Georgetown University
Health Policy Institute
CENTER FOR CHILDREN
AND FAMILIES

VIA ELECTRONIC TRANSMISSION

June 30, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality; Proposed Rule - CMS-2439-P

Dear Secretary Becerra,

Thank you for the opportunity to comment on, "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality; Proposed Rule - CMS-2439-P," hereinafter referred to as the "proposed managed care rule." The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005 with a mission to expand and improve high quality, affordable health coverage for America's children and families. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offers solutions to improve the health of America's children and families, particularly those with low and moderate incomes.

We broadly support the framework of CMS's proposed managed care rule; our comments include suggestions below to improve it. We strongly support CMS's efforts to improve access in Medicaid managed care, bring transparency and public reporting to managed care spending, improve quality systems, and facilitate the use of "in lieu of services" to address health-related social needs. We urge CMS to implement regulatory provisions on a faster timeline to begin improving access as soon as is feasible. We also recommend that CMS consider how it can pursue policies that promote alignment across fee-for-service and managed care, using this proposed regulation and the companion proposed access rule as an opportunity for alignment. CMS should also consider how it can, through these regulations: 1) improve access by setting Marketplace policies as minimums for Medicaid, and 2) align Medicaid payment rates with Medicare. Finally, we recommend that CMS consider how it can design network and payment policies to level the playing field in managed care and improve access to primary, pediatric, and maternity care.

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I. Access

We support the provisions of the proposed rule intended to ensure that Medicaid beneficiaries enrolled in managed care organizations (MCOs) have access to the services they need and to which they are entitled. We have a number of recommendations for strengthening some of those provisions.

a. Information requirements (§§ 438.10 (c), 457.1207)

Current regulations require that the state Medicaid agency operate a website that provides certain specified information, either directly or by linking to individual MCO, prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (PAHP), or primary care case management (PCCM) entity websites. The proposed rule would require that state agencies include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, on one web page; include clear and easy-to-understand labels on documents and links; verify at least every three months the accurate function of the website and the timeliness of the information presented; and explain that assistance in accessing the information on the website, including oral interpretation and written translation, is available at no cost. These requirements would become effective for the first rating period beginning two years after the effective date of the final rule.

We strongly support the proposed requirements for one web page; clear and easy-to-understand labels; quarterly verification of the accurate function and timeliness of information; and the availability of assistance. However, we do not believe that it is appropriate for a state Medicaid agency to outsource its transparency obligations to its contracting MCOs through the use of links to their websites. There should be one source of required information at the state level for beneficiaries and other stakeholders and the public: the state Medicaid agency website. Navigating multiple websites makes it challenging for enrollees and assisters to make comparisons across plans.

We do not object to the state Medicaid agency providing links to the websites of its MCOs and other contractors, but those links should not be allowed as a substitute for the state posting all required information on the agency website. We note that the requirements for one webpage, understandability, quarterly verification, and availability do not apply to the websites of MCOs or other contractors, raising questions about the user-friendliness of those websites. Referring beneficiaries and other stakeholders to MCO and other contractor websites increases barriers to the required information and shields the state agency from accountability for making the required information readily accessible to beneficiaries and the public at large.

Finally, the proposed implementation timeframe is too long. Assuming the effective date of the final rule is May 3, 2024 (one year from publication of the proposed rule), the earliest these requirements would apply is July 1, 2026. There is no reason why state Medicaid agencies cannot operate compliant websites by January 1, 2025.

Recommendations:

Revise § 438.10(c)(3) to read as follows:
*"(3). The State must operate a website that provides the content specified at § 438.602(g) and elsewhere in this part. States must: (i) Include all content on one web page; ****

Revise the first sentence of § 438.10(j) to read as follows:
*"States will not be held out of compliance with the requirements of paragraph (c)(3) of this section prior to January 1, 2025, so long as they comply ***"*

b. State monitoring requirements (§ 438.66(e))

Current regulations require that states submit to CMS within 180 days after each contract year a report on each managed care program administered by the state (MCPAR). The regulations specify ten items of information the MCPAR(s) must contain. The proposed rule would add two additional items: the availability and accessibility of any in lieu of services (ILOS) within the MCO, PIHP, or PAHP contracts, and the results of an enrollee experience survey. The proposed rule would also require that the state agency post the MCPAR(s) on its website within 30 days of submitting it to CMS.

We support the inclusion of ILOS and enrollee experience survey results in the MCPAR and the requirement that state agencies post MCPARs within 30 days of submission to CMS. However, we are unclear on the effective date of the posting requirement with respect to current MCPARs. Under the current MCPAR submission schedule, all states are required to submit their first reports by September 27, 2023. Presumably, all of the second reports will be submitted by the end of September 2024. There is no reason why state Medicaid agencies cannot post their first two MCPAR reports by January 1, 2025.

In addition, based on past noncompliance on the part of some states with the current posting requirements,[1] we do not believe that this state posting requirement is sufficient to ensure beneficiary and other stakeholder access to the MCPAR(s) in all states. As a practical matter, CMS does not have the capacity to monitor and enforce compliance with this posting requirement by all managed care states; CMS does, however, have the capacity to post on Medicaid.gov the MCPARs it receives from each state, and it should do so. That will ensure that beneficiaries and other stakeholders in states that do not comply with the posting requirement will still have ready access to the MCPARs. It will also make an important statement that the information in these reports is important, that public access to these reports matters, and that CMS has a role to play in ensuring their full transparency for stakeholders in all states.

[1] Corcoran, A. et al., "Transparency in Medicaid Managed Care: Findings from the 13-State Scan," (September 2021), https://ccf.georgetown.edu/wp-content/uploads/2021/09/MCO-13-state-scan-v3.pdf, at p. 15.

Recommendations:

Revise § 438.66(e) to add a new paragraph (4) to read as follows: "(4) CMS will post on the agency's Medicaid website each annual report submitted to CMS under paragraph (e)(1) within 30 days of receipt."

Revise proposed § 438.66(f) to add a sentence at the end to read as follows: "The requirement of paragraph (e)(3)(i) is effective January 1, 2025."

c. Network adequacy standards (§§ 438.68, 457.1218)

Current regulations require that state Medicaid agencies develop a quantitative network adequacy standard for each of seven provider types (if their services are covered by the MCO's risk contract) taking into consideration nine different elements. These quantitative standards may include appointment wait times. States may permit exceptions to any of their standards based on the number of providers of a given type practicing in an MCO's service area. State agencies are required to post their standards on their websites.

The proposed managed care rule would require states to establish and enforce appointment wait time standards for routine visits to primary care providers, both pediatric and adult (15 business days from request), obstetrics and gynecological (OB/GYN) providers (15 business days from request), and outpatient mental health and substance use providers, both pediatric and adult (10 business days from request). For each standard, compliance would be defined as a 90 percent rate of appointment availability as determined by the results of secret shopper surveys for which states would be required to contract with an independent entity. Critically, the results of secret shopper surveys would have to be submitted to CMS and posted on the state agency's website. In permitting exceptions from the standards, states would be required to consider the payment rates offered by the MCO for the provider type for which the exception is sought. The requirements relating to appointment wait time standards would be effective the first rating period beginning on or after three years after the effective date of the rule. The requirement for contracting with independent entities to conduct secret shopper surveys would be effective the first rating period beginning on or after four years after the effective date of the rule.

We support all of the proposed changes described above except for the effective dates, which are much too delayed. The current regulations have demonstrably not produced robust provider networks that result in broad access to covered services by all MCO enrollees.[2] A recent Kaiser Family Foundation survey of health insurance consumers, including 815 adults with Medicaid coverage, found that one third of those with Medicaid coverage reported that a doctor who is covered by their insurance and whom they need to

[2] Ludomirsky, et al., "In Medicaid Managed Care Networks, Care is Highly Concentrated Among a Small Percentage of Physicians," 41 *Health Affairs* (May 2022) https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01747?journalCode=hlthaff.

see did not have available appointments.[3] The minimum appointment wait time standards, combined with monitoring by secret shopper surveys and the posting of the survey results, have the potential to improve MCO provider networks, thereby increasing enrollee access to needed care. This approach can and should be improved with three additional changes.

First, while the proposed rule represents a welcome effort to align Medicaid and Marketplace Qualified Health Plan (QHP) standards, adding appointment wait time standards specific to OB/GYNs to those for primary care and mental health and substance use disorder services, more alignment is needed with respect to time and distance standards and appointment wait times for specialty care. The Medicaid network adequacy standards should be more closely aligned with those in the federally-run Marketplaces, with the Marketplace standards serving as a bare minimum standard for Medicaid. In some cases, the Medicaid population may have higher needs and, in many cases (due to lower income eligibility levels), less ability to pay out of pocket to access an urgent service. Thus, Medicaid may need to have a higher standard. *Medicaid's standard should never be lower than the Marketplace.*

Marketplace plans are required to adhere to over 40 different time and distance standards at the individual provider level (e.g., OB/GYN) and at the facility level (e.g., intensive care units) that vary by county population size and density.[4] Uniform time and distance standards should be applied to Medicaid managed care too. CMS could implement such standards over time, starting with critical services such as primary care (adult and pediatric), OB/GYN and outpatient clinical behavioral health as is proposed elsewhere in the rule. The proposed rule also does not include the minimum wait time standard of 30 business days for a non-urgent visit to specialists that will also apply to QHPs in Plan Year 2025,[5] thus we recommend that requirement be added to Medicaid.

