601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
C 202.450.8218
ahip.org

Matthew Eyles
President & Chief Executive Officer

March 7, 2022

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services (CMS)
Attention: CMS-4192-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs ("Proposed Rule")

Dear Administrator Brooks-LaSure:

The Medicare Advantage (MA) and Part D programs are models of consumer choice, competition, and innovation that help deliver high-quality, affordable coverage and care to tens of millions of Americans.[1] As discussed in detail in our recently filed comment letter on the Calendar Year 2023 Advance Notice for MA and Part D, both programs are enormously successful examples of public/private partnerships that enjoy significant bipartisan support. AHIP[2] appreciates the opportunity to comment on the Proposed Rule.

Compared to the Original Medicare program, MA plans care for a more diverse and vulnerable population; provide better care, more comprehensive benefits, and better outcomes; increase financial security; are more cost effective; and earn greater satisfaction rates among seniors.[3] Similarly, the Part D program has been a tremendous success in improving health care and pharmaceutical affordability, access, and value. Despite exorbitant launch prices for new drugs and out-of-control price increases on existing and older medicines, Part D premiums have remained steady due to the efforts of Part D plans to negotiate lower costs using tested and effective cost management and negotiating tools when available.[4]

---

[1] Currently, more than 28 million people choose MA—45% of those eligible for Medicare and more than double the number in MA a decade ago. And there are nearly 50 million enrollees in Part D, with almost 26 million receiving their benefits through MA plans and more than 23 million through stand-alone Prescription Drug Plans.
[2] AHIP is the national association whose members provide coverage for health care and related services to hundreds of millions of Americans every day, including those enrolled in Medicare Advantage (MA), Medicare Part D, Medicaid, and PACE. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.
[3] See https://www.ahip.org/resources/ahip-comment-letter-on-advance-notice-for-medicare-advantage-and-part-d.
[4] See https://www.cms.gov/newsroom/press-releases/cms-releases-2022-premiums-and-cost-sharing-information-medicare-advantage-and-prescription-drug.

Given the success and popularity of MA and Part D, AHIP strongly supports regulatory provisions in the Proposed Rule that would further expand flexibility, choice, competition, and value for consumers. In particular:

- ***Certain D-SNP provisions.*** We appreciate CMS' leadership on enhanced integration of Medicare and Medicaid through dual eligible special needs plans (D-SNPs). As CMS highlighted, research shows the value of integrated products for this population, including studies showing greater use of primary care physicians and home and community-based services, more effective quality improvement, lower inpatient hospital and emergency department use, high beneficiary satisfaction, and better performance than non-integrated plans on certain quality metrics.[5] Accordingly, we support proposed changes that enhance such integration and improve the experience of people with Medicare and Medicaid. Such changes include proposals that codify sub-regulatory guidance relating to integrated plan appeal and grievance processes, and CMS' future plans to transition away from Financial Alignment Demonstrations into a more far-reaching and permanent D-SNP program. We also support the goals of several proposals, including those that better coordinate government approvals of integrated enrollee materials for certain D-SNPs, enhance access to data on enrollees' social needs, and ensure member engagement and input. However, in our detailed comments we highlight questions and offer recommendations on ways to improve these proposals and identify places where operational considerations require later effective dates to ensure proper implementation without disruption. Finally, we have serious concerns with certain D-SNP proposals that would limit flexibility and likely lead to reduced benefits. Those issues are discussed below.

- ***We support certain proposals to clarify and improve the health care experience for consumers.*** For example, we support CMS' clarifications regarding special requirements that apply to out-of-network services during disasters and emergencies. These requirements were triggered by the COVID-19 pandemic, and the proposal will help address potential questions or confusion during the remainder of the related public health emergency (PHE), and in the event of future disasters and emergencies.

We also appreciate CMS' requests for input on important issues relating to patient transfers from hospitals to post-acute care settings during the PHE, and behavioral health networks in MA plans.

