Medicaid and Children's Health Insurance Plan (CHIP) Managed Care
(CMS-2408-P)
Summary of Proposed Rule

On November 14, 2018, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) published in the *Federal Register* (83 FR 57264) a proposed rule providing for policy and technical changes to Medicaid and CHIP managed care rules.

Major proposed changes include:

- Allowing pass-through payments for new managed care enrollment or services during a transition period;
- Making network adequacy requirements more flexible for states by replacing required time and distance standards with a requirement for "quantitative standards";
- Specifying the types of state-directed payments that CMS would permit and eliminating the requirement for advanced approval for certain directed payment approaches;
- Adding specificity on prohibited rate setting practices and allowing states to certify rate ranges as actuarially sound under certain limited circumstances; and
- Increasing the flexibility for states to coordinate benefits across Medicare and Medicaid.

Comments are due on January 14, 2019.

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I. Medicaid Managed Care

A. Background

CMS reviews the federal statutory authority for Medicaid managed care and its recent regulatory history. Under Medicaid, states are permitted to implement managed care under the following authorities:

- Section 1915(a) – Allows states to contract with managed care organizations (MCOs) to implement a voluntary managed care program.
- Section 1932(a) – Allows states to contract with MCOs to implement a mandatory managed care program with exceptions for certain beneficiaries. Those dually eligible for Medicare and Medicaid, American Indians/Alaskan Natives (with an exception), and children with special health care needs cannot be required to enroll in managed care.
- Section 1915(b) – Allows CMS to grant a waiver permitting states to implement a mandatory managed care program that includes the dually eligible for Medicare and Medicaid, American Indians/Alaskan Natives (with an exception), or children with special health care needs. Waivers must be renewed after 2 years (or 5 years if they include dually-eligible beneficiaries).
- Section 1115(a) research and demonstration authority – Permits CMS to approve waivers of Medicaid rules to allow states to demonstrate and evaluate innovative programs that may include managed care.

CMS describes two recent regulatory actions that impact Medicaid managed care. In May of 2016, CMS published "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" final rule (81 *FR* 27498, hereinafter referred to as "the 2016 final rule"). This rule sought to modernize the Medicaid and CHIP managed care regulations, align them with other major sources of coverage, strengthen actuarial soundness provisions, and promote delivery system reform efforts, among other priorities.

In January of 2017, CMS published the "Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems" final rule (82 *FR* 5415, or the "2017 pass-through payment rule") which made changes to pass-through payment transition periods, and maximum allowable amounts, and prohibited increases and new pass-through payments beyond those in place when the final rule was published.

This proposed rule addresses some stakeholders' concerns that the existing rules are burdensome and overly prescriptive. CMS states that it seeks to streamline the managed care rules by reducing unnecessary and duplicative administrative burden and to ensure that states are able to design, develop and implement Medicaid managed care programs that best meet their local populations' needs.

B. Provisions of the Proposed Rule

1. Standard Contract Requirements (§438.3)

In the 2016 final rule, CMS required state contracts with a Medicaid MCO or prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) that covers dual eligible individuals to include a Coordination of Benefits Agreement and participate in an automated crossover claims process administered by Medicare.

States have indicated, however, that the Medicare system causes confusion, sometimes sending claims to the wrong Medicaid MCO when a beneficiary is enrolled in more than one plan at the same time or when a beneficiary changes plans. (A Medicaid beneficiary may be enrolled with one managed care provider for medical care, a separate one for dental care, and another for behavioral health care, for example.)

CMS proposes to replace the 2016 requirement with a new requirement that allows a state to choose its approach to coordinating benefits across Medicare and Medicaid. Under the proposed rule, the contract with an MCO, PIHP, or PAHP that is responsible for coordination of benefits with Medicare would be required to indicate the methodology that would be used to ensure the adjudication of crossover claims. States choosing an approach that is different from a Coordination of Benefits Agreement with Medicaid must ensure that the submitting provider is informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment.

2. Actuarial Soundness Standards (§438.4)

a. Option to Develop and Certify a Rate Range

Medicaid statute and regulations require states' capitation rates paid to managed care plans to be certified as actuarially sound. In the 2016 final rule, CMS required that states develop, and certify as actuarially sound, rates based on rate cells rather than rate ranges. CMS indicated in that rule that certifying rate cells instead of ranges would increase transparency, program integrity and better align with other insurers' processes.