There is no principled rationale for such disparate treatment of Medicaid beneficiaries and QHP enrollees, either with respect to the specific wait time or time-and-distance standards, or with respect to the effective dates. A scan of state Medicaid programs found that between 2017 and 2020 most states (90 percent) used time and distance standards and the large majority (75 percent) used appointment availability standards,[6] so in most cases states already have the necessary operational experience and would only need to adjust to the federal minimum, if at all. Moreover, non-alignment could prove particularly problematic in states where insurers offer products in both the federally-run Marketplace

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[3] Politz, et al., "KFF Survey of Consumer Experiences with Health Insurance," (June 15, 2023), https://www.kff.org/private-insurance/poll-finding/kff-survey-of-consumer-experiences-with-health-insurance/.

[4] CMS, "2023 Final Letter to Issuers in the Federally-facilitated Exchanges" (April 28, 2022), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2023-Letter-to-Issuers.pdf.

[5] HHS, "Notice of Benefit and Payment Parameters for 2024," 88 FR 25740 (April 27, 2023) at 25879, https://www.govinfo.gov/content/pkg/FR-2023-04-27/pdf/2023-08368.pdf.

[6] Zhu, et al., "Variation in Network Adequacy Standards in Medicaid Managed Care," Am. J. Manag. Care (June 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9236159/.

and Medicaid and, because of the difference in wait time as well as time-and-distance standards, cause them to focus on compliance by their QHP provider networks, giving less priority to the accessibility of providers in the provider networks of their Medicaid product.

Second, the requirement that the entities contracting with the state to conduct secret shopper surveys be independent of the MCOs, PIHPs, or PAHPs subject to the surveys needs to be tightened. As proposed, an entity would be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. This limited definition of independence does not exclude entities that may have some kind of contractual relationship with any of the MCOs, PIHPs, or PAHPs subject to the surveys. It also would not exclude any person who is an owner, employee, or consultant of the entity, and also contracts with, or has a direct or indirect financial interest in, any of the MCOs, PIHPs, or PAHPs subject to the surveys. These obvious loopholes would compromise the independence of the entity conducting the secret shopper surveys.

Third, the effective dates for implementation of the minimum appointment wait time standards are far later than those for the federally-run Marketplaces. Assuming the rulemaking process on this proposed rule takes one year, the effective date of the final rule would be May 3, 2024, and the proposed effective date for the minimum appointment wait time standards would be the first rating period three years after that, or July 1, 2027 at the earliest (some states have later rating period start times). This would leave Medicaid enrollees in MCOs without the same minimum wait times for at least two and one-half years.

Recommendations:

Alignment with QHPs—

> *Revise proposed § 438.68(b)(1) by adding at the end the following: "The quantitative standards developed by the State with respect to the provider types specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section must be at least as stringent as the time and distance standards established by the Federally-facilitated Exchange under 45 CFR § 156.230(a)(2)(i)(A)." This language would align Medicaid and Marketplace time and distance standards for primary care, OB/GYN, and outpatient clinical behavioral health providers.*
>
> *Revise proposed § 438.68(e)(1) by redesignating paragraph (e)(1)(iv) as (e)(1)(v) and inserting a new paragraph (e)(1)(iv) to read as follows: "If covered in the MCO's, PHIP's, or PAHP's contract, non-urgent specialty care within State-established time frames but no longer than 30 business days from the date of request." This language would add the appointment waiting time standard in the federally-run Marketplace for non-urgent specialty care to the other two Marketplace appointment wait time standards that state Medicaid agencies must, at a minimum, apply.*

Revise proposed § 438.68(f)(3)(ii) to read as follows: "An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if:

(A) The entity is not such an MCO, PIHP, or PAHP, is not owned by such an MCO, PIHP, or PAHP, and does not own such an MCO, PIHP, or PAHP;

(B) The entity does not contract with such an MCO, PIHP, or PAHP, or with any subcontractor of such an MCO, PIHP, or PAHP;

(C) No person who is an owner, employee, or consultant of the entity contracts with, or has a direct or indirect financial interest in, any of such MCOs, PIHPs, or PAHPs.

Revise proposed § 438.68(h) by striking "on or after 3 years after" each time it appears and inserting in lieu thereof "on or after 1 year after." This language would align the effective dates for time and distance standards, appointment wait time standards, and publication of network adequacy standards with the latest effective date for network adequacy standards in the federally run Marketplace, Plan Year 2025.

We also suggest a few other improvements. First, we recommend that CMS develop protections to ensure that providers are not held liable if and when wait time standards are not met. The purpose of these new standards is to improve managed care plan contracting, not to create a basis for plans to punish providers. While neither plans nor providers may be in the position to "fix" a true provider shortage, only managed care plans control the capacity of the network. Thus, providers should not be held liable or otherwise punished when network adequacy standards are not met. Second, we recommend that CMS define "routine" in order to support a national standard rather than allowing states to define this term. Third, we recommend that CMS continually evaluate whether the proposed wait time standards (10 days for mental health and substance use providers and 15 days for primary care and OB/GYN providers) are sufficient to promote access to needed services. Some states have already imposed tighter standards, such as shorter wait times for high-risk pregnancies.

d. Assurances of adequate capacity and services (§§ 438.207, 457.1230)

Current regulations require that each MCO, PIHP, and PAHP provide to the state Medicaid agency documentation that demonstrates that it maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. The state agency, in turn, is required to submit to CMS an analysis that supports the assurance of the adequacy of the network of each MCO, along with supporting documentation.

The proposed rule would require that each MCO, PIHP and PAHP submit a "payment analysis" to the state Medicaid agency that compares the total amount paid by the plan for evaluation and management (E&M) codes for primary care, OB/GYN, mental health, and substance use disorder services during the prior rating period with the total that would have been paid by the plan if the plan had used published Medicare payment rates for those services. The state agency, in turn, would be required to include these payment analyses in the analysis it must submit to CMS and to post its analysis on the state agency's website

within 30 calendar days of submission. These new requirements would apply for the first rating period for contracts beginning on or after two years after the effective date of the final rule, except that the posting requirement would apply one year after.

We strongly support the provisions of the proposed rule relating to payment analysis, especially the requirement that percentages must be reported separately if they differ between adult and pediatric services. These provisions would begin to bring transparency to the sufficiency of payment rates to network providers furnishing primary care, OB/GYN, and mental health and substance use disorder services. Insufficient payment rates effectively guarantee inadequate provider networks; these payment analyses have the potential to flag insufficient rates and to allow stakeholder comparison of payment rates as a percentage of Medicare rates among MCOs within the same state and from state to state. We have six recommendations for strengthening these proposals.

First, there should be a clear timeframe for submission of the payment analysis by each MCO to the state Medicaid agency; we recommend no later than 90 calendar days after the end of the rating period. We recommend that the state Medicaid agency be required to submit its certification of network adequacy to CMS on the same timeframe as it is required to submit its MCPAR under § 438.66(e)(1): 180 days after each contract year. These timeframes will allow the state agency to review the payment analyses, submit its certification to CMS, and take another six months to make any necessary adjustments in the payment rates for the following rate period.

Second, in the preamble to the proposed companion access rule, CMS indicates the agency will publish the E&M codes to be used for the payment rate analysis in subregulatory guidance along with the final rule (88 FR 28008). We support this approach because it ensures that all of the rate analyses will be conducted on the same set of codes, making it easier to compare across states. CMS should also require MCOs to use this published list of codes when conducting their payment analyses in order to ensure consistency across delivery systems.

Third, in order to ensure consistency in payment analyses from MCO to MCO within the same state and from state to state, the term "primary care services" should be specifically defined for purpose of this analysis. We recommend that CMS include any of the codes described above for the access rule payment analysis *and* any additional codes in the current regulatory definition of "primary care services" found at 42 CFR § 447.400(c): E&M codes 99201 through 99499, and CPT vaccine administration codes 90460, 90461, 90471, 90472, 90473, and 90474. States and CMS both have operational experience working with these E&M and CPT codes in connection with the application of minimum Medicare Part B fee schedule rates during 2013 and 2014 under 42 CFR § 447.405**.**

Fourth, to ensure that the payment analysis submitted by each MCO is accurate, complete, and truthful, we recommend that the rule expressly clarify that each payment analysis is subject to certification by the chief executive officer (CEO), chief financial officer (CFO), or delegated individual under § 438.606. We recognize that documentation described in § 438.207(b) is currently subject to certification, but in light of the long-standing and

vigorous resistance of many MCOs to financial transparency, we believe that eliminating any ambiguity on this point will significantly reduce litigation risk for state Medicaid agencies and CMS.

