



State of California—Health and Human Services Agency
Department of Health Care Services



GAVIN NEWSOM
GOVERNOR

January 14, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2408-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Revisions to Medicaid Managed Care Regulations (CMS-2408-P)

Submitted electronically via: <http://www.regulations.gov>

The California Department of Health Care Services (DHCS) submits the enclosed comments for your consideration in response to the Centers for Medicare and Medicaid Services' (CMS) notice of proposed rulemaking (NPRM) published November 14, 2018, entitled "Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care."

As noted in our prior comment letters, CMS rulemaking in the managed care context is of critical importance to California given the prevalence of the delivery system in the Medi-Cal program. With over 13 million certified beneficiaries as of June 2018, approximately 82% (10.8 million) are enrolled in managed care plans from which they receive the vast majority of covered services. Of the remaining 18% of Medi-Cal beneficiaries, approximately 60% receive care through fee-for-service delivery for only a short amount of time, pending their enrollment with a contracted plan. DHCS has implemented managed care in all 58 California counties for various covered populations through six principle models and approximately 100 separate contracts. In addition, DHCS employs managed care delivery for the following service categories that are carved out from contracts with primary plans: (1) specialty mental health services through county-based prepaid ambulatory health plans (PAHP) on a statewide basis; (2) substance use disorder services through PAHP-based Drug Medi-Cal Organized Delivery Systems in 22 participant counties; and (3) dental services through standalone plans in Sacramento and Los Angeles counties.

Since publication of the initial final rule in May 2016, DHCS, its contracted managed care plans and various stakeholder partners have worked extensively to implement the 2016 final rule on several fronts. This included enactment and implementation of

legislation codifying the various 2016 Final Rule changes -- see Assembly Bill 205 (Stats. 2017, ch. 738) and Senate Bill 171 (Stats. 2017, ch. 768). Of particular note in the last year, DHCS reviewed and certified networks under the revamped federal and state requirements across our four current managed care delivery systems, including for the first time in the Specialty Mental Health, Drug Medi-Cal, and dental managed care settings. The 2016 Final Rule also necessitated significant financing changes in Medi-Cal managed care, including the repurposing of several provider payment initiatives into approved directed payment programs. For State fiscal years 2017-18 and 2018-19, DHCS worked extensively with stakeholder partners in securing CMS approval for multiple hospital-based directed payment programs, as well as Proposition 56 tobacco tax payment initiatives for physicians and dentists in managed care.

Both of these efforts, while just two of many changes brought about by the 2016 Final Rule, highlight the sheer complexity of implementing such an overhaul in a multifaceted program the size of Medi-Cal. As much of this implementation work remains ongoing in nature, it is important for CMS to continue to prioritize flexibility for states to employ, and refine as necessary over time, carefully tailored approaches that best reflect state/local needs. With that in mind, DHCS appreciates and supports CMS' efforts in the NPRM to streamline the regulatory framework, relieve regulatory burdens, and support flexibility and innovation in the delivery of care.

By and large, the NPRM achieves these goals admirably, but there are a few instances where overly rigid or proscriptive rules or timelines are unnecessarily imposed, or imposed without allowing flexibility for CMS to make exceptions to those rules or timelines in appropriate circumstances. Generally, we believe CMS should promote flexibility and provide multiple options for states to comply with the regulations in lieu of one-size-fits-all prescriptive measures, so long as the underpinning policy or operational goals are being met by states and plans. Beyond this immediate NPRM, DHCS encourages CMS to apply this same general approach in subregulatory guidance and in ongoing interpretations for purposes of annual contract and rate certification approvals. On a related note, and in recognition of the considerable implementation work that has already occurred, DHCS also requests clarification regarding the exact timeline(s) under which these new rules will become effective. As you are well aware, the 2016 Final Rule was implemented with staggered and delayed enforcement dates. So as to avoid disruption for unaffected contract/rate years and to ensure adequate time to implement any new changes, we recommend a similarly deliberate approach for this NPRM.