At the time, CMS was concerned that states were making significant retroactive changes to rates that had been approved using a rate range without notifying CMS or the public. Rate ranges were sometimes considered unreasonably wide (as much as 30 percent) and retroactive changes were sometimes unrelated to utilization, the cost of medical care or services, or the health status of

enrollees. CMS indicates that retroactive changes to rates were often used to provide additional reimbursements to plans or providers that were intended to effectively shift costs to the federal government (for example, via intergovernmental transfer (IGT) agreements).

In response to the 2016 final rule, CMS learned that some states find the lack of flexibility as a result of approving rate cells means that they can't obtain the best rates and are overly burdensome. In response, CMS is proposing an option for states to certify rates based on a range so long as a number of conditions are met. The conditions are intended to limit any gaming of the capitation payment rates to shift costs to the federal government. To approve a rate range a state would be required to ensure that:

- The upper bound of the range is no more than 5 percent higher than the lower bound;
- The rate certification identifies and justifies the assumptions, data, and methodologies for both the upper and lower bounds of the range;
- Both the upper and lower bounds are certified as actuarially sound;
- The rate certification documents the state's criteria for paying the MCOs, PIHPs, and PAHPs at different points within the rate range; and
- The state does not base payments at different points within the rate range on (a) The willingness or agreement of the MCOs, PIHPs, or PAHPs or their network providers to enter into, or adhere to, IGT agreements; or (b) The amount of funding the MCOs, PIHPs, or PAHPs or their network providers provide through IGT agreements.

States choosing this proposed rate range option would be required to document the rates permitted within the rate range prior to the start of the rating period and would not be permitted to modify the rates except in the case of errors in their application or methodology.

CMS requests comment on whether additional conditions should be considered to ensure that rates are actuarially sound; whether CMS has appropriately balanced the need for state flexibility with program integrity; any unintended consequences that could arise from the proposal; and whether additional conditions should be placed on the use of rate ranges. CMS also seeks quantitative data to help quantify the benefits and risks of the proposal and encourages other comments on the need, benefits, risks, and proposed risk mitigations in the proposed provision.

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, CMS established standards that capitation rates must meet in order to be approved as actuarially sound. One of those provisions prohibits different capitation rates based on FFP associated with a particular population. This prohibition was intended to prevent rates that included higher payments to providers for populations with higher FFP. CMS points out that this practice is sometimes used to shift costs from the state to the federal government and is not based on generally accepted actuarial principles and practices nor valid rate development standards.

In the intervening years, additional guidance has been requested on the prohibited practices. As a result, CMS proposes several additions to the existing prohibition to clarify it and to add examples of prohibited activities.

CMS proposes to add clarification (in bold) to existing §438.4(b)(1), a paragraph that describes what is necessary for capitation rates to be approved by CMS as actuarially sound. Under the proposed change, 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 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.**

In addition, CMS proposes new paragraph (d) to further describe rate development practices that increase federal costs and vary with the rate of FFP, to require a state to provide written documentation that differences in factors used to develop rates are based on actual cost differences, and to require an evaluation if it determines that differences in rates were based on FFP and increase federal costs. The evaluation would be required across the entire managed care program of the state and across all of its managed care contracts.

In proposed (d)(1), CMS lists specific rate development practices that would be prohibited under the rule. CMS points out that the list is not meant to be exhaustive.

- Using higher profit margin, operating margin, or risk margin when developing capitation rates for any covered population, or contract, than that used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP;
- Factoring into rates higher cost provider fee schedules, or minimum levels of provider reimbursement for a covered population as compared with that of the covered population, or contract, with the lowest average rate of FFP; and
- Using a lower remittance threshold for a medical loss ratio for any covered population, or contract, than that of the population, or contract, with the lowest average rate of FFP.

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

Existing rules require states, as part of the rate setting process, to use base data that is no older than that from the 3 most recent and complete years prior to the rating period. The data must be used in accordance with actuarial standards for data quality. States must provide in the rate certification an explanation of why those specific data are used. States unable to meet these data standards may request approval for an exception. States that request an exception from the base data standards must set forth a corrective action plan to come into compliance with the base data standards *no later than 2 years from the rating period for which the deficiency was identified*.