Fifth, we recommend that the transparency proposals be strengthened by requiring the state Medicaid agency to post on its website not just the report it submits to CMS but also the individual payment analyses submitted by each MCO. The state agency should also be required to make the payment analysis submitted by an MCO available to the state Medicaid Advisory Committee and Beneficiary Advisory Group to inform their oversight of the performance of individual MCOs.

Finally, we recommend that the effective date for all of the new requirements relating to payment analyses be accelerated. Specifically, the payment analyses should apply with respect to the first rating period starting on or after the effective date of the final rule. Assuming a final rule effective date of May 1, 2024, this would require MCOs to provide, and state Medicaid agencies to review, payment analyses for rates paid to providers during the rating period beginning July 1, 2024. The submissions by the MCOs to the state Medicaid agency, and the submissions by the state agencies to CMS, would not be due until October 1, 2025 and December 31, 2025, respectively.

<u>Recommendations</u>: The recommendations above can be executed with the following modifications to the proposed text.

Revise proposed § 438.207(b)(3) by adding a sentence immediately prior to paragraph (b)(3)(i) to read as follows: "The payment analysis must be submitted to the State within 90 days of the end of the rating period to which the payment analysis applies." Additionally, revise proposed § 438.207(d) in the matter before paragraph (d)(1) to read: "After the State reviews the documentation submitted by the MCO, PHIP, or PAHP as specified in paragraph (b) of this section and the secret shopper survey results as required at § 438.68(f), but in no case later than 180 days after the end of the most recent rating period, the State must submit an assurance of compliance to CMS…."

Revise proposed § 438.207(b)(3) by adding at the end the following new paragraph (b)(3)(v): "The payment analysis must include all of the E&M CPT/HCPCS codes issued in the most recent subregulatory guidance related to implementation of the requirements in § 447.203(b)(2)(i)-(iii)."

Revise proposed § 438.207(b)(3) by adding at the end the following new paragraph (b)(3)(vi): "For purpose of this section, the term "primary care … services" means "primary care services" as defined in § 447.400(c) and any additional E&M codes identified by the agency."

Further revise proposed § 438.207(b)(3) by adding at the end a new paragraph (b)(3)(vii) to read as follows: "The payment analysis described in paragraph (b)(3) of this section is subject to the certification requirements set forth at § 438.606."

Revise proposed § 438.207(d)(3) to read as follows: "States must…post the submission to CMS described in paragraph (d)(1) and the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, on the State's website required in § 438.10(c)(3) within 30 calendar days of submission to CMS and must make the payment analysis submitted by an MCO, PIPH, or PAHP available to any member of the Medicaid Advisory Committee under § 431.12 upon request."

Revise the first sentence of proposed § 438.207(g) to read as follows: "Paragraphs (b)(3) and (d)(2) of this section apply with respect to the first rating period for contracts with MCOs, PHIPs, or PAHPs beginning on or after [insert the effective date of the final rule]."

II. State Directed Payments

Since being established in 2016 regulations, state directed payments (SDP) have allowed states some limited flexibility to direct the payments made by their managed care contractors, including requiring them to use a minimum or maximum fee schedule, use value-based payment mechanisms, or make other rate increases. SDPs have been important to states, allowing them to continue supplemental payments to Medicaid providers after transitions to managed care, where traditional supplemental payments are often prohibited by regulation. Without the SDP payments, the Medicaid providers would suffer an effective loss of revenue in managed care. Consequently, the use of SDPs has grown quickly in just a short time. By 2020, states had already channeled over $25 billion dollars to providers through SDPs (and this is likely a large undercount due to data limitations).[7] In just the first four years, SDPs already surpassed other long-standing supplemental payment mechanisms, including disproportionate share hospital and upper payment limit payments.[8] However, CMS has insufficient information about how access to care is being improved. CMS also does not have adequate information about how the money is being *spent*. It is critical to Medicaid program integrity and efficiency – and ultimately to access to care – that CMS better understand where the dollars are going and how they are impacting access to Medicaid services.

We believe CMS's proposed managed care rule is an important step forward to improve SDP processes, accountability, and transparency. Our comments support finalizing many of the proposed managed care rule policies, though we do make recommendations to improve or not finalize certain provisions. We believe that in the coming years CMS will need to do more to require states to justify the expenditure of SDP dollars. In the context of managed care programs which are *already* supposed to be actuarially sound and have adequate networks, CMS ultimately needs to examine the evidence and document the value of the *additional* SDP dollars. If CMS fails to require states to fully report on SDP spending, and ensure it promotes value, the risk of inappropriate use of SDPs will rise and threaten public trust and support for the Medicaid program.

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[7] MACPAC, June 2022 Report to Congress on Medicaid and CHIP, 33 (June 2022), https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.

[8] *Id*.

a. Evaluation and reporting

The Medicaid and CHIP Payment and Access Commission (MACPAC) has expressed concern that CMS's current review of SDPs is only prospective, and CMS cannot determine how much states are ultimately paying through SDPs, nor how much is being paid to which providers.[9] In the managed care rule, CMS proposes a short and long-term approach to getting data on actual spending. Short-term, CMS proposes to use existing medical loss ratio (MLR) reporting as a vehicle to collect actual expenditure data. Longer-term, CMS proposes annual provider-specific data reporting through the transformed Medicaid statistical information system, specifying the total dollars expended by each MCO for SDPs, including amounts paid to individual providers. CMS indicates it will develop a uniform template with minimum data fields.

Both the Government Accountability Office (GAO) and MACPAC have expressed concerns about the lack of sufficient evaluation information for SDPs.[10] Current regulations require states to have an evaluation plan for SDPs, but do not provide details for the plan content or require a final evaluation report. The managed care rule proposes specific elements for the evaluation plan and requires states to submit an evaluation report for most types of SDPs if the SDP amounts to more than 1.5 percent of managed care program costs. CMS specifies some requirements for the evaluation report, including that it must be publicly available on a website and that states must file it within two years of the conclusion of a three-year evaluation period (and every three years thereafter).

Our comments support the proposals for reporting on actual SDP spending and evaluations, but recommend dropping the 1.5 percent threshold for evaluations.

We strongly support the requirement for final reporting on SDP payments, including the specific requirement to have provider-level payment amounts. It is critical that CMS get clear data on how many SDP dollars are being paid to which providers. We also strongly support the creation of required elements for evaluation plans and the requirement for an evaluation report. We specifically support the requirement to publicly post the evaluation report.

We have not recommended in these comments that CMS establish a total limit on SDP spending, in part because of concerns that such a limit could effectively cap payment increases for providers with less political clout. Instead of setting such a limit, we believe CMS should require evaluation of all SDPs that require written approval, without the 1.5 percent (or other) threshold. We believe that 1.5 percent of managed care *program* costs could be a very large sum, particularly considering that the SDP could be targeted toward a narrow group of providers. Given the need to understand more about the value and impact

[9] *Id*. at 46.
[10] MACPAC, "Directed Payments in Medicaid Managed Care" (June 2022), https://www.macpac.gov/wp-content/uploads/2022/06/June-2022-Directed-Payments-Issue-Brief-FINAL.pdf; U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care'' (June 28, 2022), https://www.gao.gov/assets/gao-22-105731.pdf.

of SDP programs, it is critical for CMS to require evaluations of all SDPs. We note that the regulatory definition already excludes fee-schedule based SDPs, which tend to be the smallest in terms of spending, and we agree with that exclusion.

Recommendations: We strongly recommend that CMS finalize the proposals for reporting on SDP spending, including specifically reporting at the provider level. CMS should require any SDP arrangement to have clear, timely, and public data on how much money from each arrangement is going to each provider. We also support the evaluation plan requirements and the evaluation report requirements, including public posting of the evaluation report, with one suggested change. We recommend that CMS remove the 1.5 percent threshold for evaluation reports and require evaluations for all SDPs that require prior written approval.

While we strongly support the requirement to publicly post evaluation reports, we recommend that CMS do more to promote transparency. We recommend that CMS require public posting of: SDP preprints, evaluation plans, CMS approvals, rate certifications, and all short and long-term reporting on payments under proposed § 438.6(c)(4).

We recommend that CMS require independent evaluators for SDPs.

Finally, we recommend that CMS reduce the five-year total timeline for evaluation reports. Currently, the vast majority of SDP funding goes to fee-schedule or uniform rate increase (at least 83 percent of spending) SDPs which do not represent a classic "investment" model requiring three years to pay off.[11] Additionally, states should not need two years to issue a report which will be heavily based on the two required § 438.6(c)(2)(iv)(A) metrics. We recommend that CMS implement a two-year evaluation period and allow states one year to issue their initial report. (Subsequent reports should be every two years.)

b. Limits on SDP payment rates

CMS generally requires that SDP payment rates be reasonable, though this is not a regulatory requirement. In addition, while CMS sets outer limits for FFS supplemental payments based on Medicare payment rates, CMS has allowed states to set SDP rates up to the Average Commercial Rate (ACR), which can be a significantly higher rate for many services. The proposed managed care rule would codify in regulation the general requirement that SDP rates be reasonable. CMS also proposes to maintain the current ACR maximum for some SDP payments, but requests comment on whether it should revert to a Medicare limit for all SDP payments. Our comments recommend setting the SDP maximum at the Medicare payment level, except for services that have no corresponding Medicare payment rate.