At the same time, we are concerned that several key proposed changes would limit flexibility, choice, competition, and value for consumers. For example:

- ***Proposal to Require Pharmacy Price Concessions in Negotiated Prices Will Harm Part D and Authority is Questionable.*** We urge CMS to withdraw the proposal to require all

[5] 87 Fed. Reg. 1842, 1849-50 (January 12, 2022).

possible pharmacy price concessions be included in a Part D plan's point-of-sale "negotiated price." The proposal would not address the root cause of high drug prices: pricing and market practices that are solely under the control of drug makers. It would increase premiums for all Part D enrollees, increase costs for taxpayers, and give windfalls to drug makers—with the impacts likely larger than CMS estimates. It would chill the use of evolving and innovative value-based pharmacy contracts that promote cost-effective generics, reduce the use of high-risk medications, and improve medication adherence. It would not comply with the statutory non-interference clause, a key linchpin of the Part D program's continued success and popularity. Finally, if CMS were to finalize the proposal, the 2023 effective date would be wholly unworkable. Speeding implementation would exacerbate the negative impacts of the proposal and dramatically increase the risks of serious program disruption. As a practical matter, any program of this nature could not possibly be implemented before 2024.

- ***CMS' Proposed Regulation Fails to Account for the Ongoing Impacts of the COVID-19 Pandemic on 2023 Star Ratings.*** We appreciate CMS' statement that it intends additional rulemaking in response to comments submitted to the March and September 2020 Interim Final Rules with Comments (IFCs). We continue to have serious concerns about 2023 Star Ratings given how the PHE affected the 2021 measurement year (including the spread of the Delta variant and the surge of the Omicron variant), and the potential impacts for provider and plan performance on a variety of measures across different geographies. We urge CMS, through an IFC, to extend its COVID-19 disaster relief policy and special rules to all applicable measures for 2023 Star Ratings. Extension of the COVID-19 special rules would provide needed stability to ensure plans, their network providers, and the affordable benefit offerings and options they provide to their enrollees are not adversely affected. We also remain concerned about the scheduled increase in weighting for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures in 2023 Star Ratings, with serious questions about the potential impacts of the pandemic on survey response rates and other aspects. We renew our call for CMS to issue an IFC that maintains the weighting of patient experience/complaints and access measures at 2 for 2023 Star Ratings.

- ***Proposal to Impose New Mandate in Calculating Maximum Out of Pocket (MOOP) Limits Can Reduce MA Plan Benefits.*** The proposal would impose a new requirement on how all MA plans track out-of-pocket spending for purposes of the MOOP limit. Under the proposal, enrollee cost sharing covered by Medicaid and other third-party payers would be required to apply toward the MOOP limit, as would enrollee cost sharing that is owed but unpaid (e.g., because of Medicaid rules). We are concerned this proposal could significantly increase premium costs and/or limit available supplemental benefits. D-SNPs could be especially hard hit, but given that the proposal is broadly

written, it could negatively affect premiums and supplemental benefits for all MA enrollees. We also note that CMS applied the MOOP limit to all MA plans without specific statutory authorization. We question CMS' authority to now make MA enrollees pay higher premiums or receive reduced benefits through expanded MOOP accruals in order to shift liability from Medicaid to Medicare, reduce state Medicaid costs, and increase Medicaid provider revenues.

- ***Allowing States to Require "D-SNP only" Contracts Could Cause Operational Issues and Negatively Affect Premiums and Benefits.*** We have significant concerns about the negative impacts of this proposal on the Star Ratings program and the potential impacts on the financial viability and robust benefits provided by D-SNPs. D-SNPs with low enrollment in their own contracts may be unable to report on many Star Ratings measures due to minimum sample size requirements. The proposal could also affect data reliability, increase volatility, and produce even less visibility into D-SNPs' local performance than under the current system. Moreover, the proposal could make it more challenging for D-SNPs to attain eligibility for quality bonuses that reduce premium costs and enhance supplemental benefits. We urge CMS to consider more effective, less disruptive alternatives such as supporting supplemental reporting on quality measures at the state level rather than separate contracts.

- ***Proposed Change to Network Adequacy Rules Could Create Barriers to Enrollee Choice***. AHIP is concerned with CMS' proposal that would require MA plans to demonstrate that they meet network adequacy standards during the application process. There may be circumstances, particularly in rural and medically-underserved areas, where it would be challenging for a plan to have a full network in place in a new service area almost one year prior to the beginning of the contract year. Furthermore, we have expressed longstanding concerns about the ability of the current exceptions process to address legitimate network challenges in certain geographies. While we support the proposed credit CMS would apply to help satisfy network adequacy requirements during the application process, it would not be enough to address these concerns. If CMS were to move forward with the proposal, CMS at a minimum should provide plans with more flexibility (e.g., additional credits) and time to build their provider networks and work with stakeholders to improve the exceptions process.