CMS states in the preamble to this proposed rule that the current regulation text regarding the corrective action timeline is not clear nor consistent with the timeline that it described in the preamble to the 2016 final rule. The preamble text in the 2016 final rule 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."

CMS proposes to clarify this timeline by altering the regulation text to require a correction plan that comes 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*."

CMS provides the following example of the timeline: If the state's rate development for calendar year 2018 does not comply with the base data requirements, the state would have 2 calendar years after the last day of the 2018 rating period to come into compliance.

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

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

CMS proposes changes to §438.6(b) to clarify documentation requirements for risk adjustment mechanisms and the timing of such documentation and to make clear that risk-sharing mechanisms cannot be added or modified after the start of the rating period. CMS proposes that a description of such mechanisms be included in the rate certification.

In part, these modifications are intended to make clear that risk-sharing mechanisms should be developed in conjunction with capitation rates and must use the same actuarially sound principles and practices. In addition, the proposed changes make clear that retroactive risk-sharing mechanisms are not permitted. CMS acknowledges that certain retroactive adjustments to rates may be appropriate. Under existing §438.7(c)(2), they may be permitted so long as they are supported by sufficient data, assumptions and methodologies, are described in sufficient detail, and are submitted in a new rate certification along with the contract amendments.

b. Delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts (§438.6(a) and (c))

CMS proposes a number of changes to §438.6(a) and (c) that are intended to address directed payment arrangements and limit the use of supplemental payment arrangements. Existing rules, which were largely the product of the 2016 final rule, permit states to direct a managed care plan's expenditures under limited circumstances. Directed payment arrangements must be approved by CMS; and can be used:

- As part of a value-based arrangement or multi-payer delivery system reform or performance improvement initiative;
- To implement a minimum fee schedule for network providers that provide a particular service under a contract; or
- To implement a maximum fee schedule for network providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP can manage risk and has discretion in accomplishing the goals of the contract.

After reviewing states' plans incorporating directed payment arrangements since the 2016 rules were finalized, CMS proposes the following amendments to §438.6(c) to incorporate common arrangements, to provide for additional flexibility and to encourage payment models that provide high value. CMS proposes to:

- Allow states to direct payments to adopt a minimum fee schedule that *uses the same rates as approved under an existing state plan*. This proposed change includes that supplemental payments do not constitute state plan approved rates. In addition, CMS proposes new definitions in §438.6(a) for 'state plan approved rates' and 'supplemental payments' that make clear that supplemental payments are not included in amounts approved in a state plan rate methodology. CMS points out that states often direct payments in this way to ensure adequate access to providers.
- Allow states to adopt cost-based rates, Medicare equivalent rates, commercial rates, or other market-based rates for network providers that provide a particular service under the contract.
- Eliminate the existing prohibition on states that direct payments to MCOs, PIHPs or PAHPs under a value-based arrangement, multi-payer delivery system reform or performance improvement initiative from setting the amount or frequency of directed expenditures. CMS notes that the provision may have created unintended barriers to innovative payment models such as global payment initiatives.
- Codify a process for approval of multi-year payment arrangements consistent with subregulatory guidance issued in 2017.[1] New §438.6(c)(3) would allow for a multi-year directed payment arrangement to be approved so long as the arrangement is described in the contract and (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 it 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; 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 prior CMS approval.

In addition, CMS proposes a change to the process for approving directed payment arrangements. Prior rules required all directed payment arrangements to be approved by CMS. The proposed change would permit those arrangements that use state plan-approved rates to be implemented without written prior approval.

c. Pass-through payments under MCO, PIHP, and PAHP contracts (§438.6(d))

In the 2016 final rule and the 2017 pass-through payment rule, CMS limited states' ability to use pass-through payments. Pass-through payments are payments to managed care plans that are

[1] See 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).

disconnected from the amount, quality, or outcomes of services delivered to enrollees under the contract. The rules effectively limited pass-through payments to those in place as of July 5, 2016.

CMS has since recognized the challenges associated with transitioning supplemental provider payments into payments based on the delivery of services or value-based payments, particularly for states that are newly transitioning beneficiaries or services from fee-for-service (FFS) into managed care.

