore, this rule is an E.O. 13771 deregulatory action. We estimate that this final rule generates $11,704,348 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated cost savings of this final rule can be found in the preceding analyses.

We did not receive any public comments on our assumptions or analysis.

*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 final rule is the result of that review and streamlines 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 sought comment on a number of requirements included in this final rule to identify potential alternatives to proposed provisions.

The following is a summary of the public comments we received on the requirements included in this final rule to identify potential alternatives to proposed provisions.

*Comment:* One commenter expressed concerns that the only alternative considered was leaving the 2016 final rule as is. This commenter noted that there were already errors acknowledged in the previous rule and noted that rather than improving on the rule, these changes will not benefit families and their children.

*Response:* We understand the commenter's concerns; however, as noted, we undertook a comprehensive review of the current regulations and developed proposals to achieve a better balance between appropriate Federal oversight and state flexibility. As the commenter did not offer other alternatives for CMS to consider, we are not including additional alternatives under this final rule, other than the alternatives already discussed.

*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 sought comment on these kinds of issues with the intent to modify and add to the common terminology in this final rule as appropriate based on the comments received.

We did not receive any public comments on our assumptions or analysis.

In accordance with the provisions of Executive Order 12866, this final 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 final 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. | | | | | | |

TABLE 4—ACCOUNTING STATEMENT—Continued

| Category | Primary estimate | Low estimate | High estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|
| | | | | Year dollars | Discount rate | Period covered | |
| **Costs** | | | | | | | |
| Annualized Monetized $ millions/year | −12 | | | 2018 | | 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 collections as defined in the Paperwork Reduction Act) that will be necessary for generating the benefits listed in this final rule. | | | | | | |
| **Transfers** | | | | | | | |
| Non-Quantified | Relative to the current pass-through payment baseline, this final 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 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 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 amends 42 CFR chapter IV as set forth below:

## PART 438—MANAGED CARE

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

**Authority:** 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 ensures that the appropriate MCO, PIHP, or PAHP receives 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 State has not denied payment and that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

* * * * *

■ 3. Section 438.4 is amended by revising paragraph (b)(1) to read as follows:

**§ 438.4 Actuarial soundness.**

* * * * *

(b) * * *

(1) Have been developed in accordance with the standards specified in § 438.5 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. 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. 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 represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

* * * * *

■ 4. Section 438.4 is further amended, effective July 1, 2021, by adding paragraph (c) to read as follows:

**§ 438.4 Actuarial soundness.**

* * * * *

(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 is increasing or decreasing the capitation rate per rate cell within the rate range up to 1 percent during the rating period. However, any changes of the capitation rate within the permissible 1 percent range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at paragraph (b)(1) of this section. Any modification to the capitation rates within the rate range greater than the permissible 1 percent range will require the State to provide a revised rate certification for CMS approval, 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.

(iv) Post on the website required in § 438.10(c)(3) the following information prior to executing a managed care contract or contract amendment that includes or modifies a rate range:

(A) The upper and lower bounds of each rate cell;

(B) A description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, the specific assumptions used for the upper and lower bounds of each rate cell; and

(C) A description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, the specific data and methodologies used for the upper and lower bounds of each rate cell.

■ 5. 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.

* * * * *

■ 6. 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).

The revisions and additions read as follows:

**§ 438.6 Special contract provisions related to payment.**

(a) * * *

*State plan approved rates* means amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan. Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.

*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 demonstration or waiver thereof and are in addition to State plan approved rates. Disproportionate share hospital (DSH) and graduate medical education (GME) payments are not, and do not constitute, supplemental payments.

* * * * *

(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.

(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.

(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) and (ii) and (c)(1)(iii)(B) through (D) 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 provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the 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;

(C) May not set the amount or frequency of the expenditures; and

(D) 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 paragraphs (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.

* * * * *

■ 7. Section 438.6 is further amended, effective July 1, 2021, by adding paragraph (d)(6) to read as follows:

**§ 438.6 Special contract provisions related to payment.**

* * * * *

(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 paragraph (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 state plan approved rates for hospital services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(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 state plan approved 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. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(C) *Physicians.* For physician services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through state plan approved 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. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(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.

* * * * *

■ 8. 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 during the rating period 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.

■ 9. 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.

* * * * *

■ 10. 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).

* * * * *

■ 11. Section 438.10 is amended by—

■ a. Revising paragraph (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 languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, 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, information on how to request auxiliary aids and services, 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.

* * * * *

■ 12. Section 438.54 is amended by adding paragraph (b)(3) to read as follows:

**§ 438.54 Managed care enrollment.**

* * * * *

(b) * * *

(3) States must provide the demographic information listed in § 438.340(b)(6) for each Medicaid enrollee to the individual's MCO, PIHP, PAHP, or PCCM entity at the time of enrollment.

* * * * *

■ 13. Section 438.56 is amended by revising the paragraph (d)(5) heading 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.

* * * * *

■ 14. Section 438.68 is amended by—

■ a. Revising paragraphs (b)(1) introductory text and (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) *Provider types.* 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]**

■ 15. 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.''

■ 16. 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.

* * * * *

■ 17. Section 438.334 is amended by revising paragraphs (b) and (c)(1) and (3) and adding paragraph (c)(4) to read as follows:

**§ 438.334 Medicaid managed care quality rating system.**

* * * * *

(b) *Quality rating system.* (1) CMS, after consulting with States and other stakeholders and providing public notice and opportunity to comment, will develop a framework for a Medicaid managed care quality rating system (QRS), including the identification of the performance measures, a subset 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 described in subpart D of part 422 of this chapter, and other related CMS quality rating approaches.