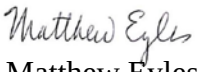
- ***Other Proposed Compliance Requirements***. The Proposed Rule includes a number of compliance-related provisions that raise concerns. Examples include more detailed Medicare Medical Loss Ratio reporting requirements that raise significant reporting challenges and could release competitively sensitive information that would harm competition; new criteria preventing plans from receiving CMS approval for service area expansions that raise a number of methodological and fairness concerns; and a proposal

to hold MA plans liable for activities of Third Party Marketing Organizations (TPMO) with whom they do not contract. We discuss our concerns and related recommendations regarding these and other proposals in our detailed comments.

Conclusion

Again, we appreciate the opportunity to comment on the Proposed Rule and your continued commitment to partnership with MA and Part D plans. Attached are detailed comments on the foregoing proposals and other provisions in the Proposed Rule. Our recommended changes are designed to maintain and grow strong and stable MA and Part D programs so the millions of seniors and people with disabilities who rely on them continue to receive the high-quality, coordinated care they deserve. We look forward to continuing to work together on policies that ensure affordable and innovative choices in MA and Part D to improve the health and well-being of Americans.

Sincerely,



Matthew Eyles
President & Chief Executive Officer

AHIP Detailed Comments

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

I. Pharmacy Price Concessions in Negotiated Prices (§ 423.100)

The proposal would remove the current regulatory provision that excludes contingent discounts from pharmacies that cannot reasonably be determined at the point-of-sale (POS) from the definition of Part D "negotiated price." Under the proposal, the negotiated price would have to reflect the lowest possible reimbursement a network pharmacy or other network dispensing entity will receive for a drug, taking into account price concessions including all contingent discounts. Part D requirements based on the negotiated price, including provisions relating to enrollee cost sharing and bidding, would be determined based on this new definition. CMS says additional payments that could be made to a pharmacy, e.g., as an incentive to encourage efficient drug choices such as higher generic dispensing, would still be permitted. Those contingent amounts would be excluded from the negotiated price and instead would be reported as negative direct or indirect remuneration (DIR) during the Part D reconciliation period. CMS further proposes a definition of "price concession" to mean "any form of discount," whether a direct or indirect subsidy or rebate received by a Part D sponsor or its intermediary that serves to decrease the costs incurred under the plan by the Part D sponsor.

Discussion and Recommendations: AHIP has very serious concerns with this proposal and urges CMS to withdraw it. The proposal would:

- **Fail to address the root cause of high drug prices**: drug manufacturers set prices for drugs that often have limited competition, raise them repeatedly, and engage in numerous schemes to increase their revenues at the expense of patients and taxpayers;
- **Exacerbate these problems by increasing premiums and overall costs for enrollees and taxpayers**—likely more than CMS concedes in the preamble—**while providing windfalls to drug manufacturers**;
- **Weaken the tools available to sponsors to promote quality and cost effectiveness**;
- **Expand CMS' role in private contracting arrangements in an unprecedented way, inconsistent with the intent of the non-interference clause** in section 1860D-11(i) of the Social Security Act (SSA); and
- **Fail to provide plans and their contracted pharmacy benefit managers (PBMs) with enough time** to adequately reflect these changes in bids, modify contracts and make system changes needed for the proposed 2023 effective date, thereby further increasing costs, confusion and disruption.

Successive Administrations have considered but repeatedly rejected similar proposals in the past, given the negative impacts on Medicare beneficiaries and the broader Part D program. **CMS**

should once again withdraw the proposal and instead work with all stakeholders on alternative approaches that address any concerns CMS might have about current DIR arrangements without compromising the ability of plans to drive value, keep premiums low, and ensure accountability from pharmacy network participants on behalf of beneficiaries and the Medicare program. **However, if CMS moves forward, the effective date must be delayed until at least 2024 so that the changes can be operationalized while minimizing disruption for enrollees as much as possible.**

Our concerns with this proposal are discussed in detail below.

- **The proposal does not address high drug pricing.** Any changes to address how pharmacy pricing is used in Part D should be part of a broader package designed to address the sole driver of pricing: the fundamental lack of market competition for the manufacturers of many drugs, and gaming of the system by drug makers that are blocking patient and consumer choice.

