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

On November 13, 2020, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) published in the *Federal Register* (85 FR 72754) a final rule providing for policy and technical changes to Medicaid and CHIP managed care rules. CMS states that the goals of the rule are to relieve regulatory burden, support state flexibility, and promote innovation in the delivery of care. Except where noted below, the rules go into effect on December 14, 2020.

Major provisions finalized in this rule include:

- Allowing pass-through payments for new managed care enrollment or services during a transition period (effective for managed care rating periods starting on or after July 1, 2021);
- 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 will permit;
- Allowing states to certify rate ranges as actuarially sound under certain limited circumstances (effective with rating periods starting on or after July 1, 2021; and
- Increasing the flexibility for states to coordinate benefits across Medicare and Medicaid.

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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. States are permitted to implement Medicaid 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 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, 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. Pass-through payments are

amounts required by the state, and taken into account in determining the actuarially sound capitation rate, to be added to the contracted payment rates paid by the managed care plan to hospitals, physicians, or nursing facilities that is not for one of the following: payment for a specific service or benefit provided to a specific enrollee; graduate medical education; or federally-qualified health center or rural health clinic wrap around payments. (Defined at §438.6(a)).

In November of 2018, CMS published the "Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care" proposed rule (83 *FR* 57264, the "2018 proposed rule") which included proposals to reduce the administrative burden of Medicaid and CHIP managed care rules and to support state flexibility, and promote transparency and innovation in the delivery of care.

This final rule addresses some stakeholders' concerns that the existing rules remain burdensome and overly prescriptive and responds to comments from a total of 215 commenters. Those commenting included state Medicaid and CHIP agencies, advocacy groups, health care providers and associations, health insurers, managed care plans, and the general public.

B. Provisions of the Final 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 that covers dual eligible individuals to include a Coordination of Benefits Agreement (COBA) and participate in an automated crossover claims process administered by Medicare.

States have indicated, however, that the Medicare system sometimes sends 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 proposed to replace the 2016 requirement with a new flexibility permitting states' contracts with managed care plans (MCOs, PIHPs, or PAHPs) 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. The provision allows a state to choose its approach to coordinating benefits across Medicare and Medicaid instead of requiring managed care plans to enter into a COBA with Medicare and participate in the automated claims crossover process directly. It finalizes the proposal with a clarification in response to comment that when a state forwards a claim to an MCO, it must inform the provider that the claim was not denied but was redirected to a managed care plan for adjudication.

Response to Comment. Some commenters raised concerns that the flexibility could encourage states to implement inefficient manual processes, create inefficiencies for plans and providers operating across state lines when states choose different coordination of benefit processes, or slow provider reimbursement where providers are not notified about a change in the processes. In response, CMS states that it is not requiring that states make any changes but expects that states making changes implement efficient systems, educate providers and plans about changes, and review the timelines for claims adjudication in §447.45 that continue to apply.

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 reimbursement 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 regulations to be overly burdensome and interfere with states' ability to get the best rates. In response, CMS finalizes its proposal with three changes as noted below, to provide an option for states to certify rates based on a range so long as a number of conditions are met. In the final rule, CMS is delaying the effective date for this flexibility to rating periods starting on or after July 1, 2021.

The new conditions for a rate range are intended to limit gaming of the capitation payment rates that would shift costs to the federal government. To approve a rate range a state is 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 rate range option are required to document the rates permitted within the rate range prior to the start of the rating period. The final rule permits modifications of rates during the rating period within a range of plus or minus one percent without the need to submit a revised rate certification or in case of errors in their application or methodology. (The proposed rules would have only permitted modifications in the case of errors.)

In the final rule, CMS adds transparency requirements. States are required to post the following information on their public websites when developing and certifying a rate range as actuarially sound: (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.

Response to Comment. CMS received comments raising concerns that rate ranges decrease transparency and diminish federal oversight. In response, CMS adds the above transparency requirements and notes that by requiring states to justify rates and to have them approved before a rating period begins, oversight will be sufficient. It sought to strike a balance between increasing state flexibility and program integrity. CMS also describes the guardrails in place to ensure that the increased flexibility does not result in reduced rates for managed care providers including the continued application of actuarial soundness requirements as well as beneficiary protections in 42 CFR Part 438.