Before outlining our full and detailed comments to the proposed rule, I would like to particularly highlight three priority areas for California, identified briefly below:

- Actuarial soundness standards: Please note the requested language changes DHCS believes are critical with respect to the rate range and federal financial participation (FFP) provisions. The suggested language changes are consistent with CMS' intention to provide flexibility as needed to states.
- Special contract provisions related to payment: DHCS has significant concerns regarding the timing requirements in the risk-sharing provisions and

suggests the additional language to ensure that CMS and states are able to respond appropriately to issues that may arise, as well as recognize the challenging timeframes of rate-setting in a state as large as California.

- Network adequacy standards: CMS did not address in this NPRM changes to the periodicity of network certifications. DHCS again implores CMS to consider our comments of requiring such certifications instead on a biannual or triennial basis.

DHCS offers below detailed comments and suggested language in response to select NPRM changes in the order presented in the preamble.

1. Standard Contract Requirements (42 C.F.R. §438.3)

- *Coordination of Benefits Agreements (COBA) for Medicare crossover claims*

DHCS supports removing the requirement that plans directly enter into COBAs and participate in the automated Medicare crossover claim process. It will make claims processing easier for plans and enable more prompt payments to providers, while possibly lowering the number of provider claims to be processed. More generally, this is consistent with the overall rulemaking theme of flexibility so long as states and plans have sufficient alternative measures in place. As discussed above, DHCS encourages CMS to continue prioritizing this type of approach in lieu of one-size-fits-all mandates in applying and interpreting managed care rules.

2. Actuarial Soundness Standards (42 C.F.R. §438.4)

- *Option to certify to a rate range (§438.4(c))*

DHCS welcomes the restoration of the ability to certify to a rate range but, without further changes, we do not anticipate being able to make use of the flexibility in Medi-Cal. As noted in our previous comments to 2016 Final rule, the use of rate ranges in actuarial practice is widely accepted and routine, and in some cases optimal as compared to certifying a single, exact point of the range. Beyond the advantages for competitive bidding outlined in the preamble, the use of rate ranges provides much needed maneuverability for states in responding to changes in costs or other dynamics that are not sufficiently known prior to submission of rate certifications or, in some cases, once the contract/rate year begins. For this purpose, rate ranges remain a particularly effective and efficient tool for implementing valid payment strategies that target categories of safety net providers for enhanced reimbursement in managed care or that make use of alternative sources for nonfederal share, such as provider fee revenue or voluntary local contributions, that are relatively more volatile as compared to the traditional State General Fund sources. Since the elimination of rate ranges starting in SFY 17-18, DHCS has experienced increased costs and administrative burdens in rate development that we feel are largely attributable to the increased volume of revised

or supplemental rate certification submissions upon each and every incremental rate adjustment exceeding the current 1.5% threshold in 42 C.F.R. §438.7(c)(3). We continue to believe that both CMS and states are better served with a less restrictive approach that allows use of rate ranges within an appropriate magnitude, and requires states to submit adequate documentation of any movement within the range during the contract/rate year. For California in particular, the workload for both the State and CMS is significant for any contract/rate year given that the State currently sets approximately 1,500 rate cells per year.

We offer the below specific comments and recommendations on the proposed rate range option:

- **§438.4(c)(1)(iii):** DHCS appreciates the flexibility in proposed §438.4(c)(1)(iii) that the upper bound of the rate range may equal (up to) the lower bound multiplied by 1.05. When considered for the total rate, however, a 5% range is likely too small in magnitude to make it useful in rate development for Medi-Cal. We recommend applying the 5% restriction to the benefit component of the rate range development only, and exempting the non-benefit component (i.e. administrative load and risk/contingency/underwriting gain). To achieve this, we recommend revising proposed §438.4(c)(1)(iii) to read: "The **benefit component of the** upper bound of the rate range does not exceed the **benefit component of the** lower bound of the rate range multiplied by 1.05."
- **§438.4(c)(1)(v):** The prohibition on varying payment within a certified rate range based on the existence of IGT arrangements imposes new and expansive restrictions on the longstanding ability of states to make use of a variety of nonfederal share sources and to improve reimbursement to safety net providers in managed care. As written, we fear this prohibition would constrain exercise of longstanding state authority, pursuant to Sections 1902(a)(2) and 1903(w) of the Social Security Act, to draw upon a variety of state and local sources to fund the nonfederal share, including in furtherance of these initiatives in the managed care context. Currently, California relies on voluntary local contributions to finance increased capitation to managed care plans, intended to target increased reimbursement to safety net providers based on actual differences in cost experienced by public providers in certain geographic regions and service categories. This new restriction risks sweeping in these legitimate and actuarially-justified variations based purely on the existence of an IGT arrangement, or the use of an IGT funding source. These programs and funding streams are vital to the State and our local subdivisions in promoting access and quality objectives in a manner that can be readily tailored to local market dynamics. We recommend revising proposed §438.4(c)(1)(v) to read: "The State does not use as **a the sole** criterion..." This will ensure that the simple existence of an IGT agreement or the use of an IGT as a funding source does not impede States from exercising their, otherwise legitimate, discretion to pay at different points within the rate range when actuarially justified.

- **§438.4(c)(2)(i)**: DHCS is concerned that the requirement to document capitation rates “prior to the start of the rating period” is unnecessarily rigid and unrealistic in practice. The time- and labor-intensive process of developing and certifying actuarially sound rates can, and often does, result in unexpected delays that inevitably push the process into the rating period for which the rates are being developed. This becomes even more inevitable when considering the volume of contracts and accompanying rate packages, sometimes multiple per contract, that DHCS must develop and process each year. While we agree with the intent underlying this proposed restriction, we worry that it goes too far in dictating certainty at such an early point and, at least for California, will effectively negate the utility of the practice while also exposing the State to what could be arbitrary consequences for otherwise legitimate delays, most notably a disallowance of FFP for the relevant contract. We recommend instead extending flexibility to both CMS and states around submission timing, in a manner that maintains proper CMS oversight and is consistent with current CMS practice that allows a reasonable level of retroactivity in recognition that certain post-certification or post-submission rate adjustments are necessary. To that end, we recommend revising proposed §438.4(c)(2)(i) to read: “Document the capitation rates, prior to the start of the rating period, **except as permitted under 438.7(c)(2) or as otherwise approved by CMS,** for the MCOs, PIHPs, and PAHPs at points within the rate range...” Additionally, if CMS does proceed with this timing requirement, we recommend a delayed implementation or enforcement timeline of three years. This is consistent with CMS's approach in the 2016 Final Rule, and will offer both states and CMS the opportunity to clear historical backlogs and implement operational changes necessary to meet that earlier deadline.
- **§438.4(c)(2)(iii)**: DHCS is concerned that the proposed to “not modify the capitation rates within the rate range, unless the State provides a revised rate certification...” is unnecessarily rigid. Actuarial certification to a rate range is predicated on the determination that all points within the certified rate range are actuarially sound. Therefore, while we understand the requirement to document a decision to modify the rates within the rate range, a revised rate certification is not warranted actuarially and unnecessarily imposes an undue burden on states. We recommend revising proposed §438.4(c)(2)(iii) to read: “Not modify the capitation rates within the rate range, unless the State provides **a revised rate certification adequate documentation,** which demonstrates...” This flexibility will meet CMS' goal of avoiding unnecessary or unwarranted modification of capitation rates within the rate range without imposing the additional burden on states to formally update rate certifications.
- *Capitation rate development practices that increase federal costs and vary with the rate of Federal Financial Participation (FFP) (§438.4(b)(1) and (d))*

DHCS welcomes the added clarification at §438.4(b)(1) and (d) reinforcing that development of rates is based on actuarial principles and standards, and not considerations related to FFP. We also appreciate the preamble discussion distinguishing differences in capitation rates across populations resulting from acceptable actuarial practices as opposed to differences that are solely driven by the availability of higher rates of FFP. In order to ensure balance in the regulatory text itself, we request CMS add further clarification to the regulatory text differentiating situations where rate development assumptions are intended to increase federal costs from those where such an outcome is merely incidental. For example, rate development assumptions related to costs at children's hospitals would impact targeted low income children members for whom the enhanced title XXI FFP rate would apply, but a higher rate increment in this example would be based on actuarial considerations for children's hospitals and not the availability of a greater federal match for the population.