  AHIP has previously submitted recommendations on a package of proposals that could slow the increase of or reduce drug prices. They include stopping drug maker patent games that limit entry by new generic and biosimilar competitors; ensuring federal rules promote the availability of interchangeable biosimilars; revising market exclusivity periods and orphan drug incentives; providing more transparency and timely information about drug and biologic patents to promote greater generic drug and biosimilar competition; requiring drug makers to publish true research and development costs and explain price setting and price increases; disclosing list prices in direct-to-consumer advertisements; informing patients and physicians on effectiveness and value; allowing plan sponsors maximum flexibility to employ utilization and formulary management; and eliminating barriers to value-based pricing.

  Without such comprehensive efforts, CMS' negotiated price proposal would simply shift around funds, thereby resulting in the premium increases, government cost, and manufacturer windfalls described below.

- **The proposal would increase premiums and government costs and would provide financial windfalls to drug manufacturers.** Under current rules, Part D plans can use savings from projected contingent pharmacy price concessions that are not reflected in POS prices to reduce the net Part D drug costs in their bids. This allows plans to offer coverage at lower premiums and/or offer enhanced options at the same premium amount. The preamble notes that when contingent price concessions from pharmacies are not passed on to the enrollee at the POS, they are passed on through lower premiums.[6] By requiring Part D plans to include all potential price concessions from pharmacies in calculating cost sharing, the cost of providing the Part D benefit will increase. That means fewer dollars will be available

[6] 87 Fed. Reg. 1842, 1913 (January 12, 2022).

to apply toward reduced premiums or enhanced coverage. It will also increase the cost to the government of subsidizing Part D premiums.

Moreover, the proposal will "reward" drug manufacturers with a CMS-projected multi-billion-dollar windfall over the next ten years – due primarily to slowing the enrollee's progression through the Part D benefit and reducing the total number of enrollees entering the coverage gap phase, where makers of brand drugs pay 70% of a drug's cost under the coverage gap discount program.[7] CMS of course does not speculate that manufacturers would pass on those savings by lowering list prices or offering greater discounts on their products. Based on their price hikes and other gaming at the expense of beneficiaries and taxpayers, we would fully expect drug makers to pocket the savings.

While these premium, government, and drug maker impacts are not in dispute, we are concerned that CMS' projections understate the likely impacts. Specifically, CMS estimates that under its proposal, government spending would increase $40B over the next ten years;[8] beneficiary premiums would increase an estimated $12B or 5 percent in that same timeframe;[9] and manufacturer windfalls would be at least $14.6B over ten years. However**:**

- The proposal by its terms requires POS pricing for contingent pharmacy discounts in all phases of the Part D benefit except with respect to applicable drugs in the coverage gap. **We have significant concerns that Part D plans, their contracted PBMs and pharmacies could not operationalize a process that effectively changes the methodology for calculating the negotiated price depending on where the enrollee is in the benefit.** In addition to the technical issues, it would be extremely complicated to explain to enrollees and pharmacies. We also have concerns about how this could be effectively communicated in Medicare Plan Finder files, with greater potential for errors and confusion among enrollees. And even assuming these issues can be overcome, it likely could not happen in time for the proposed 2023 effective date. While we appreciate the opportunity for flexibility to offset the impacts of this proposal, and support retaining that flexibility if the proposal is finalized, we question its operational feasibility. As a result, we think the actual impact on enrollee premiums, government costs and manufacturer windfalls would be significantly higher than CMS' estimates shown in Tables 17 – 19 of the preamble. Those estimates suggest: **Government spending would increase by $50.7B over the next ten years; beneficiary premiums would increase an estimated $15.2B in that same timeframe; and the projected manufacturer windfall would increase to $17.9B in that same timeframe.**

- **We are concerned that the proposal could end up changing negotiation dynamics in a way that increases overall net payments to pharmacies, and thus increases the cost**

[7] 87 Fed. Reg. at 1947.
[8] Id. at 1849.
[9] Id. at 1947.

impacts even more. In CMS' estimates regarding premium and government costs, the agency includes "a modest potential indirect effect on pharmacy payment as a result of pharmacies' independent business decisions." CMS goes on to say:

> "Specifically, our estimates assume that *pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties* to compensate for pricing risk and differences in cash flow and we assume that these business decisions will result in a slight increase in pharmacy payments of 0.1–0.2 percent of Part D gross drug cost."[10] (emphasis added).

