

Charles N. Kahn III President and CEO

July 3, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue SW Washington, DC 20201

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

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. The FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our views in response to the proposed Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality Regulation, 86 Fed. Reg. 28,092 (May 3, 2023) (Proposed Rule). We appreciate CMS' commitment to ensuring Medicaid beneficiaries are able to access health care services through the managed care delivery system. Medicaid managed care is the predominate delivery system under the Medicaid program, and it is essential for Medicaid beneficiaries to access covered services.

CMS acknowledges that Medicaid rates, including managed care plan payment rates, impact provider participation and patient care. Medicaid rates are generally lower than Medicare and commercial rates for the same service. As CMS recognizes, low payment rates can impact providers' participation in the program, which in turn can have adverse impacts on network adequacy. Low rates also adversely impact the capacity of providers, including FAH members, who do participate in Medicaid. Most importantly, ensuring adequate reimbursement rates is crucial to ensuring enrollees have equitable access to high quality health care.

The FAH is generally supportive of CMS' proposals addressing inequitable access, and quality and financing of Medicaid managed care services, with an eye toward reducing unnecessary and duplicative reviews and promoting efficiency and flexibility. But, as explained further below, the FAH is concerned that some proposals are counterproductive to these aims, in particular those that would limit rather than support state flexibility with respect to state-directed payments (SDPs), which are a critical Medicaid financing tool. In the aftermath of the recent preliminary injunction issued by the United States District Court for the Eastern District of Texas in *Texas v. Brooks-LaSure* (Case No. 6:23-cv-161-JDK) the FAH urges CMS to forego its proposals involving the hold harmless prohibition and instead focus on those portions of the Proposed Rule designed to improve enrollees' access to high-quality care.

ACCESS

I.B.1. Access

CMS proposes a number of policy changes that are designed to both improve access to services for Medicaid beneficiaries from managed care plans¹ and to facilitate and improve oversight of that access by states and CMS. These proposals would provide states and CMS more information about plan practices derived from the use of enrollee experience surveys, the establishment of appointment wait time standards for certain routine outpatient services, the use of secret shopper surveys, the submission of plan provider payment analyses, and requirements for state remedy plans for managed care plans that fail to meet access requirements. The FAH generally supports proposals to ensure beneficiary access to care and has long advocated to correct plan practices that result in additional barriers to care for patients, including through the use of certain utilization management practices, narrow provider networks, and inadequate payments to providers for the services they furnish. We believe that the proposals to expand oversight of and transparency around the practices of Medicaid managed care plans are of critical importance, and that CMS should require plans to make critical information available and easily accessible to enrollees, providers, and the public.

All states are required to operate monitoring systems for their managed care programs furnishing services to their Medicaid enrollee populations, including regular reports to CMS on these plans. CMS proposes to add enrollee experience surveys to the list of required elements in state monitoring systems for all managed care programs. The FAH supports this proposal as a common-sense way to provide states and the agency greater insights into the actual experience

¹ "Managed care plan" refers to Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs).

beneficiaries face when trying to access care that is covered under the managed care plans in which they enroll. However, we urge the agency to expand this proposal to also require provider experience surveys for both practitioners and facilities in order to afford states and CMS essential insights into the operation of plans. Needless barriers to care have been imposed by Medicaid managed care plans in the past that are not readily apparent to those entities tasked with oversight of those plans. These practices include certain utilization management tools, which often are needless administrative requirements that delay access to care. Providers should be given a regular forum to provide meaningful feedback to states and the public about these plan practices and to describe the time and resources expended to overcoming these barriers to assist their patients in gaining access to needed care in a timely manner. This type of input would build on the type of information CMS seeks to provide in its proposals for establishing wait time standards for routine appointments for certain outpatient care and analyses of provider payment rates, which would provide for more meaningful assessments of plan behaviors that negatively impact access to timely care.

CMS proposes to establish appointment wait time standards for managed care plans for routine appointments for providers of the following types of services: adult and pediatric outpatient mental health and substance use disorder (SUD) services, adult and pediatric primary care, OB/GYN services, and any other type of service the state specifies. The FAH supports this proposal. Maximum appointment wait time standards of 10 or 15 business days for these services will facilitate access to these needed services. **The FAH encourages the agency to finalize its proposal to establish a strict minimum federal standard of a 90 percent appointment availability rate for plan compliance with the standards**. This new standard would be a useful metric to help assess where issues of network adequacy arise and help reduce delays in access to routine care. As noted above, provider experience surveys would augment this information, which in turn would further a state's ability to determine where other barriers to access may occur. The FAH believes these two policy changes would improve the state's ability to make meaningful assessments of beneficiary access to care from their managed care plans and facilitate CMS' oversight efforts.

CMS proposes to require states to contract with independent entities to conduct secret shopper surveys of the electronic provider directory and the appointment wait times of each Medicaid managed care plan for the provider types described above to determine compliance with regulatory requirements. The FAH believes the use of these surveys can be effective in determining actual compliance with standards imposed by states on managed care plans. We agree with the agency about the importance of using independent entities to carry out these activities. The FAH urges CMS to encourage states to take necessary steps to ensure the accuracy of the information describing all network providers and facilities in plan electronic directories, which should include frequent updates of that information.

CMS proposes to require plans to submit to states provider payment analyses for primary care services, OB/GYN services, mental health services, SUD services, homemaker services, home health aide services, and personal care services. Under the proposal, states would have to analyze the payment data to determine if plan payment rates impact access to care as part of the network adequacy determinations and assure adequate in-network provider capacity. CMS also proposes to mandate that states include information on secret shopper surveys and provider

payment analyses in their reports to CMS that verify plan compliance with regulatory requirements for network adequacy and availability of services. The FAH supports these proposals, but we urge the agency to expand this proposal to include payment rates for hospitals, post-acute care providers (PAC) and other facilities. This additional data would enable CMS to annually review not only a state's payment rates for managed care plans but also provider reimbursement analyses and monitoring surveys. This would be an essential tool for agency oversight of a managed care plan's payment rates and associated network adequacy issues that adversely impact enrollees' access to care. Under the proposal, CMS would more carefully scrutinize rates if a state's rate reductions for any service might significantly diminish access, for example setting rates below 80 percent of comparable Medicare rates. The agency would also retain the authority to withhold federal payments for noncompliance. The FAH encourages CMS to finalize its proposal for provider payment analyses; to include hospitals, PAC providers and other facilities in the scope of the finalized proposal; and to consider a higher threshold than 80 percent of Medicare rates to trigger greater scrutiny and oversight of a plan's payments to providers.

