

SMD# 21-001
**RE: Additional Guidance on State
Directed Payments in Medicaid Managed
Care**

January 8, 2021

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) Medicaid managed care regulations at 42 C.F.R. Part 438 govern how states may direct plan expenditures in connection with implementing delivery system and provider payment initiatives under Medicaid managed care contracts, including those with managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs), herein referred to as managed care plans. These types of payment arrangements permit states to direct specific payments made by managed care plans to providers under certain circumstances and can assist states in furthering the goals and priorities of their Medicaid programs.

In November 2017, CMS published [guidance](#), a related [appendix](#) with examples, and a [preprint](#) for states to obtain approval of state directed payments under 42 C.F.R. § 438.6(c). In May 2020, CMS also published [guidance](#) on managed care flexibilities to respond to the COVID-19 public health emergency. Overall, CMS has reviewed and approved more than 450 state directed payment arrangements since this part of the regulation took effect beginning with contract rating periods on or after July 1, 2017. Based on our reviews, CMS believes additional guidance is needed to:

- Clarify existing policy and alleviate burden faced by states by proactively addressing common questions that arise during the preprint review;
- Enhance program integrity in the use of state directed payments; and
- Remind states of the quality-related requirements that must be met to secure CMS approval.

To this end, this State Medicaid Director Letter (SMDL) provides guidance on the broader policy regarding state directed payments, clarifies what is considered a state directed payment, and provides additional clarification on the federal requirements for state directed payments.¹

¹ The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

Contract Requirements Considered to be State Directed Payments

In general, states are not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the state and the plan or to make payments to providers for services covered under the contract between the state and the plan (42 C.F.R. §§ 438.6 and 438.60). Under the 2016 Medicaid and CHIP Managed Care Final Rule², CMS permits only the following exceptions that allow states to make payments directly to providers or direct managed care plan expenditures for plan-covered services:

- State directed payments that comply with the requirements at 42 C.F.R. § 438.6(c);
- Payments by the state to providers required by a specific provision of Title XIX or in another regulation implementing a Title XIX provision; and
- Permissible pass-through payments that comply with the requirements of 42 C.F.R. § 438.6(d).

For state directed payments, 42 C.F.R. § 438.6(c) specifies the ways states may set parameters on how expenditures under managed care contracts are made by managed care plans to assist states in achieving their overall objectives for delivery system and payment reform and performance improvement. These permissible state directed payments may include: value-based purchasing models, multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or fee schedule requirements for provider reimbursement (e.g., minimum fee schedules, maximum fee schedules, and uniform increases). These categories are not mutually exclusive.

In the November 2017 CMCS Informational Bulletin (CIB), we noted instances when states may include general contract requirements for provider payments that would not be subject to approval under 42 C.F.R. § 438.6(c). CMS also noted these contract requirements would not be state directed payments under our interpretation of the regulation as long as the state is not mandating a specific payment methodology or amounts under the contract. In addition, CMS noted that when the provider payment is tied to the utilization and delivery of a specific service or benefit provided to a specific enrollee under the contract, such payments are not pass-through payments as defined in 42 C.F.R. § 438.6(a) and not subject to the requirements under 42 C.F.R. § 438.6(d). In particular, the November 2017 CIB described two scenarios:

First scenario: States contractually implementing a general requirement for managed care plans to utilize value-based purchasing or alternative payment arrangements when the state does not mandate a specific payment methodology and managed care plans retain the discretion to negotiate with network providers the specific terms for the amount, timing, and mechanism of such value-based purchasing or alternative payment arrangements. An example of this would be when a state implements a general contract requirement for managed care plans to make 20 percent of their provider payments as value-based purchasing payments.

² 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 Fed. Reg. 27498 (May 6, 2016) (available at: <https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>).