We strongly support CMS codifying the requirement to use reasonable rates and make documentation available to CMS upon request.

[11] MACPAC, "Directed Payments in Medicaid Managed Care" 4 (June 2022), https://www.macpac.gov/wp-content/uploads/2022/06/June-2022-Directed-Payments-Issue-Brief-FINAL.pdf.

Our comments, here and in response to CMS's companion access rule, more broadly recommend that CMS align Medicaid payment rates with Medicare rates, which is the most impactful step CMS can take in promoting access through Medicaid rate-setting as it would be like a tide that raises all boats. Allowing SDPs to rise to ACR levels is not an efficient solution; it leads to a windfall for a few providers, but most providers do not benefit from the policy. At the same time, we believe that for most services there is no need to go above Medicare payment rates to enable adequate access. As such, we do not believe CMS should generally allow SDP payment to ACR levels. We believe CMS should set Medicare levels as the default maximum for SDP rates (elsewhere in our comments we have recommended that CMS work to lift all Medicaid rates to Medicare rates), but allow an exception for Medicaid services which have no Medicare equivalent. We support the designation of another payment benchmark by CMS (such as ACR or a percentage of ACR) in these circumstances where Medicare offers no benchmark.

We believe setting the maximum limit for SDPs at Medicare levels (with a very limited exception) is the best policy option for several reasons. First, the use of Medicare levels will avert potential program integrity concerns that could create problems for Medicaid. Second, we believe any ACR allowance creates a problematic misalignment with FFS limits, and CMS should minimize the misalignment. SDPs were established in part to solve a misalignment (created by the direct pay prohibition) making it hard for states to migrate supplemental funding from FFS to managed care systems, but CMS's current ACR policy creates the same problem in the reverse direction. States now face a new barrier in transitioning away from managed care, and we are aware of this materially impacting delivery systems in at least one state, Kentucky. Finally, Medicare rates are easily ascertained and more transparent. We note that there may be some services for which Medicare has a rate, but it is not a reliable comparison because it is used so infrequently or under meaningfully different circumstances. In our comments on the companion access rule, we urge CMS to consider developing a research project, for example with MedPAC and MACPAC, to evaluate any missing services and identify a more appropriate benchmark. If CMS proceeds with this type of research project, it could also evaluate services for which the Medicare benchmark is inadequate, and the findings could be used to support use of ACRs in SDPs even when there is a Medicare rate available.

If, against our recommendation, CMS continues to allow SDPs up to ACRs even when there is a Medicare equivalent rate, CMS should consider an immediate policy of requiring a state to pay all Medicaid services at least at 100 percent of Medicare levels *prior* to authorizing new rate increases for some services above Medicare levels toward ACR levels.

Recommendations: We recommend that CMS finalize the proposal to require states to use reasonable SDP payment rates and provide documentation upon request. We further recommend that CMS should set the default maximum payment level for SDPs based on Medicare payment rates (as per FFS limits), but offer a limited exception using some alternative benchmark for Medicaid services that have no equivalent Medicare payment rate.

Finally, if CMS continues policy allowing payment to ACR levels, with respect to calculating the ACR, we specifically recommend that CMS finalize the provision at (c)(2)(iii)(A) as written

to include consideration of the services addressed by the SDP, but not the provider class. We also recommend that CMS require states to pay all Medicaid services at least at 100 percent of Medicare prior to authorizing new rate increases for some services above Medicare levels.

c. Hold Harmless arrangements

As CMS guidance has repeatedly noted and we have previously written in public comments, provider taxes are a critical Medicaid financing mechanism, well-established in law and practice. Provider taxes allow providers to make essential contributions to Medicaid financing, which states use to strengthen Medicaid programs so long as such provider taxes are implemented in accordance with statutory and regulatory requirements. For example, the tax must not unfairly target certain providers and must be applied uniformly.

Another such basic requirement, set out in federal law, is that states cannot allow "hold harmless" arrangements, under which the money collected in taxes is guaranteed to be returned to the taxpayer. Since the original provider tax is collected from a wide range of providers within a provider class, including low-volume Medicaid providers that do not get back much in the form of Medicaid payments and tend to be better financed hospitals in higher income areas, the hold harmless payments typically go from high-volume Medicaid providers to the low-volume providers, to ensure that the low-volume providers "break even." As of 2019, *all but one* state had at least one health care tax in place, and likely only a handful of states had any improper hold harmless arrangement in place. Such hold harmless arrangements are not *necessary* for states to utilize provider taxes.

CMS has been pressed by oversight agencies about its lack of monitoring for inappropriate hold harmless arrangements that may violate the statutory prohibition. In an attempt to prevent hold harmless arrangements, including indirect arrangements administered by providers, CMS's managed care rule reasonably proposes to require: (1) states to comply with the prohibition to have direct or indirect hold harmless provisions in SDPs; (2) providers receiving SDP payments to attest that they do not participate in an unlawful hold harmless arrangement; and (3) states to make the attestations available to CMS upon request. CMS indicates it will require states to confirm compliance with the hold harmless prohibition in SDP preprints. Our comments support CMS's proposed hold harmless proposal.

We support CMS's policy to ensure that prohibited hold harmless arrangements, including indirect arrangements, are not occurring in Medicaid managed care. We support CMS's proposed regulation as an administratively simple policy (and an improvement on current guidance) to prevent improper hold harmless arrangements without creating an untenable obligation on states to affirmatively monitor every financial arrangement their providers enter into. States need only collect attestations and make them available upon request. We recommend that, first, as per our recommendations above regarding payment analysis in § 438.207, attestations should be subject to certification by a provider CEO or CFO (or delegated individual). Second, we recommend that CMS consider clarifying (or, if needed, develop conforming policy) that the attestations would be obligations covered under the False Claims Act.

We also agree that for clarity, CMS should require states to confirm compliance in the SDP preprint. Nonetheless, prior to finalizing the requirement, we suggest that CMS evaluate the impact the policy would have on existing provider tax financing. It is our understanding and assumption that only a few, if any, states may be in violation of the currently proposed standards, and that the new policy would primarily prevent the proliferation of future hold harmless arrangements in the new world of SDP programs.

Recommendation: We recommend that CMS finalize the proposed rules on hold harmless arrangements in SDPs, subject to analysis on the impact of the change. We also recommend that CMS require CEO or CFO certification of attestations and clarify their applicability to False Claims Act enforcement.

d. Separate Payment Terms

SDPs are currently paid through adjustments to base rates or separate payment terms (SPT). SPTs are additional provider payments, coming from of a dedicated funding pool, that are made outside of capitation base rates—a mechanism that is unique to SDPs. In the preamble to the managed care rule, CMS expresses its strong preference for payments made through base rates, but notes several reasons states use of SPTs (and that over half of SDP payments were made through SPTs in 2023). CMS's managed care rule proposes to regulate SPTs as a contract term subject to Social Security Act section 1903(m). CMS proposes to require a state actuary to certify the total dollar amount for each SPT and codifies many current review practices. CMS also would require states to submit a rate certification or amendment incorporating the SPT. However, CMS solicits comments on whether SPTs should be eliminated and SDPs should be funded only through adjustments to base capitation rates.

We support CMS's proposals to regulate and document the actuarial soundness of arrangements that include SPTs. We agree with CMS that SDPs are best implemented through adjustments to base capitation rates. If CMS does not eliminate SPTs, CMS should reduce their use to the limited situations where states could not achieve the same purpose by adjusting base rates.

Recommendation: We recommend that CMS finalize the proposed provisions to regulate SPTs and limit their use to situations where states could not achieve the same purpose by adjusting base rates.

e. Other provisions

Current regulations allow states to implement SDPs requiring MCOs to use the state's Medicaid fee schedule as the minimum for payment to providers. CMS proposes to add a similar flexibility for states to require payments based on a fee schedule that is exactly 100 percent of the Medicare payment rate. CMS also proposes to allow states to choose to not implement an SDP or eliminate an approved SDP without notice.

We support CMS's proposal to allow for SDPs based on the Medicare fee schedule as a minimum payment level. This is consistent with the flexibility states have to pay up to this rate through other arrangements, and it is more closely tied to services provided if built into the payment itself. There is no reason CMS should not allow this flexibility. In contrast, we do not support the flexibility for states to not implement or eliminate SDPs without notice. State should be required to provide public notice if not moving forward with or eliminating an SDP.

Recommendations: We recommend CMS finalize the proposal to allow use of SDPs based on the Medicare fee schedules. We recommend that CMS rescind the proposal to allow states to not implement or eliminate SDPs without notice, and instead recommend that CMS require public notice.

III. State Oversight of the minimum Medical Loss Ratio (§ 438.74)

Current regulations require state Medicaid agencies to submit to CMS annually a "summary description" of the annual MLR reports received from each MCO with which they contract. The regulations specify that the summary description must include the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed. The proposed managed care rule would clarify that the summary description must be provided for each MCO under contract with the state and that it also includes line items for the amount of SDPs made by the MCO to its providers and the amount of SDPs made by the state Medicaid agency to each MCO.