Finally, CMS proposes to require state remedy plans for those managed care plans that fail to meet access requirements, including those described above. Remedy plans would be developed by the state and submitted to CMS; they would identify specific steps to correct failures to meet standards and requirements and deadlines for those steps. Remedial action could include increasing provider payment rates; expanding use of telehealth; reducing barriers to provider credentialing and contracting; improving timeliness and accuracy of claims processing and utilization management tools such as prior authorization procedures; and improving outreach and problem resolution to providers. States would have to submit quarterly updates to CMS describing the progress of the implementation of the remedy plan. However, the proposal is silent on the issue of whether providers or beneficiaries may provide input to the state in developing the state remedy plan. The proposed rule is also silent on whether these stakeholders could include their feedback in the quarterly reports that states would have to make to CMS on the progress of the remedy plan in addressing the access failures. The FAH supports specific regulatory requirements for states and managed care plans to correct failures of those plans to meet access and network capacity standards and associated requirements. However, we strongly encourage CMS to ensure that the perspectives of providers and patients are considered when a state assesses which of the various potential remedial actions to include in its remedy plan, as well as including feedback by these stakeholders in any state reports on the progress of the remedy plan to meet the goals of correcting access failures.

STATE DIRECTED PAYMENTS

<u>Part I.B.2.c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), § 438.6(c)(2)(i), and § 438.6(c)(5)(iii)(A)(5))</u>

The FAH supports CMS' proposed waiver of the prior written approval requirement for SDPs that adopt a minimum fee schedule using Medicare approved rates as part of CMS' broader efforts to eliminate unnecessary and duplicative review processes and promote efficient and effective administration of the Medicaid program. As explained in the Proposed Rule, the

Medicare rate development process ensures that an SDP adopting a minimum fee schedule based on total published Medicare payment rates would not increase program integrity risk or create a lack of Federal oversight, and as such, written prior approval of such an SDP would be unnecessary and duplicative.

The FAH, however, recommends that proposed § 438.6(c)(1)(iii)(B) be revised to specify that such a minimum fee schedule must use a total published Medicare payment rate that was in effect no more than one year prior to the start of the rating period. The Proposed Rule indicates that a limit of three years would "be consistent with how § 438.5(c)(2) requires use of data that is at least that recent for rate development," but the cited regulation requires the use of the "most appropriate data." The FAH believes that the ready availability of current Medicare payment rate data makes the use of older data (particularly data approaching the proposed three-year limit) unnecessary and inappropriate. In essence, the use of older Medicare payment rates to develop the minimum fee schedule is like an SDP arrangement that is "simply based off of an incomplete total published Medicare payment rate," and such an SDP should be included in the SDPs described in paragraph (c)(1)(iii)(C) instead. In its March 2023 report, MedPAC estimated that "IPPS hospitals' Medicare margin will decrease in 2023 to about *negative* 10 percent . . . and that the median Medicare margin for relatively efficient hospitals will decrease to modestly below break-even." Against this backdrop, an SDP arrangement that uses expired Medicare payment rates to set the minimum fee schedule risks producing provider rates that are insufficient to meet the aims of promoting equitable access to health care services and enhancing quality.

In addition, the FAH recommends permitting the minimum fee schedule to be within 100 to 105 percent of the Medicare payment rate that was in effect no more than one year prior to the start of the rating period in order to provide states with appropriate flexibility to make appropriate projections for the rate period. In the FAH's view, the rationale that supports waiving the prior written approval requirement for an SDP that adopts a minimum fee schedule using Medicare approved rates extends to one adopting a minimum fee schedule that includes a modest projection of Medicare approved rates.

Part I.B.2.d. Non-Network Providers (§ 438.6(c)(1)(iii))

The FAH supports CMS' proposal to remove the term "network" from the descriptions of SDP arrangements for minimum fee schedules and uniform dollar or percentage increases in proposed § 438.6(c)(1)(iii)(A)-(D), but does not support the corresponding change to clause (E) concerning maximum fee schedules. As a general matter, the FAH supports removing barriers to SDPs that are likely to promote access and quality of care for Medicaid managed care enrollees. Here, the FAH shares CMS' concern that the inclusion of the word "network" in the SDP arrangement descriptions for minimum fee schedules and uniform dollar or percentage increases has created an unintended barrier to the goal of ensuring access to quality care for beneficiaries. Proposed clauses (A) through (D) would appropriately

² 88 Fed. Reg. at 28,114.

³ MedPAC, Report to the Congress: Medicare Payment Policy, ch. 3, p. 60 (March 2023), at https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf.

eliminate this barrier, creating additional flexibility for states to address access to care issues through SDPs.

The FAH, however, is concerned about potential unintended consequences related to the corresponding change to the maximum fee schedule description in proposed § 438.6(c)(1)(iii)(E). Although the Proposed Rule provides examples of ways in which an SDP requiring Medicaid managed care plans to pay out-of-network providers a minimum fee schedule could promote access to care, no corresponding justification is offered for establishing a maximum fee schedule for out-of-network providers. In fact, an SDP that is a maximum fee schedule and is made applicable to non-network providers could have an adverse impact on access by limiting the Medicaid managed care plan's ability to arrange for out-of-network services that might be needed by particular enrollees. Therefore, the FAH recommends that proposed § 438.6(c)(1)(iii)(E) be revised to limit the provision to network providers.

In addition to finalizing the proposed revisions to § 438.6(c)(1)(iii)(A) through (D), the FAH also urges CMS to consider revising § 438.6(d)(6) to remove the limitation to "network providers." This change would enable a state transitioning services and populations from a feefor-service delivery system to a managed care system to require pass-through payments to *network and non-network* providers that are hospitals, nursing facilities, or physicians during the transition period. Although the proposed rule concludes that it is not appropriate or necessary to eliminate the word "network" from § 438.6(d), it does not separately assess the propriety of removing this network limitation from § 438.6(d)(6) while leaving it in place for existing pass-through payments that are phasing down or have phased out. States that are transitioning services and populations to a managed care system for the first time require a greater degree of flexibility in order to promote access and quality during this transition (as acknowledged with the adoption of § 438.6(d)(6)), and the FAH supports further extending this flexibility to permit transitional pass-through payments to non-network providers.

Part I.B.2.f. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for certain SDPs and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I) and (c)(2)(iii))

The FAH supports CMS' conclusion that the Medicaid fee for service upper payment limit (UPL) is not applicable to or appropriate for SDPs and the Medicaid managed care context and it adoption in 2018 of the average commercial rate (ACR) as "the standard benchmark for all SDPs." The FAH likewise strongly supports CMS' proposed continued use of the ACR for this purpose, but opposes finalization of the proposed additional requirements around documentation of the ACR for each SDP arrangement as unnecessarily burdensome on States and providers, particularly in the absence of any indication that CMS' existing process fails to meet CMS' goals. Moreover, the FAH does not believe that a limit on total payment rates to providers is a component of actuarial soundness or within CMS' statutory authority. To the extent that CMS finalizes a total payment rate, the FAH strongly opposes the use of any limit less than the ACR because a lower limit would fail to provide States with the flexibility necessary to ensure that Medicaid managed care enrollees have access to care that is comparable to the broader public.

⁴ 88 Fed. Reg. at 28,121.

Proposed § 438.6(c)(2)(ii)(I), which would ensure that the "total payment rate" to *providers* for each service and provider class included in an SDP is "reasonable, appropriate and attainable," is not supported by the Medicaid Act. Nor does the Act support proposed § 438.6(c)(2)(iii), which would limit the total payment rate for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center average commercial rate (ACR).