Second scenario: States contractually implementing a general requirement for the managed care plans to increase provider reimbursement for covered services provided to Medicaid beneficiaries covered under the contract, as long as the state is not mandating a specific payment methodology or amounts and managed care plans retain discretion for the amount, timing, and mechanism for making such provider payments. An example of this would be when a state implements a general requirement for managed care plans to increase their overall rates for primary care services provided to all Medicaid enrollees covered under the contract.

When CMS published that guidance, we believed that both types of general contract requirements for provider payments left sufficient discretion to plans and maintained the link between payments and delivery of services under the contract. We believed that these types of contract requirements would not trigger the prohibition and limits in 42 C.F.R. § 438.6(c) and that the general contract requirements maintained the link between payment and delivery of services under the contract as to not trigger the prohibition and limits in 42 C.F.R. § 438.6(d) on pass-through payments. As CMS has continued to review managed care contracts and rate certifications since the publication of the November 2017 CIB, general contract requirements described in the first scenario seem to continue to leave sufficient discretion to plans by including minimal direction from the state and link payments to the delivery of services under the contract such that prohibitions and limits under 42 C.F.R. §§ 438.6(c) and 438.6(d) are not triggered.

However, CMS has grown concerned that the November 2017 sub-regulatory guidance created an unintentional loophole in regulatory oversight in relation to general contract requirements described in the second scenario that require managed care plans to increase provider reimbursement for covered services. For example, some states are including general contract requirements for provider payments that require an additional amount be added to the contracted payment rates for a specific service (e.g., hospital services) but without any further accountability to ensure that the additional funding included in the rate certification is linked to a *specific service or benefit provided to a specific enrollee* covered under the contract (see the definition of pass-through payment in 42 C.F.R. § 438.6(a)).

CMS is concerned that vague contract requirements, particularly when significant amounts of funding are being added to the rates and rate certification(s) as part of the actuarially sound capitation rate, do not provide sufficient accountability to ensure that the additional funding will be used to pay for specific services provided to specific enrollees covered under the contract. Additionally, such vague contract requirements do not provide sufficient accountability for the substantial increase in funding and circumvent the intent of the 2016 Medicaid and CHIP Managed Care Final Rule and the subsequent 2017 Pass-Through Payment Final Rule³ to improve the fiscal integrity of the program and ensure the actuarial soundness of all capitation rates. As stated in the preamble of the 2016 Medicaid and CHIP Managed Care Final Rule, “[w]e believe that the statutory requirement that capitation payments to managed care plans be

³ Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems; Final Rule; 82 Fed. Reg. 5415 (January 18, 2017) (available at: <https://www.federalregister.gov/documents/2017/01/18/2017-00916/medicaid-program-the-use-of-new-or-increased-pass-through-payments-in-medicaid-managed-care-delivery>).

actuarially sound requires that payments under the managed care contract align with the provision of services to beneficiaries covered under the contract. ... In our review of managed care capitation rates, we have found pass-through payments being directed to specific providers that are generally not directly linked to delivered services or the outcomes of those services. These pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services.” We further explained that “[a]s a whole, § 438.6(c) maintains the MCO’s, PIHP’s, or PAHP’s ability to fully utilize the payment under that contract for the delivery and quality of services by limiting states’ ability to require payments that are not directly associated with services delivered to enrollees covered under the contract.”⁴

In light of these concerns, CMS has reconsidered the previously published guidance to realign our implementation of the regulation with the original intention of the 2016 Medicaid and CHIP Managed Care Final Rule and the 2017 Pass-Through Payment Final Rule. If the state includes a general contract requirement for provider payment that provides for or adds an amount to the contracted payment rates but the provider payments are not clearly and directly tied specifically to the utilization and delivery of a specific service or benefit provided to a specific enrollee under the contract, such contract requirements must be modified to comply with either 42 C.F.R. § 438.6(c) or (d). Absent modification of such contract requirements to comply with 42 C.F.R. § 438.6(c) or (d), we would consider such contract requirements out of compliance with federal regulations. This interpretation is consistent with the intent of the 2016 Medicaid and CHIP Managed Care Final Rule and will ensure federal regulatory oversight of managed care payments. Therefore, when a state includes a contract or payment requirement, even if vague or that leaves some discretion to the managed care plan, to control or direct payment to providers or adds any amount to the contracted payment rates which is considered in calculating the actuarially sound capitation rate, CMS will require compliance with 42 C.F.R. § 438.6(c) or (d). Moving forward, CMS will continue to monitor contract requirements described in the first scenario in light of the concerns raised with contract requirements in the second scenario.