To address those states' requests to continue making some supplemental payments and to assist with transitioning services or beneficiaries into managed care, CMS is proposing in new §438(d)(6) to allow states to make pass-through payments under new managed care contracts for a transition period so long as certain criteria are met.

Specifically, CMS proposes to allow a state that is initially transitioning Medicaid populations or services from FFS to managed care to require an MCO, PIHP, or PAHP to make pass-through payments to network hospitals, nursing facilities, or physicians for each rating period of a transition period that may last for up to 3 years. To do so, the following conditions would need to be met:

- The services would 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.
- The state made supplemental payments to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first year of the transition period.
- The aggregate amount of the pass-through payments that the state could require under the proposal must be below a ceiling for each provider type as described below.
- Pass-through payments would be permitted for the 3 transition years as long as the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

For each of the three provider types (hospitals, nursing facilities and physicians) the amount of pass-through payments that would be permitted during the transition years would be equal to the actual supplemental payments paid to each provider type multiplied by the proportion of total payments for that service type that are being transitioned from FFS to the managed care contract. In calculating these ceilings, the state would have to use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the transition period.

d. Payments to MCOs and PIHPs for enrollees that are patients in an institution for mental disease (IMD) (§438.6(e))

In the 2016 final rule, CMS permitted federal matching payments for MCO or PIHP enrollees who receive inpatient treatment in an IMD for a stay that is no more than 15 days of a month. States and other stakeholders have asked CMS to consider allowing for stays of longer than 15 days in a month especially in light of substance use disorder (SUD) treatment needs.

CMS is not proposing changes in this area but requests feedback from stakeholders identifying additional data that would support FFP for stays of longer than 15 days in a month. In addition, CMS encourages states to apply for a section 1115(a) research and demonstration waiver under CMS' SUD demonstration initiative to enable reimbursement for longer lengths of stay in IMDs.[2]

5. Rate Certification Submission (§438.7)

CMS proposes to clarify its existing rule that states may increase or decrease final capitation rates for each rate cell by a de minimis amount that is less than plus or minus 1.5 percent without submitting justification to CMS. In adding clarification to §438.7(c)(3), CMS proposes to state that such adjusted rates would still need to be developed in accordance with other rate development standards (in §438.5) and be based on generally accepted actuarial principles and practices, valid rate development standards, and not based on the FFP associated with the different covered populations (in §438.4(b)(1)).

CMS proposes to add new paragraph §438.7(e) which codifies an annual CMS publication providing rate development and procurement guidance. CMS believes the annual guidance would make the review and approval process more efficient and increase the likelihood that states first transitioning to a managed care delivery system will set actuarially sound rates.

The guidance would identify:

- Standards for capitation rate development;
- Documentation needed to ensure that capitation rates would provide for all necessary costs, were developed in accordance with all applicable rules, and that competitively bid rates comply with required procurement rules; and
- Any updates or developments in the rate review process to reduce state burden and facilitate prompt actuarial reviews.

6. Medicaid loss ratio standards (MLR): Technical correction (§438.8)

CMS proposes a technical correction to correct a reference to a provision that was proposed but never finalized in the 2016 final rule.

[2] SMD #17-003: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.

7. Non-emergency medical transportation (NEMT) at PAHPs (§438.9)

CMS states that it inadvertently left out an exemption from MLR requirements for NEMT PAHPs to be consistent with a separate provision that specifically exempts them from rules in part 438 (with exceptions). CMS proposes adding that exemption for NEMT PAHPs from MLR requirements.

8. Information Requirements (§438.10)

a. Language and Format (§438.10(d))

Existing rules require states and managed care plans to provide required plan information in a manner and format this is easily understood. Written materials must include taglines in prevalent non-English languages and in large print for all written materials provided for potential enrollees and enrollees. CMS proposes to change the requirements applicable to written materials so that they only apply to written materials *that are critical to obtaining services* and would eliminate the requirement that they must all be in large print, instead requiring material critical to obtaining services be printed in *a conspicuously-visible font size*. CMS believes this flexibility would allow states to use post-cards and tri-fold brochures when those shorter form documents would be useful. It points out that states and plans would have the flexibility to continue to use large font if they chose.

b. Information for all enrollees of MCOs PIHPs, PAHPs, and PCCM entities: General requirements (§438.10(f))

Existing rules require plans to provide notice to enrollees of a provider's termination within 15 days of a covered plan's receipt or issuance of the termination notice for those enrollees who received primary care from, or were regularly seen by, the terminated provider. CMS notes, however, that there are circumstances when plans or providers send a termination notice to a beneficiary while continuing to negotiate with the provider to resolve the issue that triggered the decision to terminate. If the issue(s) are resolved, then the termination notice is sometimes rescinded. Doing so may cause confusion for enrollees, especially those who believe that they need to locate a new provider.