We support the provisions in the proposed managed care rule, which would give CMS greater ability to oversee the financial performance of individual MCOs as well as the deployment of SDPs by state Medicaid agencies and individual MCOs. However, the proposed managed care rule does not go nearly far enough in advancing transparency around individual MCO financial performance. State risk contracts with MCOs in total mediate hundreds of billions of federal and state dollars; individual contracts can mediate billions of dollars. It is not sufficient that only state Medicaid agencies, MCOs, and CMS know how those funds are being spent. Other Medicaid stakeholders, including providers, Medicaid Advisory Committees, beneficiaries, and the public have a compelling interest in understanding how MCOs are using Medicaid funds. In particular, as the September 2022 Office of Inspector General study[12] demonstrates, there is a strong public interest in how much each MCO is spending on quality-improving activities and non-claims costs.

Recommendations: To advance transparency, we recommend the following revisions.

[12] Office of Inspector General, "CMS Has Opportunities to Strengthen States' Oversight of Medicaid Managed Care Plans' Reporting of Medical Loss Ratios," OEI-03-20-00231 (September 22, 2022), https://oig.hhs.gov/oei/reports/OEI-03-20-00231.asp.

1. *Revise § 438.74(a)(2) by inserting "the amount of expenditures on quality-improving activities and the amount of non-claims costs" after "the amount of the denominator." This revision would enable CMS to assess how much MCOs spend on administrative costs nationally and on a statewide basis, and to compare individual MCO spending on quality-improving activities and non-claims costs with peer MCOs in the same state and other states.*

2. *Revise § 438.74 by inserting a new paragraph (a)(5) to read as follows: "CMS shall post on Medicaid.gov the summary description submitted by each State under paragraph (a)(1) within 30 days of receipt." This revision will enable other stakeholders and the public to conduct the assessments and comparisons described above.*

3. *Further revise § 438.602(g), which the proposed managed care rule would revise (see our comments above), to add a new paragraph (g)(14) to read as follows: "the annual report submitted by each MCO, PIHP, or PAHP under section 438.8(k)." This revision adds the annual MLR reports submitted by each MCO to the information that the state Medicaid agency is required to post on its website.*

4. *Further revise § 438.602(g), which the proposed managed care rule would revise (see our comments above), to add at the end a new paragraph (j) to read as follows: "Medicaid Advisory Committee and Beneficiary Advisory Group. The State must make available to the Medicaid Advisory Committee and Beneficiary Advisory Group described in § 431.12, upon the request of any member of the Committee, any of the documents and reports described in paragraph (g) of this section and any of the data, information, and documentation described in § 438.604(a)." This revision is needed to enable MACs in states contracting with MCOs to carry out their responsibility under § 431.12 (as proposed in the companion access rule, CMS-2442-P, 88 FR 27960) to advise the Medicaid Agency Director on "matters related to the effective administration of the Medicaid program." The performance on individual MCOs is by definition such a matter.*

IV. In Lieu of Services and Settings

Medicaid managed care plans have long had authority to cover "in lieu of services" (ILOS) in substitution of traditional state plan services. ILOS have been a favored flexibility for states and managed care plans because the new services that are included can be factored into rate-setting, thus giving the health plans an incentive to provide the services. However, there has been insufficient standardization of ILOS processes and services. Additionally, a narrow definition of substitution has made it historically difficult for states to make strategic ILOS investments (such as prevention) to reduce the need for more expensive health care treatments over time (such as acute care).

CMS's managed care rule is intended to address some of these long-standing concerns. The proposed rule would bring uniformity and transparency to the delivery of ILOS and open the door to states making longer-term investments through ILOS, including ILOS that may

begin to address health-related social needs. Our comments are supportive of CMS's approach, with some suggestions to improve the proposed regulations.

a. ILOS definition and general parameters (§§ 438.2, 438.16, 457.10)

CMS's proposed managed care rule builds upon 2016 regulations[13] and recent guidance[14] by establishing a new and broader definition of ILOS, allowing both immediate and longer-term substitution of services. CMS also clarifies the types of services that can be ILOS and sets new fiscal protections for use of ILOS – including an outer limit of five percent of capitation on ILOS for managed care plans. States will also be required to provide cost percentage calculations and an annual report of actual managed care plan ILOS spending based on claims and encounter data. Our comments support these provisions.

We support the new proposed definition of ILOS, and specifically the inclusion of ILOS substitutions that are based on longer-term investments in care. Many community-based services may take time to produce the substitution effect, and states should be able to make strategic investments in such services. We also support the creation of a five percent cost percentage threshold for ILOS. CMS should set a limit on ILOS usage to ensure program integrity and to give CMS, states, and plans an opportunity to evaluate how well ILOS investments are achieving their objectives prior to broader expansion. We also support the requirement for states to provide cost percentages and an annual report of ILOS spending, specifically based on claims and encounter data. We believe CMS should make this data public.

Recommendations: We recommend that CMS finalize the proposed provisions, but add requirements for public reporting of cost percentages and annual reports.

b. Enrollee rights and protections (§§ 438.3(e)(2), 438.10(g)(2)(ix), 457.1201(e), 457.1207)

The proposed managed care rule sets enrollee rights and protections as one of its "key principles." CMS includes several new provisions for enrollees in the proposed managed care rule that CMS states are current policy: (1) enrollees retain all rights and protections available under part 438 (including appeals rights); (2) enrollees retain the right to receive state plan services, regardless of being offered, using, or previously using ILOS; (3) ILOS may not be used to discourage access to state plan services; (4) a requirement for plans to include these protections in enrollee handbooks; and (5) a requirement for states to include these requirements in plan contracts. Our comments support this proposal, but make suggestions for improvement.

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[13] CMS, Final Rule, "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability," 81 FR 27498 (May 6, 2016), https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf.

[14] CMS State Medicaid Director Letter 23-001, "Services RE: Additional Guidance on Use of In Lieu of Services and Settings in Medicaid Managed Care" (Jan. 4, 2023), https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.

We strongly support the inclusion of beneficiary protections for ILOS in the managed care rule, including all of the provisions in §§ 438.3(e)(2), 438.10(g)(2), and 438.16(d)(1).

While we strongly support the general requirement for Part 438 protections, inclusive of due process, we have two concerns. First, we are concerned that tying the protections only to those for managed care plans in Part 438 may ignore some Medicaid protections in other parts of the statute, such as Fair Hearing processes and other due process protections against the state. Second, we believe that CMS must address practical problems for the ILOS system to achieve the equivalent due process of state plan services. Enrollees, and in particular their providers, will need some simple way to understand what ILOS services are available and who is eligible for them (i.e., targeting criteria). In addition, under CMS's design, managed care plans always retain the right "to not offer ILOS," which may create confusion since health care providers would often be the expected prescribers of ILOS services. CMS must address these issues in regulation or else ILOS will exist in theory but be a mystery in practice.

We also strongly support the requirement that ILOS cannot be forced upon consumers, nor that their being offered or used can block access to state plan services. Since ILOS are conceptually substitution services, we are particularly concerned that consumers will have an "either-or" choice between ILOS or state plan services, particularly in the case of "longer-term" ILOS where ILOS access may have no impact on shorter-term continued need for state plan services. We appreciate the specific protections CMS built into the regulation. However, we also believe that it is vital that CMS address this in the rate-setting process. Enrollees retain the right to use all medically appropriate services, therefore the capitation rate must reflect that in many cases there will be payment for *both* a state plan service and its substitution ILOS. We are particularly concerned that, in the context of state budget pressure or managed care plans desire for profits, there will be an incentive to assume unrealistically short payoffs on ILOS investments, that will in practice erode access to state plan services. We urge CMS to ensure that all services are appropriately captured in the rate setting process to help prevent an unintended erosion in access to needed care.

<u>Recommendations</u>*: We strongly recommend that CMS finalize the beneficiary protections for ILOS in the managed care rule, including all of the provisions in §§ 438.3(e)(2), 438.10(g)(2), and 438.16(d)(1).*

We recommend that CMS improve the regulations by clarifying that all Medicaid access protections (and not only those in Part 438), such as due process, apply in the context of ILOS. We further recommend that CMS require states or plans to create a simple one-stop-shop ILOS webpage for each plan detailing the available ILOS services and related targeting criteria, as well as providing this information directly to enrollees (via enrollee handbooks) and providers (via direct mailing). If an ILOS is identified in state contract, and yet the managed care plan chooses not to make it available, that too should be clearly and prominently identified. Finally, we believe that CMS should develop explicit rate-setting regulations clarifying that capitation can and should include "two treatments" for one unit of need, where a longer-term ILOS is implicated, and that CMS should require systems to evaluate if consumers are being "forced to choose" between a state plan service and a longer-

term ILOS, as well as systems to ensure that longer-term ILOS are actually being provided as per the capitation assumptions.

c. Medically appropriate and cost effective (§§ 438.16(d), 457.1201(e))

Although current regulations require that states determine that ILOS must be medically appropriate and cost effective, there are not strong requirements to document this. The managed care rule proposes numerous documentation requirements for states implementing ILOS, including the name and definition of ILOS, what service is being substituted, documentation of medical appropriateness and cost effectiveness of the ILOS, and the clinically defined target population for the ILOS. Our comments support these documentation requirements.