To allow states time to amend their existing contract requirements, CMS will begin applying the regulation consistent with this guidance for contract rating periods that begin on or after July 1, 2021.

Basing Payment on the Utilization and Delivery of Services

State directed payments must be based on the delivery and utilization of services to Medicaid beneficiaries covered under the contract. CMS further clarifies that state directed payments need to be conditioned on the delivery and utilization of services covered under the contract for the applicable rating period. Therefore, state directed payments must be tied to utilization and delivery of services covered under the contract during the corresponding contract rating period; payment cannot be based solely on historical utilization. To be clear, in capitation rate development, states can use historical data to inform the rate that will be paid to managed care plans for services under the contract rating period; however, payment to providers must be made based on the delivery and utilization of covered services rendered to Medicaid beneficiaries during the applicable rating period.

⁴ 81 Fed. Reg. at 27587-89.

In addition, CMS clarifies that the prior approval of a state directed payment under 42 C.F.R. § 438.6(c) provides authority for states to include such contract requirements directing a plan's expenditures in their managed care contract(s) and in the related rate certification(s), but it does not provide authority for a new benefit or service. States must have authority either as part of the state plan or through some other Medicaid authority (e.g., section 1115 demonstration, section 1915(c) waiver, etc.) to require their plans to cover the benefit or service linked to the state directed payment.

Prior Approval of State Directed Payments

Effective December 14, 2020, 42 C.F.R. § 438.6(c)(2) requires contract arrangements that direct the managed care plan's expenditures under § 438.6(c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D) to have written approval from CMS prior to implementation.⁵ Therefore, states must obtain written approval of state directed payments before approval of the corresponding Medicaid managed care contract(s) and rate certification(s). The regulation does not permit states to add new state directed payments for rating periods that have ended.

CMS remains committed to ensuring a timely review of state directed payment preprints. To help expedite the review process for state managed care contract(s) and rate certification(s), CMS strongly recommends that states submit preprints for state directed payments to CMS at least 90 calendar days in advance of the start of the rating period that includes the state directed payment. States should submit the preprint(s) to the following **new** mailbox:

StateDirectedPayment@cms.hhs.gov to ensure proper processing.

If a state has concerns or questions about a state directed payment (e.g., the state directed payment is new), CMS encourages seeking technical assistance prior to incorporating such directed payments into contract(s) and rate certification(s); such actions can help to facilitate the subsequent review of Medicaid managed care contract(s) and rate certification(s).

State Directed Payment Levels

All contract arrangements that direct an MCO's, PIHP's, or PAHP's expenditures under 42 C.F.R. § 438.6(c)(1)(i) through (iii) must be developed in accordance with 42 C.F.R. § 438.4, the standards specified in 42 C.F.R. § 438.5, and generally accepted actuarial principles and practices. Under the definition in 42 C.F.R. § 438.4, actuarially sound capitation rates are "projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract."