CMS proposes to modify the timing for the required notice to prevent unnecessary notices from being sent to enrollees. Under the proposal, managed care plans would be required to issue notices by 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.

c. Information for all enrollees of MCOs, PIHPs, PAHPs and PCCM entities: Enrollee Handbooks (§438.10(g))

CMS proposes to correct an erroneous reference, changing "paragraph (g)(2)(i)(A)" (which doesn't exist) to paragraph (g)(2)(ii)(A).

d. Information for all enrollees of MCOs PIHPs, PAHPs and PCCM entities: Provider Directories (§438.10(h))

CMS proposes two significant changes to the requirements related to provider directories:

- To eliminate the requirement that directories include whether a provider has completed cultural competence training. The 21st Century Cures Act, passed in December of 2016, established standards for provider directories for Medicaid FFS that do not require information on whether the provider has completed cultural competence training. CMS states that the proposed change would align those standards. CMS notes that directories would continue to be required to include information on a provider's cultural and linguistic capabilities, including the languages spoken by the provider or by an interpreter available at the provider's office.
- To change the requirement that information in a paper provider directory (which must be made available upon request) be updated at least monthly. CMS proposes that such updates be required quarterly if the MCO, PIHP, PAHP, or PCCM entity has a mobile-enabled electronic provider directory. If the entity does not have a mobile-enabled electronic provider directory, they would continue to be subject to the requirement for at least monthly updates to the paper directory. In the preamble, CMS provides data on the percentage of low-income U.S. adults who have access to smartphones.

CMS also proposes to change the term "directories" in these provisions to "directory" to avoid implying that a managed care entity must have more than one directory.

9. Disenrollment: Requirements and limitations (§438.56)

CMS proposes to correct mistaken references to PCCMs and PCCM entities in provisions describing the potential use of the grievance process for addressing disenrollment requests. CMS states that those entities are not required under §438.228 to have grievance systems in place.

10. Network Adequacy Standards (§438.68)

Under existing rules, states are required to have in place time and distance standards for a set of provider types in order to enforce network adequacy standards. At a minimum, current §438.68(b)(1) requires that states must develop time and distance standards for the following provider types:

(i) Adult and pediatric primary care,
(ii) Obstetrics and gynecology,
(iii) Adult and pediatric behavioral health,
(iv) Adult and pediatric specialists,
(v) Hospital,
(vi) Pharmacy,
(vii) Pediatric dental, and
(viii) Any additional provider types as determined by CMS.

CMS proposes to replace the required "time and distance standards" with more flexible "quantitative network adequacy standards." CMS notes that time and distance standards do not take into account the availability of telehealth providers, nor measure certain important factors like wait times.

In the preamble, CMS provides examples of measures that states may elect with the proposed flexibility including minimum provider-to-enrollee ratios, maximum travel time or distance to providers, minimum percentage of providers accepting new patients, maximum wait times, and hours of operations.

CMS also proposes to clarify, in the list of provider types that states may define "specialist" in whatever way they deem most appropriate for their programs. CMS proposes to do this by adding the parenthetical "as designated by the state" after the word "specialist" in the list of provider types subject to the network adequacy standards.

Finally, CMS proposes to eliminate the authority in §438.68(b)(1)(viii) permitting CMS to add additional provider types to the list of provider types to which states must apply time and distance standards. CMS states that this authority would have enabled it to address future provider workforce shortages. States, however, raised concerns that they would not be able to respond with sufficient time to new additions of provider types in order to measure adequately and to build network capacity if it were found to be inadequate.

11. Adoption of Practice Guidelines (§438.236)

In the 2016 final rule, CMS replaced the phrase "contracting health care professionals" with the term "network provider" as defined in §438.2 but missed one of those references in §438.236(b)(3). CMS proposes to make that replacement.