We generally support the documentation requirements proposed in § 438.16(d). We believe these requirements will support transparency and program integrity. However, we recommend that CMS review the documentation requirement at § 438.16(d)(iv), as we are concerned that it may create a burden for prescribers that may limit the success of ILOS.

Recommendation: We recommend CMS finalize § 438.16(d) as proposed, though (d)(iv) may need to be revised to avoid creating overly burdensome documentation requirements.

d. Payment and rate development (§§ 438.3(c), 438.7(b), 457.1201(c))

CMS regulations consider ILOS utilization and costs in rate development, but are not explicit about including them in final capitation rates and payments (though CMS's preamble says this is current policy). In the managed care rule, CMS proposes to codify the current practice and adds documentation requirements. Additionally, in the preamble at Fed. Reg. 28169, CMS notes that based on current regulations, state actuaries should adjust capitation rates to account for whether plans offer ILOS and enrollees actually use ILOS. Our comments support these provisions, with an addition.

We support the proposed provisions to explicitly include ILOS in capitation rates, as well as the related rate documentation requirements.

We believe CMS must do more to ensure that states adjust capitation rates based on actual provision of ILOS. Given that many ILOS will be a new frontier of services, it will be hard for actuaries to predict utilization and cost in prospective capitation calculations. In addition, it is important for CMS to ensure that plans do not get a windfall of ILOS dollars for services that are never ultimately provided.

Recommendations: We recommend CMS finalize the proposed regulations, and add regulatory requirements explicitly requiring states to adjust capitation rates when their regular actuarial reviews determine they meaningfully diverge from the actual costs for ILOS.

e. Other requirements for ILOS: state monitoring, retrospective evaluation, and transition plans

The proposed managed care rule would require contracts between the state and the plan to provide for submission of encounter data to states as specified by CMS and the state, and states must review and validate the data. CMS also proposes to require that states include a contractual requirement that managed care plans use specific coding to identify each ILOS and clarifies that states should report ILOS in MCPAR.

In addition, CMS proposes that states must submit a retrospective evaluation for each managed care program using ILOS, if ILOS are being used above a 1.5 percent of cost percentage threshold. CMS seeks comment on whether evaluations should be specific to each program. CMS proposes a minimum set of required elements for retrospective evaluation, including for *each* ILOS: impact on state plan service use and costs, trends in use of ILOS, cost-effectiveness and medical appropriateness, detailed reporting on grievances and appeals, impact on health equity, impact on quality of care, and final ILOS cost percentage. CMS solicits comment on whether there should be an independent ILOS evaluator.

Lastly, CMS proposes that states must notify CMS within 30 days if an ILOS is no longer compliant with requirements around medical appropriateness, cost-effectiveness, or enrollee protections. CMS proposes that it can terminate noncompliant ILOS and that any termination (by CMS, state, or MCO), would require a transition plan including notice for enrollees and a plan for timely access to state plan services and settings.

We support the requirements for contracts to provide for encounter data per CMS or state specifications, state validation of the data, and use of specific coding to identify ILOS, as well as the clarification that states should report ILOS in MCPAR. It is critical for CMS to have encounter level data to do analysis on the ILOS being used and the enrollees using them. In addition, we strongly support the requirement for retrospective evaluation for ILOS above the 1.5 percent threshold, including specifically information about both state plan and ILOS utilization, appeals and grievances, and impacts on equity. Tracking utilization will be necessary for CMS to connect health and cost outcomes, whether positive or negative, to the substitution of state plan services. We recommend that CMS require states to use an independent evaluator to ensure that there is an objective review of the efficiency of state spending and impacts. Finally, we support the requirements for states to inform CMS about noncompliant ILOS and develop transition plans.

<u>Recommendations</u>: We recommend CMS finalize its proposals for state monitoring, retrospective evaluation, and transition plans. We recommend that CMS make evaluations specific to each state program and use an independent evaluator.

V. Quality Assessment and Performance Improvement Programs, State Quality Strategies and External Quality Review

a. Managed Care Quality Strategies (§§ 438.340, 457.1240)

Current Medicaid regulations at § 438.340, and in CHIP at § 457.1240(e), require states to implement a written quality strategy for assessing and improving the quality of health care services furnished by an MCO, PIHP, or PAHP. The quality strategy is intended to serve as a foundational tool for states to set goals and objectives relating to the quality of care and access for managed care programs. The proposed managed care rule would increase opportunities for interested parties to provide input on the state's managed care plan. It requires states to seek public comment on the state's quality strategy at least every three years regardless of whether significant changes are made. States must post the full evaluation of the effectiveness and results of the triennial review of the quality strategy, not just the state's proposed plan. States would also be required to submit the plan for CMS review and input.

Recommendations: We support these changes to the quality strategy review process. We note that while the proposed managed care rule was silent on the purpose of quality reviews and strategies, other documents including the national quality strategy and the managed care quality strategy toolkit reinforce that quality strategies are intended to promote health equity by addressing disparities and improving health care access and outcomes.[15,16] We encourage CMS to reinforce this messaging and use its review process to ensure that state quality strategies continue to close the gap on disparities that disproportionately affect children and families of color and people with disabilities.

b. External Quality Review (EQR) Period (§§ 438.358(b)(1), 457.1520(a))

The current rules lack uniformity in the EQR review periods and do not specify when the EQR activity must take place relative to finalization and posting of the annual report. As a result, states may report the results of EQR activities that are three or more years old and less useful for quality improvement and oversight. The proposed rules would ensure consistency and align data in the annual reports with the most recently available information used to conduct the EQR activities.

Recommendations: We support these changes to the EQR review periods. Aligning the review periods and requiring states to conduct EQR activities in the twelve months preceding finalization and publication of the annual report will result in more current data being publicly posted in the annual EQR technical reports. This will ensure that EQR technical reports are a more meaningful tool for monitoring and comparing quality between plans.

c. Optional EQR Activity (§ 438.358(c)(7))

The proposed managed care rules would establish a new optional EQR activity to support current and proposed managed care evaluation requirements. Specifically, the rule would allow states to conduct evaluation requirements for quality strategies, SDPs, ILOS that

[15] CMS, National Quality Strategy, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.
[16] CMS, Medicaid and CHIP Managed Care Quality Strategy Toolkit (June 2021), https://www.medicaid.gov/medicaid/downloads/managed-care-quality-strategy-toolkit.pdf.

pertain to outcomes, quality, or access to health care services as an EQR activity. The rule would apply to CHIP except the provision relating to SDPs, which are not applicable to CHIP.

Recommendations: We support these changes that would provide states with enhanced matching funds to use the EQR process and technical assistance to support more robust evaluations, which could lead to greater transparency and quality improvement.

d. EQR Results (§ 438.364)

i. Data to be included in EQR technical reports

Current regulations limit the data that must be included in technical reports to performance measurement data and do not require other types of data that may be used to measure the outcomes associated with performance improvement projects (PIPs). As a result, the reports often focus on whether the methods used to implement or evaluate a PIP were validated, but do not include measurable data such as the percentage of enrollees who participated in the PIP or patient satisfaction based the outcomes of the PIP. Additionally, the regulations do not currently require the reports to include data obtained from the mandatory network adequacy validation data.

The proposed managed care rule at § 438.364(a)(2)(iii) would require EQR technical reports to include any outcomes data and results from quantitative assessments, as well as data from the mandatory network adequacy validation activity.

Recommendations: We support these proposed changes and believe they will result in more meaningful EQR technical reports that can be used to drive quality improvement and oversight in managed care.

ii. Guidance on stratification in EQR protocols

In the preamble to the NPRM, CMS asked for comment on whether it should consider adding guidance in the EQR protocols for states to stratify performance measures collected and reported in the EQR technical reports to facilitate monitoring of efforts to monitor disparities and address equity gaps.

Recommendations: We encourage CMS to include guidance on stratification of performance measures in future updates to EQR protocols to ensure consistency in reporting that aligns with proposed requirements for mandatory reporting of the Core Sets of Health Care Quality Measures and proposed requirements for the Medicaid and CHIP managed care quality rating system (MAC QRS).

iii. Revising the date annual EQR technical reports must be finalized and posted (§ 438.364(c)(1))

The proposed managed care rule would change the required date for finalizing and posting EQR technical reports from April 30th to December 31st.

<u>Recommendations</u>: We support this change to better align with HEDIS measures that are audited and finalized annually in June. While this moves the posting date out, other proposed changes to EQR review periods discussed above will ensure that data reflected in the EQR technical reports remain timely.

iv. State posting of EQR technical reports

The proposed rules at § 438.364(c)(2) would require states to notify CMS when annual EQR technical reports are posted and to maintain EQR reports on state websites for five years. Prompt notification will facilitate CMS's review and aggregation of the required data, including ensuring that data are complete, before inclusion in the annual report to the Secretary. Additionally, the proposed managed care rule would require states to maintain at least five years of EQR technical reports on their website.