As part of ensuring that the final capitation rates paid to the plan are reasonable, appropriate, and attainable for the populations to be covered and the services to be furnished under the contract, as well as adequate to ensure access to care, CMS has required states to demonstrate that the state directed payments result in provider payment rates that are reasonable, appropriate, and

⁵ Prior to December 14, 2020, 42 C.F.R. § 438.6(c)(2) required contract arrangements that direct the managed care plan's expenditures under § 438.6(c)(1)(i) through (iii) to have prior written approval. The regulation was amended by the Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule, which appeared in the Federal Register on November 13, 2020. (85 FR 72754).

attainable as part of the review of the preprint. To do this, CMS has required an analysis from states to understand the relative effect of the directed payment on reimbursement for each service type and each provider class receiving the state directed payment(s). Specifically, this analysis must provide the average base rate paid by plans to providers absent the impact of state directed payments, the effect each state directed payment(s) has on reimbursement for the service type(s), and any additional effects of permissible pass-through payments on reimbursement using a standardized measure (e.g., as a percent of Medicare or the Medicaid state plan rate). This analysis must be specific to each service type included in the state directed payment and specific to each provider class identified. For example, if a state directed payment provides a uniform increase for inpatient and outpatient hospital services with two provider classes (rural hospitals and non-rural hospitals), then states must provide CMS the following information:

Provider Class	Average Base Rate Paid by Plans	Effect on Total Reimbursement (as a Percent of Medicare or Another Standardized Measure)		
		Effect of State Directed Payment	Effect of Any Other State Directed Payments	Effect of Any Pass-Through Payments
Rural Hospitals – Inpatient Services				
Rural Hospitals – Outpatient Services				
Non-Rural Hospitals – Inpatient Services				
Non-Rural Hospitals – Outpatient Services				

To ensure appropriate oversight and prudent program management, CMS has initiated a review of state directed payments and may issue future guidance and/or rulemaking based on the findings of this evaluation. This review was initiated based on our experience reviewing state requests for state directed payments, as we have seen proposals for significant changes to provider reimbursement, which may in turn have an impact on program expenditures.

Provider Class Definition

State directed payments are required under 42 C.F.R. § 438.6(c)(2)(ii)(B) to direct expenditures equally, using the same terms of performance, for a *class of providers* providing the service under the contract. As stated in the May 2020 CIB, historically, CMS has deferred to states in defining the provider class for purposes of state directed payment arrangements, as long as the provider class is reasonable and identifiable, such as the provider class being defined in the state’s Medicaid State Plan.

Regardless of how a state defines the provider class, the same terms of performance must be applied to all providers that are in that provider class. To clarify, this requirement does not require that each provider that meets the provider class definition earns the same total dollars for the delivery of services. If a state directed payment arrangement is a fee schedule requirement,

the fee schedule requirement would need to apply to the services provided by all providers that meet the class definition; however, the final amount earned by the provider would depend on the number of services provided.

For quality-based or value-based purchasing payments under 42 C.F.R. § 438.6(c)(1)(i) and (ii), the state directed payment arrangement would need to have the same terms of performance for all of the providers that are in the provider class. For example, for a state directed payment arrangement that was a pay for performance initiative, the same metrics and thresholds/benchmarks for earning the payment would apply to all the providers in the class. The amount each provider would earn would be based on each provider's individual performance.

Regardless of arrangement, the regulations at 42 C.F.R. § 438.6(c)(2)(ii)(E) require that the payments cannot be conditioned upon the provider entering into or adhering to intergovernmental transfer agreements. Additionally, states must provide an analysis of the reimbursement level with sufficient detail for CMS to understand the relative effect of the directed payment on total reimbursement for each service and each provider class receiving the state directed payment(s). This analysis will need to be specific to the provider class(es) defined in the state directed payment preprint. For example, if the state defined the provider class for a state directed payment as primary care physicians, the analysis of the reimbursement levels would need to be specific to primary care physicians; it should not include all physicians (primary care and specialty physicians).

Incorporation of State Directed Payments into Capitation Rates

All state directed payments must be incorporated into all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in 42 C.F.R. § 438.7(b)(6). As part of the [2020-2021 Medicaid Managed Care Rate Development Guide](#), CMS provided guidance on two ways that states could incorporate state directed payments – either through adjustments to the base capitation rates as an adjustment to the rate or through a separate payment term.⁶ The rate guide describes the documentation requirements for each option. Incorporating state directed payments as adjustments to the base capitation rates is consistent with the nature of risk-based managed care. Most states adopting minimum or maximum fee schedules incorporate these directed payments through adjustments to the base capitation rates. However, there are an increasing number of states that are now incorporating directed payments into their rate certification(s) through separate payment terms.