We agree with CMS that this proposal could change the negotiating dynamic between plans and pharmacies and thereby result in fewer net discounts and higher pharmacy payments. Having the parties focus discussion on payments that "assume the worst" could, for reasons of cash flow and other reasons, make it more difficult to reach agreement on a worst-case level that approximates the discounts that could be obtained without CMS interference. In fact, we think there is a significant risk that CMS is underestimating this impact. We note that when considering the impact of the proposed anti-kickback rule for manufacturer discounts in the prior Administration, CMS estimated that manufacturers could keep 15 percent of current rebate dollars as additional revenue in the transition to the new "chargeback" system contemplated in that rule. **If the redefining of "negotiated price" in the proposed rule caused similar impacts, it would mean far higher premiums and government costs.** Given these risks, we believe CMS must analyze and solicit input from stakeholders on the premium, government cost, and manufacturer windfall implications before moving forward with finalizing the proposal.

- **The proposal would chill current value-based designs and limit future innovations in value-based contracting with pharmacies.** Plans use contingent pharmacy price concessions as a critical tool in creating high-quality pharmacy networks. Programs that tie pharmacy payment to quality and efficiency targets, such as increasing generic dispensing rates, reducing the use of high-risk medications, and improving medication adherence, help improve beneficiary health outcomes and drive cost-effective drug purchasing that saves money for enrollees and taxpayers. These programs have kept premiums low and provided consistently high satisfaction rates for Part D enrollees. More generally, the Administration has strongly advocated for increased use of value-based payments in Medicare and other programs.

  We recognize the proposed change to the definition of negotiated price does not expressly bar plans from establishing incentive programs relating to quality and other performance measures. However, **the proposal would create serious barriers to how such programs**

[10] Id. at 1944.

could be designed and implemented, thereby raising costs, reducing quality outcomes for enrollees, and undermining a key Administration goal of increasing the use of value-based arrangements.

- **If the proposal is adopted, it could be extremely difficult for parties to design and agree to value-based programs that offer both upside gains when performance targets are met and downside risk when performance targets are not met.** It would require using one POS negotiated price for enrollee payments and a different POS negotiated price for pharmacy payments and incentives. Parallel tracking systems would be needed to distinguish and reconcile these different approaches. The practical complexities of that program could effectively eliminate two-sided risk arrangements in favor of arrangements that mirror the proposed CMS negotiated price rule, i.e., the only incentive offered would be additional funding or "bonus" payments for reaching performance targets. It is well established that programs that use two-sided risk have the greatest impact on improving performance.[11] Accordingly, the proposal could significantly inhibit the programs that have saved money for enrollees and taxpayers while enhancing medication adherence.

- **The proposal could also limit even the *acceptance* of bonus-only programs.** Retrospective analysis and reconciliation based on assessment of a pharmacy's actual performance is a complex yet critical feature of value-based arrangements. These programs typically rely on population-based metrics that are only stable with sufficient volume. And while individual data points informing some metrics (e.g., generic dispensing) can be measured at the pharmacy counter, others (such as medication adherence for enrollees with chronic conditions, or the awarding of improvement points) require assessment over a period of time. CMS effectively is requiring that discounts built on population-level performance be incorporated real-time into individual enrollee pricing. **We are concerned this will add additional complexities and confusion around the design and metrics for these programs and could generate a push to abandon critical population-based goals.** And as noted above, the parties would have to "assume the worst" even for pharmacies that typically meet performance metrics or have invested significant resources to improve performance. **This could discourage some pharmacies from entering into quality programs at all.** They instead may opt to negotiate for higher up-front pricing (without the potential for additional bonuses) to increase cash flow and limit risk – a result wholly at odds with the goals of value-based contracting.

- **The proposal does not provide information that would enhance enrollee choice**. CMS argues that the revised definition of negotiated price as proposed will allow enrollees to better compare plan cost sharing and premiums, and that requiring a consistent approach that

[11] The Future of Value-Based Payment: A Road Map to 2030 - Penn LDI (upenn.edu); available at: https://ldi.upenn.edu/our-work/research-updates/the-future-of-value-based-payment-a-road-map-to-2030/.

incorporates contingent discounts into the negotiated price would allow for more consistent comparisons that increase plan competition. Moreover, CMS asserts that this approach better reflects section 1860D–2(d)(1)(B) of the SSA—only now, seventeen years into the program's existence. AHIP strongly disagrees with the conclusions CMS offers to support this proposal.