Other commenters supported the increased flexibility for states to respond to mid-year program changes or to seek competitive bids. Recommendations were submitted for permitting rate ranges below the finalized 5 percent and greater than 5 percent and for additional factors that should be required for states to consider in developing rates. CMS declines to make changes to the permitted ranges or to add additional considerations for developing rates as being overly prescriptive.

CMS clarifies that all of the components of the capitation rate that are currently required to be included in the rate development and certification continue to be required in the rates developed under this flexibility, including: pass-through payments, administrative expenses, taxes, licensing and regulatory fees, government mandated costs, and underlying benefit costs. Capitation rates should not include incentive payments for managed care plans under §438.6(b)(2) nor for state budget factors to influence the rates. In addition, risk adjustment methodologies apply outside of the certified rate range.

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 proposed to clarify the existing prohibitions at §438.4 and add several examples. CMS finalizes the additions to §438.4(b)(1) with several changes as described below. It does not, however finalize proposed new paragraph §438.4(d).

CMS proposed clarifications (in bold) to §438.4(b)(1), a paragraph that describes what is necessary for capitation rates to be approved by CMS as actuarially sound. It finalized those clarifications -- including 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 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.**

CMS had proposed 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 they 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. Because CMS is not finalizing new paragraph (d), these changes are instead incorporated into §438(b)(1).

CMS proposed but does not finalize new (d)(1) that would have listed specific rate development practices that would have been prohibited under the rule.

- 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.

Response to Comment. CMS drops the list of rate development practices that would have been prohibited ((d)(1)) in response to commenters' concerns that it may have resulted in certain

actuarially appropriate rate development practices being prohibited. CMS restates, however, that its overall policy has not changed and that practices that increase federal costs and vary with the rate of FFP where not actually appropriate are generally prohibited and if used, will result in rate denial.

In response to a recommendation that rate differentials that existed prior to a group's FFP being increased continues to be permitted, CMS dismisses this as a potential loophole and clarifies that the rules apply regardless of when the differential rates were started. CMS also clarifies that these provisions do not apply to CHIP programs.

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 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 that prior regulation text regarding the corrective action timeline was 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 problems "would be resolved in no more than 2 years after the rating period in which the deficiency was discovered."

CMS finalizes without change, its proposal to clarify the 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. Base data for CY 2021 rate development would also need to be in compliance.

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

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

CMS finalizes as proposed, changes to §438.6(b) to clarify documentation requirements for risk sharing mechanisms (such as reinsurance, risk corridors, and stop-loss limits) 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 requires a description of such mechanisms be included in the rate certification.

In part, these modifications make clear that risk-sharing mechanisms must be developed in conjunction with capitation rates and must use the same actuarially sound principles and practices. In addition, they clarify that retroactive risk-sharing mechanisms are not permitted. CMS acknowledges that certain retroactive adjustments to *rates*, as opposed to risk-sharing mechanisms, may be appropriate. Under existing §438.7(c)(2), certain retrospective rate changes are 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.

Responses to Comments. In response to questions from commenters, CMS clarifies that risk-sharing mechanisms are distinct from risk adjustment. Risk adjustment is defined at §438.5(a) and other requirements applicable to risk adjustment are in §§438.5(g) and 438.7(b)(5). The finalized requirements in this paragraph do not impact risk adjustment. Risk sharing mechanisms are described as any means, mechanism, or arrangement that has the effect of sharing risk between the managed care organization and the state.

In response to a suggestion that "risk pools" be added to the list of risk-sharing arrangements in the finalized amendment, CMS declined clarifying that risk pools are a mechanism to share risk between plans and the state so would be subject to the finalized requirements. CMS also clarifies that a minimum MLR requirement with a remittance would be considered a risk-sharing mechanism as would other restrictions on profits or profit caps.

Some commenters disagreed with the prohibition on making retroactive adjustments to risk-sharing arrangements. CMS reiterates that after the claims experience for a period is known, it is inappropriate to modify risk-sharing mechanisms and restates that retroactive rate adjustments may be made when appropriate under §438.7(c)(2).