As CMS has reviewed state directed payments and the related rate certifications, CMS has identified a number of concerns around the use of separate payment terms. Frequently, while there is risk for the providers, there is often little or no risk for the plans related to the directed payment, which is contrary to the nature of risk-based managed care. This can also result in perverse incentives for plans that can result in shifting utilization to providers in ways that are not consistent with Medicaid program goals. To further enhance program integrity and financial oversight of state directed payments, CMS intends to require additional documentation and

⁶ This guidance has appeared in the Medicaid Managed Care Rate Development Guide for rating periods starting between July 1, 2019 and June 30, 2021. Medicaid Managed Care Rate Development Guides for every rating period are located at: <https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html>.

justification from states as to their rationale for incorporating state directed payments through means other than adjustments to the base capitation rates as part of the preprint review.

Please note that CMS can provide technical assistance if a state has questions or concerns about how to include the impact of the payment arrangement in their Medicaid managed care rate certification(s). We also encourage states to consult the latest Medicaid Managed Care Rate Development Guide.

Financing of State Directed Payments

States can use permissible funding sources, including intergovernmental transfers and provider taxes that comply with federal statute and regulations to fund the non-federal share of state directed payments. Guidance provided in this SMDL is not intended to change this policy. However, approval of a state directed payment does not constitute approval of the financing mechanism for the non-federal share. States will need to work with the appropriate CMS staff to obtain the necessary approvals of a financing mechanism. Certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system or program (that is, fee-for-service, managed care, state directed payments, demonstration authorities, etc.). Such requirements include, but are not limited to, limitations on financing of the non-federal share applicable to health care-related taxes, bona fide provider related donations, and intergovernmental transfers.

For states that are using intergovernmental transfers to fund, in part or in whole, the non-federal share of a state directed payment, 42 C.F.R. § 438.6(c)(2)(ii)(E) requires that states demonstrate in writing (except for minimum fee schedules using State plan approved rates) that the arrangement does not condition provider participation in contract arrangements that use state directed payments (that is, the contract and payment arrangements described in § 438.6(c)(1)(i) through (iii)) upon the provider entering into or adhering to intergovernmental transfer agreements.⁷ To clarify, states can use intergovernmental transfers to fund the non-federal share of a state directed payment; however, states cannot limit either the provider's ability to participate in state directed payments or the amount the provider is eligible to obtain through the state directed payment based on the provider's participation in or adherence to an intergovernmental transfer. Similarly, provider classes cannot be defined or tailored to only include providers that provide intergovernmental transfers. If the provider meets the criteria for the provider class, the provider must be eligible to participate in the state directed payment arrangement regardless of whether the provider participates in any intergovernmental transfer agreements.

⁷ Prior to December 14, 2020, 42 C.F.R. § 438.6(c)(2) required contract arrangements that direct the managed care plan's expenditures under § 438.6(c)(1)(i) through (iii) to have prior written approval. The regulation was amended by the Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule, which appeared in the Federal Register on November 13, 2020 (85 FR 72754). Specifically, minimum fee schedules for network providers that provide a particular service under the contract using State plan approved rates as described in 42 C.F.R. § 438.6(c)(1)(iii)(A) do not have to obtain written approval prior to implementation though they still need to comply with the regulatory requirements for state directed payments as described in 42 C.F.R. § 438.6(c).