First, the Part D program is already highly competitive; the proposal is clearly unnecessary to enhance something that demonstrably exists. Second, rather than help enrollees make comparisons, we think the proposal could actually increase complexity and create more confusion among both prospective and current plan enrollees. Medicare Plan Finder already provides key comparative metrics that helps enrollees select a plan that best meets their needs, including cost sharing, premiums, formulary coverage, pharmacy participation, quality ratings, and integration or non-integration with MA plans. Creating a single approach to calculating "negotiated price" would fail to simplify those assessments further, and in fact could divert attention from more important considerations for individual enrollees. Moreover, to the extent CMS envisions adding additional explanations in Medicare Plan Finder or elsewhere about how contingent pricing is reflected in negotiated prices, it seems far more likely to confuse rather than inform. The current process indisputably simplifies the comparison of prescription drug price information between plans while incenting pharmacies to provide high quality services while keeping premiums lower than what would be offered under the proposed system. The proposed changes will undo this already effective Medicare Plan Finder feature to the detriment of enrollees.

Finally, CMS states that its previous interpretation of SSA section 1860D–2(d)(1)(B) means ". . . that some, but not all, price concessions must be applied to the negotiated price. . ." was permissible, but that now ". . . our initial interpretation may have been overly definitive . . . [and] that a proper reading of the statute supports requiring that all pharmacy price concessions be applied at the point-of-sale."[12] AHIP questions how—more than seventeen years into the program's existence—the previous interpretation that had been repeatedly supported by past, bipartisan, Administrations could now be characterized as not "proper." Moreover, as we discussed above, the proposed changes will not improve the program in any measurable way for enrollees but could substantially hamper efforts by plans to improve the quality of care provided by pharmacies or drive efficiency and value in the benefit. We therefore reiterate our recommendation that CMS not proceed with finalizing this new interpretation of section 1860D–2(d)(1)(B) that changes the definition of negotiated price.

- **The proposal is not needed to address alleged bidding issues.** One of the justifications CMS puts forward for the proposal is that pharmacy price concessions are not being appropriately estimated in Part D plan bids. However, the Part D bidding process is subject to rigorous oversight and, ultimately, approval by the CMS Office of the Actuary (OACT). If there is a systemic issue with how contingent pharmacy discounts are being estimated in

[12] 87 Fed. Reg. 1915.

bids, CMS has the information necessary to address it through the bid review and approval process.

- **AHIP strongly believes the proposal runs afoul of the non-interference clause.** If CMS finalizes this proposal, it will materially reinterpret the non-interference clause in SSA section 1860D-11(i), constructively rewriting and ultimately undermining a key linchpin that plays a significant role in the program's continued success and popularity.

  The statutory provision specifies that in order to promote competition under Part D, the Secretary is prohibited from "interfering with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," and from requiring a particular formulary or instituting a price structure for the reimbursement of Part D covered drugs. CMS has regularly interpreted the non-interference clause as being applicable to negotiations between any combination of the three parties listed above, including negotiations between Part D sponsors and pharmacies. This interpretation is evidenced in the preamble discussions in the agency's August 2004 proposed rule and January 2005 final rule promulgating the original Part D program regulations. Further, in the preamble to CMS' final rule containing revisions to the MA and Part D Prescription Drug Benefit programs for CY 2012 published on April 15, 2011, the agency explicitly stated that CMS was "prohibited from interfering with negotiations between Part D plans and pharmacies."[13]

  CMS anticipates our concern about this potential conflict with the non-interference clause by stating that the proposal does not interfere with negotiations because contracts could continue to provide for performance-based payment adjustments and the proposal does not dictate the amount or timing of payments. **However, the statutory language prohibits <u>interference</u> with negotiations, not just CMS prohibitions or specifications. Clearly the proposal interferes with negotiations between Part D plans (or their contracted PBMs) and pharmacies.**