The Act does not contemplate the imposition of Federal limits on provider payments under the Medicaid managed care delivery system. Under the Medicaid FFS delivery system, section 1902(a)(30)(A) of the Act requires that payment to <u>providers</u> for care and services under an approved state plan be consistent with efficiency, economy, and quality of care. To ensure that provider payments were consistent with the statutory goals of economy and efficiency, CMS established an upper limit on aggregate FFS payments for certain types of services or providers.⁵

Provider payments under the Medicaid managed care delivery system are not subject to similar requirements. Rather, the actuarial soundness requirement in section 1903(m)(2)(A)(iii) of the Act speaks only to the prepaid (capitation) payments made under the contract between *the state and the Medicaid managed care plan*. This provision specifies that services must be provided "in accordance with a contract between the State and the [Medicaid managed care organization (MCO)] under which prepaid payments to the entity are made on an actuarially sound basis." As CMS explained in the 2016 final rule:

The underlying concept of managed care and actuarial soundness is that the state is transferring the risk of providing services to the MCO and is paying the MCO an amount that is reasonable, appropriate, and attainable compared to the costs associated with providing the services in a free market.⁶

Similarly, the actuarial soundness requirements in § 438.4(a) provide that capitation rates must be projected to "provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract" between the state and the plan and be developed in accordance with § 438.4(b).

In short, the requirement for payments to be "actuarially sound" and "reasonable, appropriate and attainable," applies to the capitation payments made by states to plans, not by plans to providers. There simply is no requirement that the payments made by the plans to providers must be actuarially sound (*i.e.*, "reasonable, appropriate and attainable"), and such an interpretation would be inconsistent with CMS' past interpretation of the actuarial soundness requirement. Moreover, actuarial soundness requirements are common in the regulation of managed care plans and insurers, and such requirements are not interpreted by regulators as inviting the imposition of maximum payment rates to providers.

⁵ See 42 C.F.R. §§ 447.272 and 447.321.

⁶ 81 Fed. Reg. 27,497, 27,588 (May 6, 2016).

Moreover, it is unnecessary to codify a limit on provider payments by Medicaid managed care plans. The Proposed Rule does not indicate that CMS' current processes are inadequate such that a regulatory cap on total provider payments is necessary. By their very nature, capitation payments incentivize Medicaid managed care plans to simultaneously manage the care of their enrollees, while also allocating resources efficiently to provide covered benefits to enrollees. No more is required. Rather, the imposition of a payment limit on Medicaid managed care payments to providers could potentially limit the ability to address disparate health outcomes, or otherwise impede innovative payment arrangements designed to improve health outcomes for vulnerable populations. Finally, existing and other proposed standards for SDPs are sufficient to ensure that SDPs are properly aligned with programmatic goals (*e.g.*, uniform increases must be based on the utilization and delivery of services under existing § 438.6(c)(2)(ii)(A) and proposed (c)(2)(vii)) while offering appropriate flexibility for states to address access and quality goals in the program. As such, the imposition of a regulatory limit on total payments rates is unnecessary.

The ACR Benchmark for Total Payments

Despite the FAH's concerns with the necessity or appropriateness of monitoring total provider payments by Medicaid managed care plans, the FAH appreciates and supports CMS' current interpretation that the ACR represents the appropriate "standard benchmark for all SDPs," and proposal to maintain the ACR as the benchmark. The ACR represents an appropriate benchmark that is "generally consistent with the need for managed care plans to compete with commercial plans for providers to participate in their networks to furnished comparable access to care." In addition, the demographics of Medicaid managed care enrollees are similar to commercial plan members, such that the ACR is largely reflective of a similar service mix. Ultimately, an ACR benchmark is consistent with the obligations of Medicaid managed care plans and the needs of their enrollees and provides the states with critical flexibility to further state policy objectives through implementation of SDPs.

The FAH strongly opposes the alternative total payment rate limits set forth in the Proposed Rule, each of which would adopt a total payment limit of less than the ACR. In particular, the Medicare rate is not an appropriate payment rate limit for managed care payments when Medicaid managed care plans compete with commercial payers for participating providers and Medicaid managed care enrollees are demographically more similar in terms of demographics, disability and health care needs to commercial plan members than to Medicare beneficiaries. It would be particularly inappropriate to explore total payment rate limits (to the extent any are finalized) that are less than the ACR when Medicaid managed care has historically been marked by network adequacy issues attributable to low provider payment rates. Placing downward pressure on the total payment rates and restraining states' flexibility to use SDPs to

⁷ 88 Fed. Reg. at 28,121.

⁸ *Id.* As noted in the Proposed Rule, there are exceptions to this observation, particularly in the context of service categories where Medicaid is the most common or only payer and access concerns have been raised in the commercial market (*e.g.*, home and community-based services, among others). *Id.* at 28,122. For such service lines, an ACR benchmark would be inadequate to support access to care for Medicaid managed care enrollees.

meet program goals would ultimately be counterproductive to critical efforts to improve access and equity in Medicaid managed care programs.

The FAH is also concerned by the alternative proposal to set a total payment rate limit for SDP arrangements described in paragraphs (c)(1)(i) and (ii) at the ACR but use a lower total payment rate limit for SDP arrangements described in (c)(1)(iii). It is inappropriate to disfavor uniform increases and minimum and maximum fee schedule SDPs in this manner. Many states have adopted SDPs under paragraph (c)(1)(iii) in alignment with appropriate programmatic goals, and such a disfavored status for these SDPs would limit state flexibility and undermine the significant efforts states have made to shift to SDPs with the phase out of pass-through payments. In addition, such a policy would be counterproductive insofar as it could disincentivize the adoption of a new SDP under paragraph (c)(1)(i) or (ii). For example, if a state currently uses a uniform increase SDP, it appears that this alternative proposal would prevent the state from adding a value-based purchasing SDP (for example) that brings the total payment rate up to the ACR for the same class of providers because the value-based purchasing SDP would be considered when reviewing the total payment limit for the uniform increase SDP.

In the end, there does not appear to be a basis for CMS' concern that limiting the total payment rate by the ACR would incent states and interested parties to increase payment rates in ways that fail to promote the goals of advancing meaningful and equitable access to care and quality of care in Medicaid managed care programs. CMS currently uses the ACR as a benchmark for total payment rates, and this policy has not created the incentives described; rather, there continues to be an ongoing need to support more robust total payment rates so that quality and access goals can be advanced. Reducing states' flexibility with respect to SDPs in such a manner would be counterproductive to promoting innovative SDPs (including value-based payment and delivery system reform SDPs) and the pursuit of the core aims of equitable access and quality.