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

Under existing rules, managed care entities are required to report enrollee encounter data that states are required to report to CMS. CMS proposes to clarify this requirement to say that enrollee encounter data includes allowed amounts and paid amounts. This clarification is in response to plans raising the concern that these data are proprietary. CMS states its position that such information is already public because it is available on enrollees' explanation of benefits so it does not consider them to be trade secrets.

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

CMS proposes several changes to existing §438.334 which describes Medicaid's Managed Care Quality Rating System. States are required under this section to either adopt the managed care quality rating system developed by CMS or to develop their own system. A state's system must be approved in advance by CMS and must produce performance data which are *substantially*

comparable to that yielded by the CMS system. They must also obtain input from the state's Medical Care Advisory Committee, provide an opportunity for public comment, provide documentation to CMS about the public comment process, including issues raised by the Medical Care Advisory Committee and the public and any policy revisions or modifications made in response to the comments, including a rationale for comments not accepted.

Both in response to stakeholder feedback about the challenges of producing substantially similar performance data across plans and across state programs that are very different from one another as well as to reduce burden on states, CMS proposes the following changes:

- To permit state-developed QRS frameworks to align with the CMS framework *where appropriate* (instead of requiring that the data be *substantially comparable*).
- To incorporate that such systems should also, *where appropriate* align with the systems applicable to Qualified Health Plans (under 45 CFR 156.1120), Medicare Advantage's 5-Star Rating System, and other CMS quality rating systems.
- To enable states to implement an alternative QRS without obtaining prior approval by CMS. Instead, states would be required, upon CMS request, to submit their alternative framework, including performance measures and methodologies, documentation of the public comment process, issues raised by their Medical Care Advisory Committee and by the public, changes made in response, comments not accepted, and any other information specified by CMS.

In addition, CMS specifies that the CMS-developed QRS framework must identify a set of mandatory performance measures and states' alternative QRS systems must include those mandatory measures.

CMS proposes to codify that it will, in consultation with states and other stakeholders, issue guidance describing the criteria and process for determining if an alternative QRS system is aligned with the CMS developed system. CMS states that it expects to coordinate measures selected for its recently-launched Scorecard Initiative with those selected for the CMS-developed QRS.

14. Managed Care State Quality Strategy (§438.340)

In the 2016 final rule, CMS expanded managed care state quality strategy requirements to apply to PCCM entities in addition to MCOs, PIHPs and PAHPs. Under this section those managed care entities are required to have quality strategies in place for assessing and improving the quality of health care services furnished by MCOs, PIHPs, PAHPs, and risk bearing PCCM entities. Section 438.340(b) sets out the minimum elements of a managed care state quality strategy.

In making the regulatory changes in 2016, however, CMS left off the references to PCCM entities in a number of places where it should have appeared. CMS proposes to add those missing references to paragraphs defining the following elements of a state's quality strategy:

- The state's goals and objectives for continuous quality improvement;

- The state's quality metrics and performance targets; and
- 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.

CMS notes that it does not propose to add references to PCCM entities to paragraphs relating to state-defined network adequacy, availability of service standards, clinical practice guidelines, and performance improvement measures because those requirements do not apply to PCCM entities.

Under existing rules, one of those required elements of a state's quality strategy is to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. "Disability status" is defined in the element as being based on whether the individual qualified for Medicaid on the basis of a disability. CMS proposes more flexibility with respect to identifying individuals with disabilities by eliminating any specific definition of disability status from the element.

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

CMS proposes a technical change to add cross-references that were inadvertently dropped when those provisions were moved to different sections in the 2016 final rule.

16. Exemption from External Quality Review (§438.362)

Under existing rules, states may exempt certain MCOs from undergoing an external quality review (EQR) if the MCO meets certain conditions. First, the MCO must have a current Medicare contract under Part C or section 1876 of the Social Security Act, as well as a current Medicaid contract under Medicaid. Second, the two contracts must cover all or part of the same geographic area within the state. Third, the Medicaid contract must have been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years, the MCO has been found to be performing acceptably for quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

CMS proposes new paragraph 438.362(c) to require states to annually identify on their EQR website, the names of the MCOs exempted from EQR and when the exemption period began. CMS is considering an alternative to the proposal in which exempted MCOs are identified in the annual EQR technical report. **CMS solicits comments on the alternative approaches and welcomes information on how states are currently using the exemption and if and how they are making the names of those plans publicly available.**

17. External Quality Review Results (§438.364)

CMS proposes to correct an incorrect reference in paragraph (d) by replacing the reference to paragraph (b) with the correct reference to paragraph (c).