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 regulations, 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 finalizes its proposed amendments to §438.6(c) with some changes to incorporate common arrangements, to provide for additional flexibility and to encourage payment models that provide high value. Under the final rule:

- States can direct an MCO, PIHP, or PAHP to adopt a minimum fee schedule that *uses the same rates as approved under an existing state plan*. The final rule makes clear that supplemental payments do not constitute state plan approved rates. In the final rule, CMS adds to the definition of "supplemental payments" to state that disproportionate share payments and graduate medical expenditure payments are not considered to be supplemental payments. CMS points out that states often direct payments in this way to ensure adequate access to providers.
- States can require the managed care plan 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.
- The prohibition on states directing 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 is eliminated. CMS notes that the provision may have created unintended barriers to innovative payment models such as global payment initiatives.
- CMS codifies a process for approval of multi-year payment arrangements consistent with subregulatory guidance issued in 2017.[1] New §438.6(c)(3) allows for a multi-year directed payment arrangement to be approved as long as (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 final rules permit those arrangements that use state plan-approved rates to be implemented without written prior approval.

Response to Comment: Some commenters raised concerns that by permitting directed payment arrangements that use state plan-approved rates to be implemented without written prior approval, federal oversight will be reduced. CMS points out that only duplicative reviews will be eliminated under the finalized provision. In response to a request, CMS clarifies that a state will still need prior approval if they were to implement a uniform percentage increase that is

[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).

concurrent with the same increase on the FFS side. CMS declines to require states to seek public comment before mandating a payment arrangement permitted under this section, as recommended by some commenters.

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 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 finalizes 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 as proposed.

Specifically, the final rules permit 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 need to be met:

- The services are being 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 can require must be below a ceiling for each provider type as described below.
- Pass-through payments are 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 permitted during the transition years are equal to the actual supplemental payments paid to each provider type multiplied by the proportion (ratio) of total payments for that service type that are being transitioned from FFS to the managed care contract. In calculating these ceilings, 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. The final rule

clarifies that in calculating the maximum amounts permitted, both the numerator and denominator of the ratio should exclude any supplemental payments to applicable providers.

In addition, the effective date for the provision is delayed until managed care rating periods starting on or after July 1, 2021.

Response to Comments. CMS addresses concerns that pass-through payments are necessary to increase reimbursement for safety-net providers and should, therefore, not be transitioned out after 3 years. CMS responds that there are other payment arrangements and mechanisms to increase provider reimbursement that do not necessitate pass-through payments. CMS also responds to requests to clarify the first month of the 12-month period immediately 2 years prior is 24 months and not 36 months before the first month of the first rating period for the managed care contract. Commenters also requested additional provider-types be added to the list of relevant provider types and the transition period (finalized at 3 months) be longer. CMS declines changes to those provisions.

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 did not propose changes in this area but requested stakeholders identify additional data sources for CMS to review that would support FFP for stays of longer than 15 days in a month. A few commenters recommended CMS use data collected under a requirement in the 21st Century Cures Act requiring a CMS study and report of such IMD coverage. In addition, another commenter recommended that CMS use data available through approved section 1115(a) SUD demonstrations. CMS will take those data sources into consideration for future rulemaking.

5. Rate Certification Submission (§438.7)

CMS finalizes its proposal 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 the final rule, CMS adds the words "during the rating period" to make clear that these de minimis changes may be made during the contract year. As proposed, CMS adds to §438.7(c)(3) to make clear 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 states that the de minimis adjustment permitted in this section cannot be used if a state is opting to use a rate range as newly permitted in this final rule under §438.4(c)(2)(ii).

CMS finalizes new paragraph §438.7(e) as proposed to codify an annual CMS publication providing rate development and procurement guidance. CMS believes the annual guidance will 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 will identify:

- Standards for capitation rate development;
- Documentation needed to ensure that capitation rates 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 reduce state burden and facilitate prompt actuarial reviews.

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

CMS finalizes, as proposed a technical correction to a reference relating to the ability to include fraud related activities in the MLR calculation as finalized in the 2016 final rule. Commenters requested additional clarification of the types of fraud prevention activities that may be included and some requested that those activities align with Medicare Advantage MLR rules. CMS states that Medicare Advantage adopted a different policy – the policy clarified in the final rule with respect to Medicaid plans was aligned with private market MLR regulations where the standards for identifying fraud activities are in 45 CFR part 158.

7. Non-emergency medical transportation (NEMT) under 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 finalizes as proposed 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 that 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 finalizes its proposal to change the requirements applicable to written materials so that they only apply to written materials *that are critical to obtaining services* and to 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 will allow states to use smaller formats such as post-cards and tri-fold brochures when those

shorter form documents would be useful. It points out that states and plans retain the flexibility to continue to use large font if they chose.