Implementation of the ACR

The Proposed Rule would adopt significant changes to CMS' current process for using the ACR as a benchmark for total payment rates for SDP reviews involving inpatient hospital services, outpatient hospital services, nursing facility services, and the services of qualified practitioners at an academic medical center. The Proposed Rule describes an existing process whereby CMS works with States to collect documentation to compare the total payment rate to the ACR benchmark when necessary and appropriate to CMS' review. This flexible process allows for the minimization of burdens on states as well as providers where there is little risk that the total payment rate would exceed the ACR. Overall, burden reduction should be a key priority, both with respect to the burdens on states seeking approval for an SDP and with respect to the burdens on providers that might be called on to supply data for purposes of the determination of the ACR. And here, the Proposed Rule does not provide any indication that shifting toward a more burdensome process is justified based on CMS experience with SDP applications or otherwise.

The FAH is also concerned that the specific and restrictive ACR data requirements in proposed § 438.6(c)(2)(iii)(A) do not provide adequate flexibility for States to use data that are

nonetheless sufficient to establish that the total payment rate does not exceed the ACR. As CMS notes, some State Medicaid agencies may have ready access to commercial payment data (*e.g.*, through an all-payer claims database) such that data to approximate the ACR is readily available and consistent with the proposed ACR demonstration requirements. But, in other states, this may not be true, and the simplest approach may involve data that does not meet the requirements in proposed § 438.6(c)(iii) (*e.g.*, the data includes data from certain non-commercial payers and is more than three years old, such that it understates the actual ACR) but nonetheless provides a sufficient assurance that the total payment rate does not exceed the ACR benchmark. Alternatively, a State (or its consultant) might look to use data on contracted rates rather than historical payment data to approximate the ACR in light of price transparency initiatives that make this data available. In each of these cases, the resulted ACR may be understated but sufficient to meet CMS' needs while minimizing burdens.⁹

The Proposed Rule notes the range of data sources and processes that have historically been used by states to demonstrate satisfaction of the ACR benchmark (including ACR analyses provided by actuaries or outside consultants or data in private commercial databases) and indicates that "each of these approaches, provided the data used for the analyses meet the proposed requirements in § 438.6(c)(2)(iii), would be acceptable to meet our proposed requirements." But the Proposed Rule does not include any assessment of the extent to which these approaches use data that meet the proposed requirements, raising concerns that the Proposed Rule would actually require significant changes to the data used by states to approximate the ACR and that such changes would not materially advance any cognizable goal. In short, states should have the flexibility to calculate an understated ACR using data that does not meet the proposed criteria if that is all that is required to confirm that the total payment rate does not exceed the ACR benchmark and provided that the ACR is not used for any purpose beyond the comparative evaluation of the total payment rate.

The FAH also believes that states need the flexibility to address particular issues involving regional and other variation in the ACR. The FAH appreciates CMS' confirmation that, under proposed § 438.6(c)(2)(iii)(A), a state could demonstrate the ACR either at the service level or at the service and provider class level, allowing states flexibility to determine whether it is appropriate to differentiate the ACR data based on provider class. As noted in the Proposed Rule, the flexibility to demonstrate the ACR only at the service level may be important to address the needs of rural hospitals because demonstration of the ACR at the service and provider class level may "result in a lower ceiling than if the State were to broaden the category to include hospitals with a higher commercial payer mix." This flexibility may be critical to address access gaps among underserved and vulnerable rural populations. On the other hand,

⁹ Because the calculation of the ACR should be designed only to provide any necessary assurances that the total payment rate does not exceed the ACR, the FAH notes that the ACR calculated by a state is likely to *understate* prevailing commercial rates and should not be used for any purpose beyond confirmation that the total payment rate does not exceed the ACR.

¹⁰ 88 Fed. Reg. at 28,126.

¹¹ *Id*.

¹² *Id.* at 28,125.

there may be instances where demonstration of the ACR at the service and provider class level is more appropriate to capture the actual market conditions and in recognition of the need for Medicaid managed care plans to compete with commercial plans for providers to participate in their networks. The FAH recommends that CMS consider revising § 438.6(c)(2)(iii)(A)(3) to add "and may be specific to the provider class addressed by the State directed payment." In addition, CMS may consider further refining the text of § 438.6(c)(2)(iii)(B)(2) consistent with the preamble to note that the total payment rate is specific to each provider class, but the ACR against which the total payment rate is compared need not be specific to the provider class.

In sum, the FAH supports CMS' practice of approving SDPs that produce total payment rates up to the ACR, but does not believe that a limit on total payment rates is necessary for any service (including for inpatient and outpatient hospital services) or that the regulation of the actuarial soundness of capitated payments to Medicaid managed care plans authorizes the regulation of total provider payments. To the extent that a limit on total payment rates is finalized notwithstanding these issues, the FAH opposes the use of any limit benchmarked to a rate less than the ACR as counterproductive to assuring equitable access and quality for enrollees and the FAH opposes the use of specific ACR data requirements that preclude states from efficiently demonstrating with readily available data that total payment rates do not exceed the ACR.

Expenditure Limit for SDPs

CMS also requests comment on whether there should be a limit on total SDP expenditures as a percentage of total costs, which could or could not be focused on inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. The Proposed Rule does not present a specific proposal or provide a regulatory impact analysis for any such expenditure limit, making it difficult for stakeholders to provide meaningful feedback. CMS does suggest that an SDP expenditure limit could be 10 to 25 percent of total costs, but notes that the percentage of Medicaid managed care spending currently paid through SDPs is as high as 58 percent in some states. The FAH has significant concerns that an expenditure limit for SDPs would inappropriately limit states' flexibility to appropriately design their Medicaid managed care programs and to promote quality and access. SDPs are an important financing and payment mechanism in many states, and state Medicaid managed care financing can be extremely complicated and varied. The FAH therefore believes that there is an unacceptable level of risk of unforeseen and adverse consequences for Medicaid managed care enrollees if an expenditure limit for SDPs were imposed and we oppose CMS setting an artificial limit.

Part I.B.2.g Financing (§ 438.6(c)(2)(ii)(G) and (H)) and Provider Attestation

The FAH strongly opposes proposed § 438.6(c)(2)(ii)(H), which would require each provider receiving payment under an SDP to attest that it does not participate in any hold harmless arrangement, and the FAH strongly urges CMS to abandon its renewed efforts to reformulate the prohibition on hold harmless arrangements to reach so called "redistribution"

¹³ *Id.* at 28,227.

arrangements" that are purely between private parties and do not involve direct or indirect State action or guarantees. The prohibition on private redistribution arrangements articulated in the preamble to the Proposed Rule follows on the path set forth in CMS' recently enjoined February 17, 2023 informational bulletin on hold harmless arrangements (2023 Bulletin), ¹⁴ and it conflicts with the clear statutory definition of a hold harmless provision under section 1903(w)(4) of the Act. As recently explained by the United States District Court for the Eastern District of Texas, an impermissible hold harmless arrangement under section 1903(w)(4) of the Act "requires that the *state*, not a private party, provide the 'payment' that 'guarantees' to hold taxpayers harmless." Private providers are not "[t]he State or other unit of government imposing the tax" and wholly private arrangements among providers do not implicate the hold harmless prohibition in section 1903(w)(4).