<u>Recommendations</u>: We support these changes that would provide access to historical data and information for CMS and other stakeholders. Notably, many PIPs are conducted over a three-year period and the current reporting structure does not provide the longevity needed to follow results.

<u>Recommendations</u>: We recommend that CMS take steps to specify more rigor in how outcomes and lessons learned from PIPs are documented in technical reports. We also believe CMS should specifically require an assessment of health equity activities and outcomes.

e. Medicaid and CHIP Managed Care Quality Rating System (QRS) (§§ 438.334, 457.1240)

The 2016 final managed care rules established the authority to require states to create and maintain a managed care quality rating system. Its purpose is to hold states and plans accountable for care provided to Medicaid and CHIP enrollees; to arm enrollees with useful information about plans available to them; and to provide a tool for states to drive improvements in plan performance and the quality of care provided by their programs. The proposed managed care rule would advance the QRS as a one-stop-shop where enrollees could access information about Medicaid and CHIP eligibility and managed care; compare plans based on quality and other factors key to plan selection, such as the plan's drug formulary and provider network; and to aid enrollees in selecting a plan that meets their needs.

The preamble of the proposed managed care rule goes describes in detail the extensive consultations, research, and consumer testing that CMS has embarked upon to inform the MAC QRS framework proposed in the rule. The proposed framework includes mandatory measures, a rating methodology, and a mandatory website format. The robust website envisioned in the proposed managed care rule recognizes that quality ratings alone are not useful in selecting a health plan without additional information. It also intends to align QRS

website information with beneficiary choice counseling to aid beneficiaries in selecting a plan that meets their unique needs (although this is one of a few provisions in the proposed managed care rule that does not apply to CHIP since separate CHIP programs are not required to have a beneficiary support system). The proposed QRS framework would align, where appropriate, with Medicare Advantage and Part D quality rating system and other related CMS quality rating approaches to reduce state burden across federal quality reporting systems.

Recommendations: We applaud CMS for its more robust approach to the QRS and generally support these changes and the proposed QRS framework.

i. Timeline

The proposed managed care rule requires that states implement their MAC QRS (or CMS approved alternative) by the end of the fourth year following effective date of the rule. However, more interactive features of the QRS to aid beneficiaries in plan selection would be delayed for at least an additional two years.

Recommendations: We recommend that states be required to implement the second phase of the QRS in two years rather than "at least" two years, which is open ended and could lead to further delays in providing beneficiaries with the tools and information they need to make informed decisions in choosing a plan. Already, the QRS has been delayed beyond the initial implementation date of 2018 and states have four years to implement phase one. That provides six years for states to achieve the vision of the QRS framework.

ii. Mandatory measures (§§ 438.510(c), 457.1240(d))

The proposed managed care rule would require state QRSs to include all mandatory measures, regardless of whether the state implements the model MAC QRS or adopts a CMS-approved alternative QRS. The proposed rule includes 19 mandatory measures, all but one of which are also required for the current Child and/or Adult Core Sets of Health Care Quality Measures. CMS notes three considerations that guided the process of selecting the initial mandatory measure set and in making future changes: 1) the measure must meet five of out six specific measure inclusion criteria; 2) it would contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas (e.g., preventive health, long term services and supports); and 3) the burdens associated with the measure do not outweigh the benefits to the QRS framework. To determine whether a measure meets these standards, CMS would rely on the input of a sub regulatory process like the current process used in reviewing the Child and Adult Core Sets, which is described below.

The six measure inclusion criteria are: 1) the measure is meaningful and useful to enrollees in choosing a managed care plan; 2) the measure aligns with other CMS rating programs; 3) the measure assesses health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity; 4) the measure provides an opportunity for MCOs to

influence their performance; 5) the measure is based on data that are readily available and feasible for states to report; and 6) the measure demonstrates scientific acceptability – meaning the measure produces consistent and credible results. These criteria are described in more detail in the preamble to the rule.

Recommendations: We support these criteria but recommend a seventh criterion be considered: Does the measure advance health equity?

The proposed managed care rule would establish these criteria for removal of a measure: 1) the external measure steward retires or stops maintaining a mandatory measure; 2) there are changes in clinical guidelines associated with the measure; or 3) there is low statistical reliability in the measure.

The rule proposes a biennial stakeholder process for updating mandatory measures like the process used for the annual review of the Child and Adult Core Sets. Additionally, a second step in the process would be for CMS to provide public notice and opportunity to comment on mandatory measures identified for addition, removal, or updating through public engagement.

CMS will update guidance to states on mandatory measures in an annual technical resource manual. States would be given at least two calendar years from the start of the measurement year immediately following the technical resource manual to report (required by August 1, 2025, and annually thereafter).

Recommendations: We recommend that states be given no more than two calendar years to report a new or revised mandatory measure. As the proposed managed care rule currently reads there is no outer limit to when states would be required to report a mandatory measure.

f. MAC QRS Rating Methodology (§§ 438.334(d), 438.515, 457.1240(d))

The proposed QRS rating methodology seeks to balance two themes – state burden associated with data collection and quality rating calculations with beneficiary need for transparent, representative quality ratings.

Currently states are only required to publish a single quality rating for each MCO, PIHP, or PAHP on the website. Under the proposed rule, states would be required to issue a quality rating for each mandatory measure, not a single overarching rating for each plan. Reporting on a domain level basis (e.g., preventive care or behavioral health) remains under consideration and may be included in future rulemaking.

The proposed managed care rule would require states to not only collect data from each managed care plan but also validate the data used to calculate and issue quality ratings for each mandatory measure on an annual basis. Under the NPRM, states would use the validated data to calculate a measure performance rate for each managed care plan that is contracted to provide the service. Additionally, states must report quality ratings at the plan level for each managed care program. For example, states may have separate physical

and behavioral health managed care programs, which might include dual participation by a plan. In those cases, the state would report separate quality ratings for the plan separately for each program.

The proposed methodology also requires states to include FFS or other delivery system data if all necessary data cannot be provided by the MCO. For example, follow-up after hospitalization for a mental illness requires data on two services: hospitalization and mental health services through separate health plans. The quality rating for the measure would be reported for the plan responsible for follow-up services.

States can receive an enhanced match for assistance with quality ratings of MCOs performed by an EQRO, including the calculation and validation of data as an optional external quality review activity.

Recommendations: We support these provisions requiring states to validate, calculate, and publish quality ratings for each mandatory measure for each plan separately for all managed care programs in which the plan participates.

g. QRS Website Display (§§ 438.334(e), 438.520, 457.1240(d))

The NPRM would establish new requirements for a robust, interactive website display, which were informed by intensive consultation with prospective users and iterative testing of a MAC QRS website prototype. The display components identified as most critical fall into three categories: 1) information to help navigate and understand the content of the QRS website; 2) information to allow users to identify available managed care plans and features to tailor information displayed; and 3) features that allow beneficiaries to compare plans on standardized information, including plan performance, cost, and coverage of services and pharmaceuticals, and provider network.

Based on user testing, CMS proposes that a MAC QRS website include: 1) clear information that is understandable and usable for navigating the website; 2) interactive features that allow users to tailor specific information, such as formulary, provider directory, or quality ratings based on the selection criteria they enter; 3) standardized information so users can compare plans and programs; 4) information that promotes beneficiary understanding of and trust in the quality ratings; and 5) access to Medicaid and CHIP eligibility and enrollment information, either through the website or through external sources.

Because these provisions would require more technology-intensive implementation, the rule establishes two phases for development of the QRS website. In phase one, states would develop and implement the website not later than the fourth year after the rule is finalized. In this phase, states would develop the website, display quality ratings, and would ensure that users can access information on plan providers, drug coverage, and view quality ratings by sex, race, ethnicity, and dual eligibility status. In the second phase, states would be required to modify the website to provide a more interactive user experience with more information accessible to users directly on the MAC QRS. States would be given at least an additional two years after initial QRS website implementation to comply with phase two

requirements. In phase two states would be required to stratify quality ratings further by age, rural/urban status, disability, and language spoken by the user.

Recommendations: As noted above, providing "at least" an additional two years sets no firm date by which a state must have a fully functional QRS website. We recommend that the final rule set the phase two implementation date at no more than two years after phase one.

States would be required to provide standardized information for each managed care plan that allows users to compare plans and programs, including name, website, and customer service telephone hot line, premiums and cost-sharing, summary of covered benefits, certain metrics of access and performance (such as results of the secret shopper survey or information on grievances and appeals), and whether the plan offers an integrated Medicare-Medicaid plan. The proposed managed care rule does not address whether states would be required to include functionality for an individual to use the QRS website to enroll in a plan if they were already determined eligible.

Recommendations: We encourage CMS to describe in the final rule how the QRS website should align with the ability of a user who has been determined eligible to select and enroll in a plan.

Early user testing revealed that participants were skeptical of quality ratings, leading CMS to test clear and comprehensive language that would result in increased trust of the quality ratings. Thus, the NPRM requires the QRS website to include a description of the quality ratings in plain language, how recent the data are, and how the data were verified.