In the final rule, CMS adds back language that it had inadvertently proposed to remove (to require that taglines include information on how enrollees can request auxiliary aids and services) and to correct a typographical error.

Response to Comment. Commenters raised concerns that the changes would reduce the ability of individuals with vision impairment or with limited English proficiency to access needed information. Some commenters requested a definition of "conspicuously-visible" and identify materials that are critical to obtaining services. CMS reminds states and plans of their obligations under related statutes and rules, including to prevent discrimination on the basis of race, color, national origin, sex, age and disability, to prevent discriminatory enrollment and to meet Americans with Disabilities Act standards. It declined to define "conspicuously-visible" and notes that a non-exhaustive list of documents that are critical to obtaining services is in §438.10(d)(3).

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

Prior rules required 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 states, 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 causes confusion for enrollees, especially those who believe that they need to locate a new provider.

CMS finalizes without change its proposal to lengthen the timing for the required notice to prevent unnecessary notices from being sent to enrollees. Under the final rule, managed care plans must 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.

Response to Comment. Commenters recommended that CMS work with states to establish enforcement mechanisms, set up hotlines for consumers receiving termination notices, and to add information on how a beneficiary can disenroll or find another plan in which his provider participates to the notice. CMS declines to make changes noting that states have monitoring and oversight processes in place and are required to have beneficiary support systems (§438.71) to assist enrollees. CMS clarifies that the timeframe finalized in §439.10(f) is a minimum timeframe – states could choose to lengthen it if it determines that consumers need additional time. CMS also notes that termination of a provider from a plan network is not cause for disenrollment (under §438.56(d) and (e)) except under limited circumstances.

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

CMS finalizes without change its proposal to correct an erroneous reference, changing "paragraph (g)(2)(i)(A)" (which doesn't exist) to paragraph (g)(2)(ii)(A). It did not receive comments on this correction.

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

CMS finalizes without change its proposal to make the following changes to 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 this change aligns with 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 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. CMS reminds managed care plans that 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 directory.

Response to Comment. In response to a request for clarification of what is meant by "mobile-enabled," CMS states 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 webpage fits the browser window for the device used, and the pages are made "lighter," so they download more quickly. The goal is to improve the enrollee's ability to navigate and utilize the directory information when accessing it

on a mobile device. CMS expects such features 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.

CMS also clarifies that to the extent that Part 438 applies to a Dual Eligible Special Needs Plan or Medicare-Medicaid plan, these rules would apply to those entities.

CMS declines to make changes in responses to recommendations that a notification be provided to enrollees when the directory is updated, or to display on paper directories and websites that real-time assistance is available to enrollees. CMS notes that a phone number for assistance is already required at §438.10(d)(3).

9. Disenrollment: Requirements and Limitations (§438.56)

CMS finalizes without change a correction to 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. No comments were received on this provision.

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 ensure network adequacy. 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 finalizes as proposed, the following changes to network adequacy regulations:

- 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.

- To clarify in the list of provider types, that states may define "specialist" in whatever way they deem most appropriate for their programs. CMS does 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.
- 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.

Response to Comment. Commenters made a large number of recommendations including requiring combinations of quantitative and qualitative standards, specifying conditions that must apply for telehealth providers to be counted towards network adequacy, establishing minimum considerations for measuring network adequacy, minimum factors for meeting network adequacy, additional specificity for what qualifies as quantitative standards, etc. CMS declines to implement those recommendations in order to maintain flexibility for states but notes that it has provided guidance on network adequacy standards and described best practices in states.[2]

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 finalizes as proposed, that correction.

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

Under existing rules, managed care entities are required to report enrollee encounter data that states are then required to report to CMS. CMS finalizes without change its proposal to clarify this requirement to clarify that enrollee encounter data includes allowed amounts and paid amounts. This clarification responds to concerns 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.