Based on the clarity of the statutory language alone, the FAH believes that CMS is without legal authority to treat private redistribution arrangements as prohibited hold harmless arrangements. Moreover, the FAH strongly opposes the use of preambular language and informational bulletins rather than notice-and-comment rulemaking to announce this substantive transformation and expansion of the hold harmless prohibition. Finally, the FAH strongly urges CMS to not finalize proposed § 438.6(c)(2)(ii)(H) because it would improperly shift the state's compliance burden to health care providers, create unnecessary and untenable legal risks for these providers, and create uncertainty around critical source of non-federal share financing.

Overall, the FAH believes many portions of the Proposed Rule contain critical proposals that will improve equitable access to high quality care for Medicaid beneficiaries or otherwise make important changes to the financing and reimbursement structures which support such efforts. The FAH supports finalizing a number of other portions of the Proposed Rule in an expeditious manner. Conversely, the proposed changes to § 438.6(c)(2)(ii)(H), and the preambular language related thereto, cannot be finalized at this time. Because the recent court order in *State of Texas v. Chiquita Brooks-LaSure et al.* preliminarily enjoins CMS from implementing or enforcing an interpretation expanding the hold harmless prohibition to reach purely private redistribution arrangements, the FAH believes that CMS cannot presently finalize the preambular language relating to hold harmless arrangements or the proposed changes to 42 C.F.R. § 438.6(c)(2)(ii)(G) and (H) at this time, and urges CMS to abandon these proposals, whether or not it pursues further litigation on these issues, so that other elements of the Proposed Rule may be finalized.

¹⁴ CMCS Informational Bulletin, Health Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments (Feb. 17, 2023), *at* https://www.medicaid.gov/federal-policy-guidance/downloads/cib021723.pdf.

¹⁵ Texas v. Brooks-LaSure et al., Case No. 6:23-cv-161-JDK, slip op. at 24-25, 2023 WL 4304749, at *11 (E.D. Tex. June 30, 2023) (order granting State of Texas's preliminary injunction).

Shifting Liability to Providers

Under proposed § 438.6(c)(2)(ii)(H), CMS would require states (or plans on the state's behalf) to obtain from each SDP-participating provider, an attestation that the provider does not participate in a hold-harmless arrangement with respect to any health care-related tax. As a threshold issue, the FAH opposes unnecessary provider attestations because of the burden they create for providers. In addition, we note that the proposed attestation would be highly anomalous within the Medicaid program. At present, the only provider attestation under Federal Medicaid regulations pertains to an attestation of a specialty designation under 42 C.F.R. § 447.400(a). Among Medicaid managed care plans, only two attestations are required by Medicaid regulations, and both exclusively focus on the validity of data submissions. Under § 438.606(b), such an entity must attest "based on best information, knowledge, and belief" that certain data, documentation, and information (e.g., encounter data) is accurate, complete, and truthful. Similarly, plans must attest to the accuracy of the calculation of the medical loss ratio (MLR) under § 438.8(n). These attestations focus on the accuracy of data and specific factual representations, but do not necessitate the attesting party to make a legal judgment concerning the scope of a legal prohibition. In contrast, the proposed hold harmless attestation would require providers to evaluate the facts and apply them to legal definitions of hold harmless arrangements—an exercise that is particularly inappropriate and burdensome in the midst of ongoing legal disputes concerning the bounds of the hold harmless prohibition.

Proposed § 438.6(c)(2)(ii)(H) is also unnecessary and jeopardizes access and quality for Medicaid managed care enrollees by risking reduced provider participation in the Medicaid program and undermining Medicaid financing and reimbursement. These risks are made exponentially greater by the preamble to the Proposed Rule, which indicates CMS' view that purely private arrangements—involving no direct or indirect State action—would violate the hold harmless provision in section 1903(w)(4) of the Act. Although preambulatory text is not in itself authoritative, the FAH is gravely concerned that proposed § 438.6(c)(2)(ii)(G) and (H), coupled with the preambulatory discussion, seek to compel states and providers to accede to CMS' legally erroneous interpretation of the Medicaid Act through an extraordinary attestation requirement. CMS cannot use the proposed attestation process to indirectly impose the expansive hold harmless interpretation set forth in its 2023 Bulletin and rearticulated in the preamble to the Proposed Rule at the same time that CMS is enjoined from implementing or enforcing that interpretation. Such an approach would undermine the judicial process, and as set out in the following section, turns on a flawed and unsupported interpretation of section 1903(w)(4) of the Act.

In sum, health-care related taxes are vital to financing the non-federal share of Medicaid expenditures. Shifting the burden to providers to attest that they are not in violation of the hold harmless provision, particularly given CMS' legally erroneous position regarding that provision, only serves to increase provider risks of legal liability while simultaneously decreasing provider participation not only in health-care related taxes, but in the Medicaid program more broadly. This could in turn have a devastating impact on state Medicaid programs and the beneficiaries they serve, and CMS should not finalize its proposals concerning provider attestations and the hold harmless prohibition.

The Proposed Rule is Another Attempt by CMS to Enforce Purely Private Arrangements

As it has in the past, the FAH opposes CMS' attempts to re-write the hold harmless rules to encompass private arrangements. CMS tried to codify a similar hold harmless prohibition by regulation in a 2019 rulemaking 16, and in 2021 through negotiations over Texas's section 1115 waiver application. 17 Both efforts failed. More recently, the 2023 Bulletin purports to apply the hold harmless prohibition to private arrangements without notice-and-comment rulemaking. The 2023 Bulletin is currently the subject of ongoing litigation before the United States District Court for the Eastern District of Texas in *Texas v. Brooks-LaSure*, and on June 30, 2023, the court issued a preliminary injunction enjoining CMS from "implementing or enforcing" the 2023 Bulletin "or from otherwise enforcing an interpretation of the scope" of the hold harmless prohibition found therein. Against this backdrop, the Proposed Rule is yet another attempt at prohibiting private agreements under the hold harmless provision despite the absence of any direct or indirect *State or governmental* payment, offset, or waiver that guarantees to hold taxpayer harmless. Similar to past attempts, CMS' current efforts are neither supported by the Medicaid Act nor its implementing regulation § 433.68(f)(3) (which CMS does not propose to amend). The FAH therefore strongly opposes such efforts.

In 2019, CMS proposed to stretch the definition of hold harmless agreements to cover private arrangements. In the proposed rule, CMS explained that it had "become aware of [an] impermissible arrangement" whereby revenue from a health-care related tax was used to "fund the non-federal share of the Medicaid payments back to the taxpayers." Notably, in the proposed rule, CMS took the position that an arrangement would violate the law even if "a private entity makes the redistribution" to another private entity. 19 CMS reasoned that a purely private arrangement still constitutes an "indirect" payment from the state or unit of government, which holds the private party harmless for the cost of the tax. 20 That is because "[t]he taxpayers have a reasonable expectation to be held harmless for all or a portion of their tax amount." CMS proposed to amend 42 C.F.R. § 433.68(f)(3) to specify that CMS would consider the "net effect" of a particular arrangement—*i.e.*, whether the "net effect" is a "reasonable expectation" by the taxpayer that it will recoup all or a portion of its tax payment through Medicaid

¹⁶ Medicaid Program; Medicaid Fiscal Accountability Regulation (MFAR), 84 Fed. Reg. 63,722, 63,730 (Nov. 18, 2019).