Quality and Accountability

42 C.F.R. § 438.6(c)(2) requires that directed payments be directly linked to quality improvement. Specifically, the regulations set forth the following three requirements that states must meet in order to receive CMS approval for their directed payment proposals:

- (1) Each directed payment must be expected to advance at least one of the goals and objectives in the state's managed care quality strategy (QS)⁸;
- (2) Each directed payment must have an evaluation plan to measure the degree to which the arrangement advances at least one of the quality strategy goal(s) and objective(s)⁹; and
- (3) For states electing to direct managed care plans to implement a value-based or delivery system reform payment arrangement, the directed payments must use a common set of performance measures across all payers and providers participating in the reform or improvement initiative.¹⁰

The [November 2017 CIB](#) provided further guidance on the quality requirements for state directed payment proposals. That CIB specified that the preprint should also include: the identification of performance criteria which can be used to assess progress on the specified goal(s) and objective(s); baseline data for performance measure(s); and improvement targets for performance measure(s). The November 2017 CIB also recommended that states look to measures already being collected, or that are widely available, and provided links to the Medicaid and CHIP Adult and Child Core Sets as well as other commonly used measure sets¹¹. To facilitate the evaluation of state directed payment arrangements, the November 2017 CIB also suggested several ways that states may leverage activities they may already be undertaking, such as External Quality Reviews (EQRs), the use of consumer or provider surveys, or monitoring whether performance improves on key quality measures, in order to fulfill the evaluation requirement.

CMS is available to provide technical assistance to states for any of the quality requirements of directed payments.

Revised Preprint

To make submission of state directed payment preprints easier, more comprehensive, and to reduce processing time, CMS is releasing a revised preprint to be used for all state directed payment requests for contract rating periods that begin on or after July 1, 2021. Under 42 C.F.R. § 438.6(c)(2), contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures

⁸ 42 C.F.R. § 438.6(c)(2)(ii)(C)

⁹ 42 C.F.R. § 438.6(c)(2)(ii)(D)

¹⁰ 42 C.F.R. § 438.6(c)(2)(iii)(B)

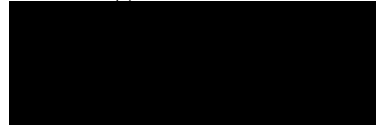
¹¹ Examples of measure sets in wide use across Medicaid programs include the Medicaid and CHIP Child Core Set (<https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/child-core-set/index.html>), the Medicaid Adult Core Set (<https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-core-set/index.html#CoreSet>), the Medicaid Health Homes Core Set (<https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-information-resource-center/quality-reporting/index.html>), and the Core Quality Measure Collaborative sets (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html>).

under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D)¹² must have written approval from CMS prior to implementation and before approval of the corresponding managed care contract(s) and rate certification(s). The revised preprint implements the prior approval process and must be completed, submitted to, and approved by CMS before implementing any of the specific payment arrangements described in 42 C.F.R § 438.6(c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D). States may use the revised preprint for contract rating periods that begin before July 1, 2021 and will be required to use the revised preprint for all state directed payment reviews for contract rating periods that begin on or after July 1, 2021. This revised preprint includes more information in tables and check-box formats to make completing the preprint easier and clearer. Additionally, by including more information in the revised preprint, CMS hopes to reduce processing time by reducing the quantity of follow-up questions during CMS review.

Technical Assistance

As noted earlier, CMS has already approved state directed payment arrangements in many states and found that early discussions with states and technical assistance on completing the preprint are beneficial for both states and CMS during the review process. We encourage states to reach out early for technical assistance to expedite CMS' review of state proposals. Please contact us at StateDirectedPayment@cms.hhs.gov for technical assistance or questions. We look forward to continuing our partnership with you to deliver on our shared goals of providing high quality and sustainable healthcare to those who need it most.

Sincerely,



Anne Marie Costello
Acting Deputy Administrator and Director

¹² Prior to December 14, 2020, 42 C.F.R. § 438.6(c)(2) required all contract arrangements that direct the managed care plan's expenditures under § 438.6(c)(1)(i) through (iii) to have prior written approval. The regulation was amended by the Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule, which appeared in the Federal Register on November 13, 2020 (85 FR 72754).