The NPRM proposes certain navigational requirements for the website display. First, states must provide users with information on the purpose of the website, relevant information on dual eligibility and enrollment through Medicare, Medicaid, and CHIP, and an overview of how the site can be used to select a managed care plan. The state would also be required to provide information on how to access the beneficiary support system currently required under §438.71, although this element does not apply to CHIP programs.

To better understand the visual nature of the website display, CMS has developed two prototypes to illustrate the information required in phase one and phase two. CMS also plans to release a MAC QRS design guide following the final rule, which will include a comprehensive overview of the results of user testing that can inform state design. User testing found that participants responded positively to features that allowed them to reduce the number of plans displayed based on specific criteria, such as geographic location or eligibility requirements. Users also wanted to be able to narrow the information displayed to plans for which they may be eligible.

Under the proposed managed care rule, states would have the option to display additional measures not included in the mandatory measure if the state has obtained input from prospective users and documents input from prospective users and the state's response, including rationale for not accepting such input.

States would continue to have the option to create an alternative quality rating system that is comparable to the QRS framework but would be limited in the changes they could make. However, states would no longer be allowed to substitute different performance measures for the mandatory measures. States will retain the ability to include additional performance measures and would no longer be required to obtain CMS approval to do so. The rule further defines the criteria and process for determining if an alternative QRS system is substantially comparable to the MAC QRS methodology. CMS intends to issue instructions on the procedures and dates by which states must submit an alternative QRS for approval.

Under the proposed managed care rule, CMS will develop and update annually a MAC QRS technical resource manual no later than August 1, 2025. The manual will include the mandatory measure set; measures newly added or removed; the subset of measures that would be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, and other factors; how to use the methodology to calculate quality ratings; and technical specification for the mandatory measures. When identifying measures to be stratified, CMS will consider stratification guidance by the measure steward and alignment with stratification requirements in the Child and Adult Core Sets.

The proposed policy requires states to submit to CMS, upon request, information on their MAC QRS to support the agency's oversight of Medicaid and CHIP and compliance with QRS requirements; to ensure that enrollees can meaningfully compare ratings between plans; and to help monitor trends in additional measures and use of permissible modifications to measure specifications to inform future updates to measures and the QRS methodology.

Recommendations: The NPRM sets out a robust vision for a user-friendly, interactive tool for Medicaid beneficiaries. As noted previously, we support this acceleration and standardization of best practices in providing Medicaid beneficiaries with the information and support they need to evaluate and choose a managed care plan that meets their unique needs.

VI. CHIP

Under current regulations, federal requirements applicable to state CHIP agencies and the MCOs with which they contract are generally, but not entirely, aligned with those applicable to state Medicaid agencies and the MCOs with which they contract. Because of this alignment, many of the changes made by the proposed managed care rule with respect to Medicaid will by cross-reference automatically apply to separate CHIP programs.

These include new requirements relating to MLR (§ 438.8, incorporated into § 457.1203); network adequacy (§ 438.68, incorporated into § 457.1218); availability of services (§ 438.206, incorporated into § 457.1230); adequate capacity and services (§ 438.207, incorporated into § 457.1230); provider selection (§ 438.214, incorporated into § 457.1233); quality measurement and improvement (§ 438.330, incorporated into § 457.1240); and external quality review (§§ 438.350 – 364, incorporated into § 457.1250).

Recommendations: We support aligning these requirements, as revised per our recommendations elsewhere in these comments, between Medicaid and separate CHIP programs.

We have additional comments on other proposed changes to the CHIP regulations.

a. Information requirements (§ 457.1207)

Current regulations require state CHIP agencies contracting with MCOs to post all notices and informational and instructional materials related to enrollees directly on the agency website or by linking to individual MCO websites. The proposed managed care rule would require the state CHIP agency to annually post MCO-specific comparative summary results of enrollee experience surveys conducted by the state. This requirement would take effect the first rating period beginning on or after three years after the final rule is effective; as a practical matter, that means 2027 at the earliest.

We support the proposal to require the state CHIP agency to annually post comparative summary results of enrollee experiences by MCO. However, we believe that this posting requirement should be effective in the first rating period beginning one year after the final rule is effective; we see no justification for states to wait until 2027 to conduct enrollee experience surveys as part of their monitoring and oversight responsibilities.

We also believe that separate state CHIP programs contracting with MCOs should be held to the same transparency requirements as CHIP programs that enroll covered children in Medicaid MCOs (at § 438.602(g)). Currently they are not, and our research has found that separate CHIP managed care programs are not as transparent as Medicaid programs that enroll CHIP children.[17] The interest of CHIP children and their parents (as well as other stakeholders and the public) in understanding how MCOs are performing is equally compelling whether the CHIP child is enrolled in an MCO contracting with a separate CHIP agency or with the Medicaid agency. In addition, the transparency interest of the federal government is even greater in CHIP than in Medicaid because of the substantially higher federal matching rate for CHIP payments to MCOs.

Recommendation: Revise current § 457.1207 by adding at the end the following sentence: "The State must post, on the State's website as described § 438.10(c)(3) of this chapter, the information described in § 438.602(g) with respect to MCOs, PIHPs, and PAHPs as defined in § 457.10, and the results of the annual enrollee experience surveys for each MCO." This revision would fully align the transparency requirements relating to Medicaid MCOs at § 438.602(g) as revised by this proposed rule with those relating to MCOs serving CHIP children in separate CHIP programs. It would also ensure that the results of the annual enrollee experience

[17] Schneider, et al., "An Introduction to Managed Care in CHIP," (March 2023), https://ccf.georgetown.edu/2023/03/24/an-introduction-to-managed-care-in-chip/.

surveys, and not just a summary comparison, will be publicly available on the state CHIP agency's website.

b. Quality measurement and improvement (§ 457.1240)

The proposed managed care rule elsewhere sets forth, in a new Subpart G, requirements for a MAC QRS. The proposed rule adds a new § 457.1240(d) that applies these requirements to separate CHIP programs that enroll CHIP children in MCOs, PIHPs, and PAHPs that do not contract with the state Medicaid program (and would therefore be subject to the MAC QRS).

Recommendations: We support the application of the MAC QRS, with the revisions we have suggested elsewhere in these comments, to CHIP programs.

c. Program integrity safeguards (§ 457.1285)

Current regulations align CHIP program integrity safeguards relating to managed care with those in Medicaid. The only exceptions relate to the Medicaid requirement that capitation rates be actuarially sound, a requirement not found in the CHIP statute. The proposed managed care rule would exempt CHIP programs from submitting annual managed care program reports to CMS as state Medicaid programs are required to do by § 438.66(e). In prior comment periods, we have urged CMS to apply all of the state reporting requirements in § 438.66 to CHIP, and we reiterate that recommendation now. These reports include, among other things, information on the financial performance of each MCO, including MLR experience; encounter data reporting by each MCO; and availability and accessibility of services, including network adequacy.

We can see no program integrity reason why CMS should not receive the same information about MCOs contracting with separate CHIP programs as it receives about those contracting with Medicaid programs—particularly since the federal share of payments to the CHIP MCOs is substantially higher than the federal share of payments to Medicaid MCOs. We have reviewed the current CHIP annual reports and they are utterly inadequate to the program integrity task.[18] The program integrity risk is elevated in cases where the same insurer offers a Medicaid product and a separate CHIP product, knowing that the CHIP product is not subject to the same transparency as the Medicaid product.

Recommendations: Revise the proposed change to § 457.1285 by striking the reference to § 438.66(e).

Apply § 438.66 to CHIP. Data elements that are already captured by the CHIP annual reports under § 457.750 would not need to be repeated, but the additional state monitoring requirements for managed care should be incorporated into subpart L of § 457 to ensure adequate oversight of managed care in separate CHIP programs.

[18] Id.

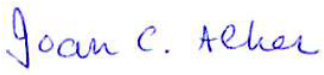
VII. Conclusion

If finalized as proposed, this managed care regulation would make significant advancements to improve access to care for Medicaid and CHIP beneficiaries. We applaud CMS's commitment to transparency as a means to improve quality and advance health equity. We generally believe that CMS, states, and managed care plans can and should adopt these provisions faster than proposed so that beneficiaries may benefit from improved access to care as soon as is feasible. We also believe that some provisions of the rule would benefit from greater alignment across delivery systems, such as provider payment rules in FFS versus managed care, as outlined in our detailed comments above. Finally, we believe that CMS should consider additional ways to achieve alignment across federal programs by using Medicare payments and Marketplace network adequacy standards as the benchmarks for Medicaid. Given their often lower incomes, in no circumstances should Medicaid beneficiaries have fewer access protections than Marketplace enrollees.

Our comments include numerous citations to supporting research for the benefit of the CMS. We direct CMS to each of the studies cited and made available through active hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the formal administrative record on this proposed rule for purposes of the Administrative Procedures Act.

Thank you for considering our comments; if you need more information, please contact Leo Cuello (leo.cuello@georgetown.edu) or Kelly Whitener (kelly.whitener@georgetown.edu).

Sincerely,



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