¹⁷ Disputes regarding the applicability of the hold harmless prohibition on private arrangements contributed to delays in agency action on Texas's proposed SDPs, and the Eastern District of Texas ultimately ordered the Secretary to issue a final decision on the proposed SDPs within 14 days. *Texas v. Brooks-LaSure*, Case No. 6:21-CV-00191 (E.D. Tex., Mar. 11, 2022). Thereafter, the SDPs were approved.

¹⁸ 84 Fed. Reg. at 63,734

¹⁹ *Id.* at 63,735

 $^{^{20}}$ *Id*

²¹ *Id.* at 63,734

payments—to determine whether a hold harmless arrangement exists. ²² The 2019 proposed rule was met with vociferous opposition. After receiving more than 10,000 comments, including the FAH's comments opposing the proposed amendment to § 433.68(f)(3) as in excess of statutory authority and jeopardizing the stability of the Medicaid program, CMS ultimately withdrew its proposed rule. ²³ The FAH strongly opposed CMS' attempts to expressly expand the regulatory definition of prohibited hold harmless arrangements in 2019, and we likewise oppose the attempt to adopt a similarly expansive and unfounded definition through preambular language and provider attestation requirements.

More recently, CMS' 2023 Bulletin advanced a similar view—characterized as a longstanding agency position—concluding that a hold harmless arrangement may exist without any State or governmental involvement in the arrangement. ²⁴ In the 2023 Bulletin, CMS described how, in its view, "taxpayers appear to have entered into oral or written agreements" to redirect or redistribute their Medicaid payments "to ensure that all taxpayers receive all or a portion of their tax back." The 2023 Bulletin concludes that these agreements between private providers violate section 1903(w)(4)(C)(i) of the Act and 42 C.F.R. § 433.68(f)(3). Although CMS acknowledged the absence of state participation in such agreements, CMS concluded they were impermissible because "[t]he redistributions occur so that taxpaying providers are held harmless for all or a portion of the health care-related tax." Accordingly, CMS promised in the 2023 Bulletin to "reduce" a State's medical expenditures by the amount of health care-related tax collections that include these arrangements. ²⁷

In advancing this expansive and unsupported view, the 2023 Bulletin invoked the "reasonable expectation" test from the 2008 final rule. But, as was recently confirmed by the Eastern District of Texas, that test as articulated in the 2008 final rule focuses on the *state's reasonable expectation* rather than any expectation the provider may develop as a result of private arrangements.²⁸ In the preamble to the 2008 final rule, CMS describes the prohibition as reaching a "state payment [that] is made to a taxpayer or a party related to the taxpayer . . . in the reasonable expectation that the payment would result in the provider being held harmless." This clearly refers to the state's reasonable expectation, and the 2023 Bulletin (like the Proposed Rule) provides no explanation as to how a state could have a reasonable expectation of any

²² *Id.* at 63,735

²³ 86 Fed. Reg. 5105 (January 19, 2021).

²⁴ CMCS Informational Bulletin, Health Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments (Feb. 17, 2023), *at* https://www.medicaid.gov/federal-policy-guidance/downloads/cib021723.pdf.

²⁵ *Id.* at 3

²⁶ *Id*.

²⁷ *Id.* at 5.

²⁸ Texas v. Brooks-LaSure, slip op. at 25, 2023 WL 4304749, at *11 (citing 73 Fed. Reg. at 9,686).

²⁹ 73 Fed. Reg. at 9694.

provider being held harmless when the state is not itself holding providers harmless or itself making payments engineered to indirectly hold providers harmless (*e.g.*, grants to third parties designed to pay increased provider fees). The *Texas v. Brooks-LaSure* Court also properly rejected CMS' characterization of its 2023 Bulletin as representing the agency's "longstanding" interpretation, noting that until now "CMS has maintained an equivocal stance on these agreements." ³⁰

As previously noted, the 2023 Bulletin is the subject of a preliminary injunction preventing CMS from enforcing or relying upon the 2023 Bulletin while the injunction remains in place. The Court found that the 2023 Bulletin "will likely be set aside" because it "conflicts with the statutory definition of 'hold harmless provision" found in section 1903(w)(4)(C)(i) of the Act. Simply put, the Court determined that the hold harmless provision in section 1903(w)(4)(C)(i) of the Act "requires that the *state*, not a private party, provide the 'payment' that 'guarantees' to hold taxpayers harmless."

Because the Proposed Rule, like the 2023 Bulletin, attempts to extend the hold harmless provision at section 1903(w)(4)(C)(i) of the Act to purely private arrangements, CMS is currently enjoined from finalizing its proposal. Moreover, the imposition of a requirement that a provider attests to compliance with the hold harmless prohibition while the scope of that prohibition is highly disputed—let alone the subject of a preliminary injunction—would expose providers to significant uncertainty and risk to the detriment critical funding sources for many states' Medicaid programs.

The Medicaid Act Does Not Provide Authority for CMS to Impose a Private Payment Limitation Under the Auspices of the Hold Harmless Prohibition

The FAH agrees with the Eastern District of Texas's determination that the hold harmless prohibition in section 1903(w)(3) of the Act does not encompass private arrangements between private parties. CMS' interpretation of the hold harmless provision in the preamble of the Proposed Rule is simply incompatible with the text of the Act.

In 1991, Congress enacted the Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991, which, among other things, added section 1903(w) of the Act. Under section 1903(w), the proceeds of health care-related taxes are deducted from a state's Medicaid expenditures for purposes of determining FFP if they are not broad-based, and uniform, or if there is in effect a hold harmless arrangement.³³ In relevant part, there is a hold harmless arrangement when "[t]he State or other unit of *government* imposing the tax *provides* (directly or indirectly) for any payment, offset, or waiver *that guarantees* to hold taxpayers harmless for any

³⁰ Texas v. Brooks-LaSure, slip op. at 13-14, 2023 WL 4304749, at *7.

³¹ *Id.* at 25, 2023 WL 4304749, at *11.

³² *Id.* at 25, 2023 WL 4304749, at *11 (*quoting* section 1903(w)(4)(C)(i) of the Act).

³³ 42 U.S.C. 1396b(w)(1)(A)(iii) disallows the use of revenues from a broad-based health care related tax is there is in effect a hold harmless arrangement under paragraph (w)(4).

portion of the costs of the tax."³⁴ As explained by the *Texas v. Brooks-LaSure* Court, "the statute includes a 'tight grammatical link between *the government*, as the actor proving for something, and a *guarantee*, as the thing provided for."³⁵ Nothing in the plain language of the statute prohibits redistributive arrangements between private parties. Rather, the defining characteristic of a hold harmless arrangement is a guarantee by the *government*—not a private party—to the taxpayer.