(2) CMS, after consulting with States and other stakeholders and providing public notice and opportunity to comment, may periodically update the Medicaid managed care QRS framework developed in accordance with paragraph (b)(1) of this section.

(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;

(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.

(iii) The State receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

* * * * *

(3) In requesting CMS approval, the State must include the following:

(i) The alternative quality rating system framework, including the performance measures and methodology to be used in generating plan ratings; and,

(ii) Documentation of the public comment process specified in paragraphs (c)(2)(i) and (ii) of this section, including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted; and,

(iii) Other information specified by CMS to demonstrate compliance with paragraph (c) of this section.

(4) The Secretary, after consulting 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.

* * * * *

■ 18. 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. In newly redesignated paragraph (b)(9) by removing ''; and'' and adding a period in its place.

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

■ f. 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:

**§ 438.340 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 will 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. For purposes of this paragraph (b)(6), ''disability status'' means, at a minimum, whether the individual qualified for Medicaid on the basis of a disability. States must include in this plan the State's definition of disability status and how the State will make the determination that a Medicaid enrollee meets the standard including the data source(s) that the State will use to identify disability status.

* * * * *

(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.

* * * * *

■ 19. 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.

* * * * *

■ 20. 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 where the EQR technical reports are posted in accordance with § 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, or that no MCOs are exempt, as appropriate.

■ 21. Section 438.364 is amended by adding paragraph (a)(7) and revising paragraph (d) to read as follows:

**§ 438.364 External quality review results.**

(a) * * *

(7) The names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period, or that no MCOs are exempt, as appropriate.

* * * * *

(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.

■ 22. 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 solely 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.

* * * * *

■ 23. 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.

■ 24. 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.

* * * * *

■ 25. 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

■ 26. The authority citation for part 457 continues to read as follows:

**Authority:** 42 U.S.C. 1302.

■ 27. 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.

■ 28. 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 in § 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.

* * * * *

■ 29. Section 457.1240 is amended by revising paragraphs (b), (d), and (e) to read as follows:

**§ 457.1240 Quality measurement and improvement.**

* * * * *

(b) *Quality assessment and performance improvement program.* (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees, in accordance with the requirements and standards in § 438.330 of this chapter, except that the terms of § 438.330(d)(4) of this chapter (related to dually eligible beneficiaries) do not apply.

(2) 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.

* * * * *

(d) *Managed care quality rating system.* The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.334 of this chapter, except that the terms of § 438.334(c)(2)(i) and (c)(3) of this chapter (related to consultation with the Medical Care Advisory Committee) do not apply.

(e) *Managed care quality strategy.* The State must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in § 438.340 of this chapter, except that the reference to consultation with the Medical Care Advisory Committee described in § 438.340(c)(1)(i) of this chapter does not apply.

* * * * *

■ 30. 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 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), and (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 this part after receiving notice under paragraph (e) of this section that the adverse benefit decision is upheld by the MCO, PIHP, or PAHP.

(3) 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 section, it includes providers and authorized representatives consistent with this paragraph (b).

(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) and (b)(1), (2), and (5) of this chapter (regarding the content of the notice of an adverse benefit determination).

(2) In addition to the requirements referenced in paragraph (c)(1) of this section, the notice must explain:

(i) 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 referenced in paragraph (b)(1) of this section, and the right to request a State external review in accordance with the terms of subpart K of this part; and

(ii) The procedures for the enrollee to exercise his or her rights provided under this paragraph (c).

(3) The MCO, PIHP, or PAHP must provide timely written notice to the enrollee of the adverse benefit determination. The terms of §§ 438.404(c)(6) and 438.210(d)(2) of this chapter apply in the circumstances of expedited service authorization decisions.

(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) (relating to the timeframe for resolution of grievances and appeals), (c)(1) and (2) (the extension of timeframes for resolution of grievances and appeals), (d) (relating to the format of the notice of resolution for grievances and appeals), and (e)(1) (relating to the content of the notice of resolution for grievances and appeals) 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 paragraph (e).

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in 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 an enrollee, in addition to the information required under paragraph (e)(1) of this section and § 438.408(e)(1) of this chapter, the content of the notice of appeal resolution must include the enrollee's right to request a State external review in accordance with the terms of subpart K of this part, and how to do so.

(5) Except as provided in paragraph (e)(3) of this section, an enrollee may request a State external review only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination. The State must provide enrollees 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 external review. The parties to the State external review include the MCO, PIHP, or PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(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) *Effectuation of reversed appeal resolutions.* 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, 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.

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

**§ 457.1270 Sanctions.**

(a) *General.* 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 temporary management.* Except as provided in paragraph (c) of this section, the State may impose temporary management under § 438.702(a)(2) of this chapter as referenced in paragraph (a) of this section, 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 (as referenced in paragraph (a) of this section), 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 as referenced in paragraph (a) of this section.

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

(c) *Required imposition of temporary management.* 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 as referenced in paragraph (a) of this section, and must notify the affected enrollees of their right to terminate enrollment.

■ 32. 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 438.608(d)(4) of this chapter do not apply.

Dated: September 14, 2020.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: September 21, 2020.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2020–24758 Filed 11–9–20; 11:15 am]

**BILLING CODE 4120–01–P**