Response to Comment. Many commenters raised concerns about the proprietary nature of allowed amounts and paid amounts. CMS reiterates its position that such information is already public and states its commitment to transparency as well as to safeguard information protected under federal law from inappropriate use and disclosure. In addition, CMS articulates its goals for the use of T-MSIS data to include: initiatives 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

[2] Promoting Access in Medicaid and CHIP Managed Care: A Toolkit for Ensuring Provider Network Adequacy and Service Availability April 2017: and is available at https://www.medicaid.gov/medicaid/downloads/adequacy-and-access-toolkit.pdf.

different types of delivery system models on beneficiary outcomes; examine enrollment, service provision, and expenditure experience of participating providers; and observe trends or patterns indicating potential fraud, waste, and abuse to prevent or mitigate those activities in the future.

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

CMS proposed several changes to §438.334 which describes Medicaid's Managed Care Quality Rating System.[3] States are required under this section to either adopt the managed care quality rating system developed by CMS or 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 finalizes a number of changes both to the CMS-developed Quality Rating System and to the alternative systems that states develop. CMS finalizes almost all of the provisions it proposed, however, the final rules incorporate several additional provisions, restate others, and drop one proposed change altogether.

With respect to the CMS-developed quality rating system, CMS finalizes as proposed that CMS will identify a set of mandatory performance measures and adds flexibility that the system align with other systems where appropriate. Other systems are identified as the system applicable to qualified health plans under 45 CFR 156.1120 and the system for Medicare Advantage plans. The final rule adds that CMS develop this system *after* consulting with states and other stakeholders and that CMS periodically update the framework after providing for a public notice and comment period.

With respect to states' alternative quality rating system, the proposed rule:

- Permitted state-developed QRS systems that align with the CMS framework by being substantially comparable *to the CMS developed framework taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation*. CMS finalizes this provision with the additional requirement that a state system must also include the mandatory measures identified by CMS in the CMS-developed QRS framework. CMS states that this provision is to facilitate comparable ratings while allowing states to have greater flexibility to include additional measures to achieve their quality goals.
- Described additional information that states must make available when requesting CMS approval for an alternative QR system. The final rules require states to submit the quality

[3] CMS notes here that because these provisions are incorporated in their entirety into CHIP at §447.1240(d), CMS is now referring to this system as the Medicaid and CHIP Managed Care Quality rating System (MAC QRS).

rating system framework, performance measures and methodologies, as well as any other information specified by CMS to demonstrate compliance.

- Permitted states to implement an alternative QRS without obtaining prior approval by CMS. CMS does not finalize this provision.
- Required CMS to issue guidance describing the criteria and process for determining if an alternative QRS system is aligned with the CMS developed system after consulting with states and other stakeholders. CMS finalizes the provision without change.

Response to Comment. Some commenters made specific recommendations for the minimum set of mandatory measures that CMS is developing; for example, to focus on outcomes, to be clinically credible, comprehensive, etc. CMS states it will take these recommendations into account. In response to a request for clarification, CMS states that plans will not be responsible for reporting measures for services that are not included in their contracts. CMS describes its stakeholder engagement process and notes that recommendations for specific measure sets will be taken into account during development.

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 as qualifying for Medicaid on the basis of a disability. CMS had proposed more flexibility with respect to identifying individuals with disabilities by eliminating any specific definition of disability status from the element. CMS does not finalize that change – agreeing with commenters who are

concerned that having no definition of disability will impede identifying individuals with disabling conditions. Instead, CMS revises §438.340(b)(6) to provide states with flexibility to define in their quality strategy "disability status" and to describe in its quality strategy how the state will determine that a Medicaid enrollee meets the state's definition, including a description of the data that the state will use to identify disability status. Under the final rule, CMS establishes as a minimum standard, that a state's definition of "disability status" must include individuals who qualify for Medicaid on the basis of disability.

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

CMS finalizes as proposed 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 finalizes largely as proposed (with minor grammatical changes) 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. In addition, in the final rule, CMS adds a requirement in new §438.364(a)(7) for states to name the MCOs exempt from EQR or to indicate that no MCOs are exempt.

17. External Quality Review Results (§438.364)

CMS finalizes without change its proposal to correct an incorrect reference in paragraph (d) by replacing the reference to paragraph (b) with the correct reference to paragraph (c). No comments were received on this proposal.

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

In the 2016 final rule, CMS finalized the definition of an ''adverse benefit determination'' to include denials in whole or in part of payment for service" in §438.400(b)(3). 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 proposed 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. CMS finalizes this provision with the addition of the word "solely" for clarity. As finalized, the rules state that 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) is not an adverse benefit determination.