Here, Congress chose to consider only the direct or indirect activity of the state (or unit of government imposing the tax) when prohibiting hold harmless arrangements. Moreover, without involvement by the state, private agreements cannot constitute a "guarantee[] to hold taxpayers harmless." ³⁶ A guarantee denotes an obligation by the guarantor. But as a non-party to any agreement that may or may not exist, the state assumes no obligation regarding any reimbursements by private providers and, in the words of the preamble to the 2008 final rule, would not have any "reasonable expectation" that its payment would result in a provider being held harmless. And in the words of the *Texas v. Brooks-LaSure* Court, it would be improper to disallow funds "where a state provides no 'guarantee[]' at all." ³⁷

In sum, neither the Medicaid Act nor its implementing regulations provides a basis for CMS to prohibit private arrangements of the kind described in the preamble. Rather, a defining characteristic of a prohibited hold harmless agreement is and always has been activity by the state designed to directly or indirectly hold a provider harmless. Indeed, this was the central finding by the *Texas v. Brooks-LaSure* Courtin granting the State of Texas's preliminary injunction. For the foregoing reasons, the FAH urges CMS to abandon proposed § 438.6(c)(2)(ii)(G) and (H) and forgo further efforts to recraft the Medicaid Act and implementing regulations as prohibiting certain purely private arrangements. Moreover, the FAH vehemently opposes the imposition of any requirement that a provider attests to compliance with a hotly disputed requirement that is the subject of a preliminary injunction and ongoing litigation.

Part I.B.2.j. Quality and Evaluation (\S 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7))

³⁴ 42 U.S.C. 1396b(w)(4)(C) (emphasis added); *see also* 42 C.F.R. § 433.68(f)(3) (stating that a hold harmless arrangement exists where the "*State* (or other unit of government) imposing the tax *provides for any direct or indirect payment*, offset, or waiver such that the provision of that payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount") (emphasis added). Subparagraphs (A) and (B) are not relevant here. They describe hold harmless arrangements involving payments not made under Title XIX and payments that vary based only upon the amount of the total tax paid, respectively. 42 U.S.C. 1396b(w)(4)(C); *see also* 42 C.F.R. § 433.68(f)(1), (2).

³⁵ *Texas v. Brooks-LaSure*, slip op. at 23, 2023 WL 4304749, at *10 (citing *Texas v. Brooks-LaSure*, 2022 WL 741065, at *8 (E.D. Tex. Mar. 11, 2022) (Barker, J.)).

³⁶ 42 U.S.C. 1396b(w)(4)(C).

³⁷ *Texas v. Brooks-LaSure*, slip op. at 23, 2023 WL 4304749, at *10.

Current regulations require that SDPs advance one or more of the goals included in the state's quality strategy, or a delivery system reform effort. In the proposed rule, CMS notes the evaluation plans that states submitted are largely incomplete, leaving a less than clear picture of whether or not the stated goals and objectives of the SPD were met.

While still in their early stages, we believe there are some guiding principles and best practices that should inform CMS policy proposals going forward. More specifically, we urge CMS to encourage states to work directly with hospitals and health systems to understand the quality measurement specific to the hospital setting, the best approach for stratifying and reporting of that data, and the opportunity for hospitals to demonstrate improvement. We share CMS' goals to improve quality of care for Medicaid patients, while limiting the increasing costs to both providers and states of administering these programs.

CMS proposes several changes to the SDP regulations to support quality improvement and evaluation, including adopting requirements for submission of evaluation plans and reports. First, the state must submit an evaluation plan for each SDP, requiring written prior approval from CMS, that includes four specific elements (that is, minimum content requirements):

- 1. On an annual basis, identify at least two quality measures to demonstrate the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the state's managed care quality strategy.
 - The measures must be specific to the SDP and attributable to the performance by the providers for enrollees where the SDP applies, when practicable and relevant.
 - At least one of the selected measures must be a performance measure, as previously described per proposed addition in § 438.6(a)—not, for example, an access measure.
- 2. Baseline performance statistics for all measures to be used in the evaluation.
- 3. Performance targets for all measures to be used in the evaluation demonstrate either maintenance or improvement over the baseline statistics and not a decline relative to baseline. The target for at least one performance measure must demonstrate improvement.
- 4. An assurance by the state committing to provide an evaluation report based on the evaluation plan's foregoing elements and satisfying additional requirements if the final SDP cost percentage exceeds 1.5 percent.

The agency recognizes and shares the concerns that oversight bodies have expressed regarding the extent to which CMS uses evaluation results to inform SDP written prior approval decisions. In response, CMS is proposing a new standard at § 438.6(c)(2)(ii)(F) requiring that all SDPs result in achievement of the stated goals and objectives in alignment with the state's evaluation plan. This would help CMS to better monitor the impact of SDPs on quality and access and would help standardize its review of SDP proposal submissions while allowing the agency to disapprove SDPs that do not meet their stated quality goals and objectives.

Generally, the FAH supports and appreciates the framework and goals outlined by the agency in seeking to incentivize quality improvement efforts through SDP evaluations. The FAH supports value-based payments that are designed to reward providers for both achievement and improvement.

We agree and support CMS' proposal for measures to be applicable to the provider-specific SDP. For example, hospitals should be assessed on hospital inpatient and outpatient care delivered to patients. We appreciate CMS' approach to further align states through a national quality strategy as outlined in the proposed rule, but this population-based strategy focuses on the use of HEDIS measures which are specific to health plan setting and identifies only one measure specific to hospital-level care—a 30-day all-cause readmission measure. While this is an important measure, the size and scope of SDPs currently financed by hospitals require additional valid and reliable hospital-specific measures that are feasible for hospitals to collect and report, and most importantly, reflect the quality of care provided in the inpatient and outpatient settings.

We urge the agency to consider expanding to an additional domain specific to hospital care—that aligns with CMS' broader national quality strategy—and allow states to augment their quality strategies to include measures that fully reflect the care delivered by provider-specific SDPs. For CMS to appropriately evaluate SDPs as outlined in the proposed rule, states must have the ability to select measures applicable to the type of provider. For example, CMS has different reporting programs for acute inpatient and outpatient facilities, inpatient psychiatric hospitals, inpatient rehabilitation facilities and long-term care hospitals that more accurately reflects the nature of the care provided. Each of the Medicare programs includes measures that are valid and feasible to be reported by those providers, and appropriate for accountability, transparency and improvement in each of those settings. Medicaid should align with Medicare hospital measures where appropriate to further focus providers' attention on areas for optimal clinical outcomes and performance improvement, while reducing reporting burden and administrative costs. We do not support the evaluation of SDPs for hospitals based on HEDIS-specific measures.

As mentioned earlier, CMS proposes that the two (or more) measures in the state's written evaluation plan of the SDP's effectiveness must (1) be specific to the SDP and, when practicable and relevant, attributable to the performance of the providers for the managed care enrollees to which the SDP applies, and (2) includes a performance measure (proposed § 438.6(c)(2)(iv)(A)). We have several concerns with these two requirements.