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

In the 2016 final rule, CMS finalized in §438.400(b)(3) the definition of an ‘‘adverse benefit determination’’ to include denials in whole or in part of payment for service." Under §438.404(a), managed care plans are required to give enrollees timely notice of an adverse benefit determination in writing. CMS states that in light of the broad meaning of the term "adverse benefit determination", some managed care plans are generating notices to each enrollee for every denied claim, even those that are denied for purely administrative reasons and which generate no financial liability for the enrollee. Such notices for adverse benefit determinations for which the enrollee has no financial liability nor interest in appealing create an unnecessary administrative burden, and unnecessary confusion and anxiety for enrollees who may misunderstand the notices as statements of financial liability.

CMS proposes to address this by adding 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. Therefore, the notice requirements would not be triggered.

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

In the 2016 rule, CMS finalized that an oral appeal must be followed by a written, signed appeal. CMS states that it has heard from states that requiring a written, signed appeal is an unnecessary burden and that sometimes an enrollee who initiates an oral appeal does not follow-up with a written, signed appeal. As a result, CMS proposes to eliminate that requirement in the two places that it appears: §438.402(c)(3)(ii) and §438.406(b)(3).

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

CMS proposes to alter the timeframe for enrollees to request a state fair hearing so that it is no less than 90 days and no more than 120 days from the date of the plan's notice of a resolution to request a state fair hearing. CMS created the existing 120-day timeframe in the 2016 final rule believing that the longer timeframe 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. CMS has heard from stakeholders, however, that the inconsistency in filing timeframes between Medicaid FFS (90 days) and managed care has creating administrative burdens for states and confusion for enrollees.

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

In the 2016 final rule, many of the changes to Medicaid managed care requirements were incorporated into the CHIP rules by reference. In a number of places the correct cross references were either missing or were overly broad so that certain Medicaid requirements that are not applicable to CHIP were inadvertently included. CMS proposes a number of those fixes as described below.

In addition, CMS proposes to clarify the compliance dates for the CHIP provisions of the 2016 final rule. Except as otherwise noted, compliance with the revisions to CHIP managed care regulations in that 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 is a multi-year contract.

Proposed CHIP technical fixes are summarized below.

- In incorporating the 2016 Medicaid managed care information requirements by reference, CMS inadvertently failed to exclude cross references for activities that are not applicable to the CHIP program. Specifically, CMS proposes to modify the language in §457.1207 to reflect that CHIP does not adopt Medicaid's beneficiary support system requirements, the Medicaid appeals process known as "aid paid pending," and Medicaid's requirements related to advanced directives.
- CMS proposes corrections to §457.1233 relating to structure and operations standards of CHIP plans to replace a mistaken reference to PCCMs with PCCM entities, to incorporate a missing cross reference to §438.242 (requiring submission of encounter data), and to correct the CHIP applicability date for health systems requirements which is different from the Medicaid applicability dat. CMS proposes to replace July 1, 2017 with the first day of the state fiscal year beginning on or after July 1, 2018.
- Corrections proposed to §457.1240 – provisions related to quality measurement and improvement – would add a missed cross reference to Medicaid standards relating to the collection and submission of quality performance measurement data by PCCM entities and to exclude references to the state's Medical Care Advisory Committee which is not applicable to the CHIP program.
- With respect to §457.1260 – which incorporate Medicaid requirements requiring managed care plans to establish an internal grievance procedure – CMS proposes to rewrite the section identifying the specific Medicaid provisions that apply to CHIP rather than proposing a long list of Medicaid provisions that should not apply to CHIP plans. Those Medicaid requirements excluded would be:
    - Definition of adverse benefit determination,
    - External medical reviews,
    - Medicaid's timing of notice of adverse benefit determinations, and
    - Medicaid's requirement that a state pay for disputed services furnished while an appeal is pending.
- Section 457.1270 incorporates by reference Medicaid provisions allowing states to apply sanctions under certain circumstances. CMS inadvertently left out PCCMs and PCCM-entities as those to which sanctions could be applied. CMS proposes to add those types of managed care plans to this section.
- Existing §457.1285, which incorporates Medicaid program integrity standards, includes a cross reference to Medicaid actuarial soundness requirements which do not apply to CHIP plans. CMS proposes to eliminate the cross reference.