Response to Comment. Commenters recommended that CMS exempt all claims that do not result in enrollee liability from the definition of adverse benefit determination. Others requested CMS provide a list of examples of clean claims under this provision. CMS declines to exempt all claims that do not result in enrollee liability from the definition of adverse benefit determination stating that enrollees should have some information about denied claims to make knowledgeable decisions about their health care. It also declines to develop a list of examples for the regulation text, stating that the concept of clean claims is well understood and that there are unlimited ways that a claim could be considered to not meet the "clean claim" concept.

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 proposed, and finalizes without change, to eliminate the requirement that oral appeals must be followed-up with a written, signed appeal in the two places that it appears: §438.402(c)(3)(ii) and §438.406(b)(3).

Response to Comment. In response to commenters concerned that the elimination of the written follow-up to oral appeals will result in a loss of documentation of appeals or will make it harder for individuals with disabilities to submit appeals, CMS states that this provision does not eliminate the option for enrollees to submit appeals in writing, nor does it change any reporting, tracking, or documentation requirements on managed care plans. CMS declines to add additional documentation requirements on plans, nor to provide a script for enrollees or managed care plans to specify how oral appeals should be stated or received.

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

CMS finalizes without change its proposal 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. The final rule corrects those cross-references and clarifies 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 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 and finalized 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 proposed 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 finalizes the amendment to §457.1207 without change. In response to commenters requesting the CMS retain the requirements that CHIP programs adopt Medicaid's beneficiary support system, CMS notes that state can choose to do so but are not required to. CMS also summarizes other beneficiary supports that must remain applicable to CHIP enrollee.
- CMS finalizes without change, 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 date. CMS replaces July 1, 2017 with the first day of the state fiscal year beginning on or after July 1, 2018.
- CMS proposed corrections to §457.1240, provisions related to quality measurement and improvement to add a missed cross reference to Medicaid standards relating to the collection and submission of quality performance measurement data by CHIP PCCM entities and to exclude references to the state's Medical Care Advisory Committee which is not applicable to the CHIP program. In the final rule, CMS and commenters identified additional mistaken cross references. CMS finalizes those corrections as well, and reformats and rewrites text for readability and to make other non-substantive revisions.
- With respect to §457.1260, which incorporates certain Medicaid requirements for managed care plans to establish an internal grievance procedure, CMS proposed to rewrite the section identifying the specific Medicaid provisions that apply to CHIP rather

than proposing a long list of Medicaid provisions that do not apply to CHIP. In the final rule, CMS incorporates a number of changes from the proposed rule. It corrects cross references throughout the section, adds parenthetical text to identify the scope and nature of the Medicaid requirements that are applicable to CHIP managed care entities, incorporates in part Medicaid's definition of "adverse benefit determination" as well as other Medicaid definitions, eliminates proposed changes that would have created duplicative CHIP rules, and adds a new paragraph (c) addressing the content and timing requirements for notices of adverse benefit determinations. The final rule clarifies the applicability of Medicaid requirements for the handling of grievances and appeals, timing and notice for grievance and appeals, requests and timing for external reviews.

- 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 finalizes adding those types of managed care plans to this section. The final rule includes a parenthetical to indicate the general subject matter addressed by the Medicaid cross references.
- 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 proposed to eliminate the cross reference. It finalizes the correction with an additional correction to a second cross reference.

Finally, CMS notes that the final changes to Medicaid rules described above relating to MLRs, information requirements, disenrollment, network adequacy, practice guidelines, health information systems, QRS, Managed care quality strategy, and EQR apply to CHIP by cross reference.

III. Collection of Information Requirements and Regulatory Impact

CMS estimates that some of the provisions are expected to impact fewer than 10 respondents. Estimates of the information collection burden are not provided for those provisions. The impact of other provisions are summarized Tables 2 and 3. Overall, CMS estimates the rule will result in total savings to plans and states of $12.1 million. The items with the largest impact are Medicaid & CHIP provisions permitting greater flexibility over taglines and font of plan materials (estimated to save $4.5 million), and CHIP grievances and appeals provisions (estimated to save $1.7 million).

In the Regulatory Impact Analysis section of the preamble, CMS discusses its expectation that the provisions of this rule will reduce administrative burden for states and managed care plans. CMS provides a qualitative discussion of the provision allowing 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 provision, however, must be equal to zero based on the requirement that any new pass-through payments 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.