CMS should support reporting of measures in the initial years of a SDP program, allow time for states to establish the data infrastructure necessary for reporting should that infrastructure not be in place, and phase-in new measures before they are moved into a value-based arrangement. This is the approach used in Medicare, where a measure will first be publicly reported in the hospital inpatient quality reporting (HIQR) program prior to its inclusion into the hospital value-based purchasing program (HVBP). This allows for provider experience and understanding of the measure and most importantly allows for the ability to make the necessary changes in care delivery to impact patient outcomes. We urge CMS to withdraw this requirement.

CMS should not limit the measures specified for selection to the Medicaid managed care population to which the SDP applies. If states are to hold providers accountable for improved quality and drive towards value-based payments, then the measures selected must be actionable,

reliable, and feasible for the patient population being measured. Currently, there are no measures specified for hospital data collection and reporting in the inpatient or outpatient setting that are applicable to a Medicaid managed care population or to specific SDPs. The process and outcome measures currently in use are specified for either all payors or Medicare fee-for-service. Many states have taken a measure specified and risk-adjusted for a Medicare population in a particular setting of care and applied the measure and methodology to a narrower Medicaid managed care population. In doing so, the measure is no longer valid, accurate, or feasible for this setting of care. The testing conducted on existing Medicare quality measures was found to be appropriate for use by a Consensus-based Entity through the application of measurement science on each measure for the setting of care in which it is used. Similarly, the risk adjustment methodology appropriate for a patient population 65 and older versus an adult under the age of 65 differs. Depending on how the state applies a Medicare-specific risk adjustment may also lead to unintended consequences such as, variation in reporting from state-to-state on the measure. In addition, it is highly likely that, in many organizations, limiting an all-payer measure to a Medicaid managed care population would not only result in an invalid measure from a reliability standpoint but could also produce an insufficient denominator of patients for measurement. For example, several states are interested in the CDC NHSN standardized infection ratios for several conditions; however, those measures have very small denominators, and it would be inappropriate to base payment adjustments on measures that lack sufficient volumes and render the measure statistically insignificant.

Finally, CMS proposes that measures be selected annually. As noted above, measures selected for value-based SDPs should start with a pay for reporting year(s) before moving to pay based on performance. To see meaningful improvement, those measures should be in place for a minimum of 3 years. Adding and/or changing measures on an annual basis does not allow for adequate evaluation of the baseline and changes over time to affect care transformation and meaningful improvements to be made. Further, it is important to note that even when a measure may be topped out, continued focus and attention will ensure that erosion of the improvements over time are not exhibited. Value-based methodologies that continue to reward performance achievement, as well as improvement should be encouraged and supported by CMS. We also encourage CMS to allow states flexibility to incorporate appropriate SDP-specific measures that reflect all settings of care provided to beneficiaries.

I.B.5.b. Managed Care State Quality Strategies

Currently, states must have a written comprehensive, quality strategy for assessing and improving the quality of health care furnished by Medicaid managed care plans. States are required to review and update their strategy at least once every three years.

To increase transparency and opportunity for ongoing public engagement, CMS proposes to require: (1) states to make their quality strategy available for public comment at the 3-year renewal, regardless of whether there are significant changes, in addition to whenever significant changes are proposed; (2) the state Medicaid agency to post on its website the results of its 3-year review, including its full evaluation of the effectiveness of the quality strategy; and (3) states (prior to finalizing a revised or renewed quality strategy) to submit a copy of the revised strategy to CMS at least every 3 years, following the state Medicaid agency review and

evaluation, in addition to when significant changes are proposed to be made. The FAH supports these recommendations. Further, CMS should continue to encourage states to make changes to their quality strategies to align with the proposed changes for the evaluation of SDPs, as noted above. As new SDP programs are developed, the quality strategy must remain in alignment and reflect the care provided so that the care delivered can be appropriately evaluated.

I.B.6. Medicaid Managed Care (MAC) Quality Rating System (QRS)

CMS proposes a MAC QRS framework with three components: (1) mandatory measures (which states must use in the CMS framework or a CMS-approved alternative framework), (2) a rating methodology (either the CMS-developed methodology or an alternative methodology approved by CMS), and (3) a mandatory website display format. States may implement additional measures without implementing an alternative QRS. Also, CMS proposes a sub-regulatory process for engaging with interested parties before making updates to the components of the MAC QRS framework.

The FAH supports a national framework that standardizes quality measurement requirements that improve the strength of the Medicaid program while reducing provider burden, and promotes optimal outcomes for Medicaid beneficiaries. In addition, we applaud CMS' efforts to put forward a meaningful set of mandatory measures across all states and we appreciate the alignment to a core set of measures that are used in the CMS MSSP program. With that said, we believe this list could be further narrowed to focus on quality improvement efforts and limit provider burden and expanded in meaningful ways over time.

According to the Georgetown University Health Policy Institute for Children and Families, five companies owned 112 of the 281 Medicaid managed care organizations (MCOs) with which states contracted as of September 2020. They include Aetna/CVS Health; Anthem; Centene; Molina; and UnitedHealthcare. Each company had subsidiaries in over 12 different states. And as of the end of 2020, according to parent company data, these MCOs were responsible for the delivery of needed health care services to over 35 million Medicaid beneficiaries. Each company experienced an increase in Medicaid enrollment between December 2019 and December 2020; in total, their Medicaid enrollment grew by 32 percent.

Medicaid managed care plans continue to consolidate and as such, we believe that CMS should recognize this consolidation and significantly limit the state variation in the quality measures used and the rating methodologies developed. While we understand that CMS wishes to allow for some state flexibility, more standardization is needed to achieve our shared goals of improving quality, while also establishing state-level benchmarks and deriving state-by-state comparisons. CMS has responsibility for the lives of 93 million Medicaid beneficiaries and is uniquely positioned to focus on a set of meaningful measures that will further drive quality improvement efforts across the health care system and improve the health and well-being of patients nationwide.

The FAH urges CMS to allow for state flexibility in the measures it uses in its MAC QRS, but limit the variation, in that measures developed de novo by the state would be prohibited. CMS should prescribe a list of limited mandatory measures and then offer a list of

valid, optional measures from which states can choose. The measures should be nationally-recognized and appropriate for value-based payment adjustments, quality improvement, and public reporting. Allowing states to create their own measures when there is a plethora of measures from which to choose, will only confuse providers, create misalignment, and drive up administrative and data collection / reporting costs. In addition, CMS should consider giving states several approved rating methodologies from which to choose. States should not have the authority to invent a rating methodology that is untested and has not been proven to achieve the desired results. We support flexibility and innovation but not when the burden associated with implementation outweighs the perceived benefit. We also support standardization that will lead to apples-to-apples comparisons across states that will allow for the expansion of tested remedies for increased patient outcomes in lagging states.

Moderate

Thank you for the opportunity to comment on the Proposed Rule. If you have any questions, please contact me or a member of my staff at 202-624-1534.