We recommend the following changes to the proposed §438.4 text:

- At (b)(1): "Any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of Federal financial participation (FFP) associated with the covered populations in a manner that increases Federal costs consistent with paragraph (d) of this section, **unless such differences are based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations.**"
- At (d)(1): "Capitation rate development practices that increase Federal costs and vary with the rate of FFP, **except when these practices reflect actual cost differences based on the characteristics and mix of the covered services or the covered populations,** are prohibited ..."

DHCS also requests clarification on proposed §438.4(d)(2) whether the "written documentation and justification" is expected to be part of the rate certification and supporting documents, or is an additional requirement separate from the traditional rate certification and supporting documents.

3. Special Contract Provisions Related to Payment (42 C.F.R. §438.6)

- *Documentation of all risk-sharing mechanisms (§438.6(b))*

DHCS is concerned that the requirement to document risk-sharing mechanisms "in the contract and rate certification...prior to the start of the rating period" is unnecessarily rigid and unrealistic in practice. The time and labor intensive process of updating contracts and developing and certifying actuarially sound rates can, and often does, result in unexpected delays that may push the process into the rating period for which the rates are being developed. This dynamic becomes even more inevitable when considering the volume of contracts and rate certifications in Medi-Cal each year.

While we agree with the need for restraints against unreasonable instances of retroactivity, we believe CMS should leave itself the same flexibility afforded for rate adjustments in allowing for retroactivity under circumstances it deems appropriate. While the preamble notes the flexibility in §438.7(c)(2) for retroactive rate adjustments, we do not see why that should not be available to both CMS and states for dealing with unexpected circumstances in the risk sharing context.

As such, we recommend revising the final sentence of proposed §438.4(b)(1) to read: "Risk-sharing mechanisms may not be added or modified after the start of the rating period, **except as permitted under 438.7(c)(2) or as otherwise approved or required by CMS.**" This will provide flexibility to implement these valuable mechanisms in circumstances where CMS finds appropriate without an unnecessarily rigid or impractical timeline. This approach is also consistent with CMS' interpretation of 1903(m)(2)(A)(iii) of the Act and implementing regulation at § 438.806. While FFP would not be allowable for any contract changes prior to approval, FFP would be permitted back to the initial date of the contract, as discussed in the State Medicaid Manual, § 2087. Additionally, if CMS does proceed with this timing requirement, a delayed implementation or enforcement timeline of three years should be included. This is consistent with CMS's approach in the 2016 Final Rule, and will offer both states and CMS the opportunity to clear historical backlogs and ramp up to meet these new and stringent deadlines.

- *Delivery system and provider payment initiatives (§438.6 (a) and (c))*

As discussed above, DHCS has worked extensively since publication of the 2016 Final Rule with plans and stakeholders to convert various managed care payment initiatives into approved directed payments pursuant to §438.6. This effort, which under the 2016 Final Rule is required annually, has proven both time- and resource intensive. Given the considerable and ongoing administrative burdens in the current process, DHCS is especially appreciative of CMS focusing on the directed payment context for purposes of streamlining the managed care regulatory framework.

We offer the specific comments below and urge CMS to consider extending such flexibility more broadly in the directed payment context:

- **§ 438.6(c)(1)(iii)(A) and (c)(2):** DHCS welcomes the added flexibility to adopt a minimum fee schedule based on approved State plan rates without the requisite preprint approval process applicable to other directed payments. We agree with the commentary about State plan rates being a frequent and logical approach to ensure adequate access to providers, and offer the significant advantage of already having been scrutinized by CMS under federal requirements including Section 1902(a)(30)(A) of the Social Security Act. This is further supported by the already existing use of State plan fee-for-service rates in managed care for non-network providers of emergency services to plan enrollees. In many cases, given the commonality in the