Finally, CMS notes that the proposed changes to Medicaid rules described above relating to medical loss ratio standards, information requirements, disenrollment, network adequacy,

practice guidelines, health information systems, QRS, Managed care state quality strategy, and EQR would all, if finalized, apply to CHIP by existing cross references.

III. Collection of Information Requirements and Regulatory Impact

In the Collection of Information section of the proposed rule, CMS explains that some of the provisions are expected to impact fewer than 10 respondents so estimates of the information collection burden are not provided for those provisions. CMS estimates the burden reduction in Table 2 and Table 3 (83 FR 57289), which are excerpted and combined in the table below.

Summary of Annual Proposed Paperwork Reduction Act-Related Requirements and Burden under 42 CFR Parts 438 and 457 (from Tables 2 and 3)

CFR Section	# of Respondents/ Responses	Burden per Response (hours)	Total Annual Hours	Labor Rate $/hr	Cost ($) per Response	Total cost ($)	Frequency	Annualized Costs ($)
§438.3(t)	10/10	1	10	$86.84	$86.84	$860.84	Once	$286.95
§438.3(t)	6/25	-4	-100	$68.22	-$272.88	-$6,822	Once	-$2,274
§438.6(c)	20/2	-1	-40	$68.22	-$68.22	-2,728.80	Annual	-2,728.80
§438.10(d)(2-3)	42/54,588,095	n/a	n/a	n/a	$0.005	-$272,940.47	Annual	-$272,940.47
§438.10(d)(2-3)	42/54,588,095	n/a	n/a	n/a	$0.005	-$272,940.47	Annual	-$272,940.47
§438.10(d)(2-3)	42/54,588,095	n/a	n/a	n/a	$0.21	-$11,463,499.95	Annual	-$11,463,499.95
§438.400(b)	42/27,294,047	n/a	n/a	n/a	$0.005	-$136,470.23	Annual	-$136,470.23
§438.400(b)	42/27,294,047	n/a	n/a	n/a	$0.005	-$136,470.23	Annual	-$136,470.23
§438.400(b)	42/27,294,047	n/a	n/a	n/a	$0.38	-$10,371,738	Annual	-$10,371,738
§438.402(c)(3)(i)	300/60,000	-2	-120,000	$38.08	-$76.16	-$4,569,600	Annual	-$4,569,600
Part 438 Sub- Total			-120,130		-$329.81	-$27,232,349.31		-$27,228,375.20
§457.1207	32/9,013,687	n/a	n/a	n/a	$0.005	-$45,068.44	Annual	-$45,068.44
§457.1207	32/9,013,687	n/a	n/a	n/a	$0.005	-$45,068.44	Annual	-$45,068.44
§457.1207	32/9,013,687	n/a	n/a	n/a	$0.21	-$1,892,876.27	Annual	-$1,892,876.27
§457.1260	32/4,506,844	n/a	n/a	n/a	$0.005	-$22,534.22	Annual	-$22,534.22
§457.1260	32/4,506,844	n/a	n/a	n/a	$0.005	-$22,534.22	Annual	-$22,534.22
§457.1260	32/4,506,844	n/a	n/a	n/a	$0.38	-$1,712,600.72	Annual	-$1,712,600.72
Part 457 Sub-Total								-$3,740,682.31

In the Regulatory Impact Analysis section of the preamble, CMS discusses its expectation that, if finalized, the provisions of this rule would reduce administrative burden for states and managed care plans. CMS provides a qualitative discussion of one of those provisions: the proposal to allow states that are transitioning services or eligible populations from FFS into managed care to incorporate new pass-through payments for a transition period of 3 years. CMS expects that the net budgetary impact of the proposal, however, must be equal to zero based on the proposed requirement that any new pass-through payments under the proposal would be subject to a ceiling based on the amount actually paid as Medicaid FFS supplemental payments in the 12-month period immediately prior to the first rating period of the transition.