- populations served and services involved, the fee-for-service schedule is often the most appropriate and fitting. For these same reasons, we also appreciate the proposal to eliminate the need for obtaining written preprint approval for State plan based minimum fee schedules. The existing approval of such rates by CMS forecloses any need to require additional written approval, evaluation framework, and the affirmative documentation of the criteria listed in proposed §438.6(c)(2)(ii)(A) through (F). DHCS requests that CMS confirm that the evaluation requirement at (c)(2)(ii)(D) and the prohibition against automatic renewal at (c)(2)(ii)(F) are inapplicable to State plan minimum fee schedules. In the event CMS will still require documentation of these factors, we recommend CMS allow that to be incorporated into the traditional rate certification submission so as to avoid duplicative administrative review processes.
- **§438.6(c)(1)(iii)(E):** DHCS supports the additional flexibility to implement directed payments using cost-based, Medicare equivalent, average commercial or other market-based reimbursement standards. This type of flexibility helps drive innovation, and enables states to better optimize their programs to accommodate their own unique policy and demographic conditions.
 - **§438.6(c)(2):** DHCS welcomes the removal of the “may not direct the amount or frequency of expenditures by managed care plans” clause from the additional conditions that apply to value based and delivery system reform payment arrangements. We agree with the commentary in the preamble that this prohibition has created unnecessary problems for proposals in this category and seemingly conflicts with the general allowance for direction of plan expenditures upon CMS approval.
 - **§438.6(c)(3):** DHCS supports the proposal to codify the November 2, 2017 informational bulletin that allows for multi-year approval for certain directed payments. The implementation of value based purchasing and delivery system reform models is a major commitment, and we appreciate CMS recognizing that by allowing for longer multi-year approval timeframes. This is especially true with respect to evaluating programs that ramp up over time, are multidimensional, and/or whose impacts may not be apparent right away. In addition, a multi-year outlook is typically necessary to appropriately evaluate the effectiveness of a program, given the length of time needed for proper implementation and adequate run-out to properly evaluate. We request that payment arrangements under §438.6(c)(1)(iii) also be eligible for multi-year approvals, subject to the same requirements specified in proposed §438.6(c)(3)(i). These arrangements, depending on the specifics, can encompass the same types of evaluation strategies that are not easily or appropriately measured on a single year basis, and can be just as complex and labor intensive to implement as are value-based purchasing and delivery system reform initiatives. For these same types of proposals, a one-year

intervals restriction limits states' ability to properly assess outcomes, causes uncertainty with respect to plans and providers as well as state budgets, and imposes excessive burdens related to actuarial rate development, programmatic implementation, and evaluation on Medicaid agencies. We recommend revising proposed §438.6(c)(3)(i) to read: "Approval of a payment arrangement under paragraph (c)(1)(i) ~~and (ii)~~, **(ii), and (iii)** of this section is..." and striking proposed §438.6(c)(3)(ii).

4. Rate Certification Submission (42 C.F.R. §438.7)

DHCS welcomes the commitment by CMS to provide annual guidance relating to federal standards for rate development, required documentation, and changes to the CMS approval process. With so many changes to the rate development and approval processes since the 2016 Final Rule, including the incorporation of the CMS Office of the Actuary clear expectations and standards for states are even more imperative. As part of this annual guidance process, DHCS recommends that states are afforded an opportunity where feasible to provide feedback on any proposed changes prior to implementation.

5. Information Requirements (42 C.F.R. §438.10)

- *Tagline and Large Font Requirements (§438.10(d)(2))*

DHCS supports the revision to require that taglines are included only on materials for potential enrollees that are critical to obtaining services, and the removal of the definition for "large-print font" and to instead adopt the "conspicuously visible" standard from Section 1557 of the Affordable Care Act. It will shorten the length of many documents sent to beneficiaries making them more useful. It will also allow states to utilize more commonly used, and potentially more beneficiary or consumer friendly, communication formats such as postcards. Finally, these proposals will ensure consistency with overlapping federal obligations.

- *Provider Termination Notices to Beneficiaries (§438.10(f))*

DHCS supports the revision to require plans to issue notices of termination to beneficiaries concerning routinely seen providers by the later of 30 calendar days prior to the effective date, or 15 calendar days after plan receipt or issuance of the termination.

- *Provider Directories (§438.10(h)(3))*

DHCS supports the proposal to allow plans that have a mobile-enabled electronic provider directory to print quarterly rather than monthly paper directories, and for such changes to be reflected in the electronic version within 30 day. The revision is

beneficial for both states and plans, and helps to promote use of more modern technologies for an improved beneficiary experience.

6. Network Adequacy Standards (42 C.F.R. §438.68)

DHCS already, pursuant to state law codifying the 2016 Final Rule at Welfare and Institutions Code §14197, imposes quantitative network standards in addition to specific time and distance standards for network certification depending on geographic region of the State. Nonetheless, DHCS supports CMS' proposal to remove mandatory time and distance standards to instead allow the use of state-adopted quantitative standards, in the interest of promoting flexibility for state programs. Amongst other utility, the proposed flexibility allows states to better accommodate newer or emerging modalities like telehealth in a manner appropriate to local conditions. DHCS considers telehealth a cost-effective and valuable alternative to in-person delivery in certain categories, particularly within traditionally underserved or rural areas. As DHCS has already identified core specialist categories in state law for purposes of network adequacy, DHCS supports CMS' proposal to explicitly reinforce states' authority to designate what constitutes a specialist.

On a related note, and consistent with the rulemaking theme to eliminate regulatory burdens for states, DHCS requests that CMS revise the required interval for State certification of networks from annual to a biannual or triennial basis, absent any substantial changes in the applicable period such as a new benefit being added to managed care. The current annual requirement for the State to certify is quite a challenge when considering the volume of plans that contract with DHCS across four separate managed care delivery systems.

A biannual or triennial basis would maintain the importance of regular certifications of network adequacy while removing the unnecessary administrative burdens to states and health plans of re-doing certifications every year, particularly when little to no changes occur. DHCS would continue to require re-assessments of networks when significant changes occur or new populations/benefits are added.

7. Enrollee Encounter Data (42 C.F.R. §438.242(c))

DHCS welcomes the proposed revision to clarify that plans must report encounter data that explicitly includes "allowed amount and paid amount." The proposal reaffirms the foundational principle that states are able to access needed data concerning the delivery of Medicaid services from its contracted plans.

8. Medicaid Managed Care Quality Rating System (42 C.F.R. §438.334)

DHCS supports the proposed revisions to align quality rating system with existing quality rating approaches and developing a set of mandatory performance measures. DHCS appreciates the revision to §438.334(c)(1) to allow states to implement

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alternative systems that will help to accommodate differences in state programs or amongst multiple managed care delivery systems employed by a state. This is particularly true for specialized carve-out programs with unique population considerations, such as special mental health in California. It would also be helpful to clarify if CMS intends for the “mandatory performance measures” to be aligned with the CMS core data sets for children/youth and adults.

9. Grievances and Appeals (42 C.F.R. §438.400, 438.402, and 438.406)

DHCS agrees with the proposed clarification that a denial of a payment for purely administrative purposes does not constitute an adverse benefit determination nor trigger a Notice of Action. The current definition presents an unnecessary risk of beneficiary confusion and added administrative burdens for states and plans. DHCS also supports CMS’ proposal to no longer require an oral appeal to be followed by a written appeal. Requiring the written follow-up is burdensome to beneficiaries and serves no appreciable purpose.

Conclusion

Again, DHCS appreciates the opportunity to comment on the NPRM, and the commendable effort CMS has made to support state and local flexibility and to eliminate undue administrative burdens in the managed care setting. As mentioned above, we recommend CMS continue to prioritize such goals in its guidance to states and in the context of managed care contract and rate approvals.

Sincerely,

Original Signed By

Mari Cantwell
Chief Deputy Director, Health Care Programs
State Medicaid Director