  - As discussed above, the proposal would alter negotiation dynamics between plans and pharmacies, leading to higher overall net payments to pharmacies and barriers to implementing effective value-based programs in the pharmacy space.
  - It would also inhibit the ability of a plan and pharmacy to negotiate over incorporating contingent discounts into that pharmacy's point of sale prices in exchange for reduced payments, as a part of an incentive for plan enrollees to choose the pharmacy.
  - Moreover, the purpose of the non-interference clause in Part D is to promote competition by and among the key parties—plan sponsors, drug manufacturers, and pharmacies. CMS' interpretation would not only affect negotiation dynamics between plans and pharmacies; it would also affect competition between pharmacies and negotiations

[13] See Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012, 76 Fed. Reg. 21432, 21529 (Apr. 15, 2011) ("As provided in section 1860D-11(i) of the Act, we are prohibited from interfering with negotiations between Part D plans and pharmacies.").

throughout the drug supply chain. It would inhibit the ability of Part D plans to use mechanisms including value-based contracts and contingent discounts to incent pharmacies to obtain drugs at the lowest possible price from drug makers or wholesalers, in a manner that adapts with frequent market fluctuations in drug prices.

We recognize there are certain current program requirements that affect negotiations (e.g., any-willing-pharmacy provisions); however, CMS should be required to ensure any new proposal does not create additional impediments to plan/PBM negotiations with pharmacies. This proposal clearly fails the test.

The proposed interpretation of the non-interference clause poses another type of threat to the long-term success of Part D. It could clear a path for future changes to other key aspects of the program that have relied on negotiation and competition. Introducing this type of risk and uncertainty can undermine the stability and predictability that has allowed Part D plans to keep program costs low, with consequences ultimately borne by beneficiaries. For this reason and the others noted, AHIP recommends that CMS continue to permit the existing flexibility for sponsors to establish post-POS pharmacy price concessions that may be reported as DIR in reconciliation.

- **Finally, if the proposal were to be finalized, it would not be possible to operationalize the changes for the proposed 2023 effective date, and thus would create significant risks of disruption**. Even if CMS chooses to proceed with adopting this proposal, the 2023 effective date is unworkable operationally for Part D plans along with their contracted PBMs and would introduce significant risks of disruption to the program and ultimately, beneficiaries.

  The proposal would require, among other things: renegotiation of thousands, or even tens of thousands, of pharmacy contracts; implementation of systems changes to operationalize these provisions; development of processes to ensure accurate information is posted on Medicare Plan Finder; and assessment and incorporation of the cost impacts in bids that (for a 2023 effective date) would be due in only three months from the comment deadline date. The likely result would be even higher premiums and greater drug manufacturer windfalls than CMS estimates. It would create massive cost and resource burdens for plans and PBMs that even now may need to develop alternative bids while awaiting a final rule. And there is the serious risk of widespread confusion and compliance problems heading into the open enrollment period in October 2022.

  AHIP is concerned that the proposed changes to negotiated prices could potentially expose sponsors to compliance issues and challenges relating to the estimation of aggregate price concessions and then assignment of such payments to specific dispensing events. Also, similar to previously shared concerns involving the past proposal addressing manufacturer rebates, we are concerned about the administrative costs and challenges in incorporating

pharmacy concessions at POS. For example, the cost and resources required to update all pharmacy network contracts would likely take significant time for plan sponsors and their contracted vendors to complete.[14] Further still, as noted above, we are concerned about the ability to operationalize "turning off" the POS pass-through of pharmacy price concessions once an enrollee enters the coverage gap phase of the Part D benefit.

We therefore strongly advise CMS to allow as much time as possible—with implementation delayed until at least 2024—so plans can develop and test the costly new systems and capabilities required by this proposal, take into account the resource-intensive changes to the multitude of existing contracts, and act on the range of other operational steps that must take place before disruptions that could affect enrollees and other stakeholders are implemented in the Part D program.

II. Improving Experiences for Dually Eligible Individuals

Medicare and Medicaid play critical roles in the lives of millions of Americans. Medicare pays for health care for about 64 million people and Medicaid provides care and services to more than 80 million. More than 12 million people are entitled to coverage under both programs, but in many cases their care is uncoordinated and fragmented between two federal health programs that were not designed to work together. As compared with typical Medicare enrollees, these "dual eligibles" have more chronic conditions, greater levels of disabilities, mental and physical impairments, and are more likely to need nursing home care.

Managed care plans serve dual eligible individuals through several delivery models that integrate Medicare and Medicaid benefits, such as D-SNPs and Medicare-Medicaid Plans (MMPs). These service delivery models have emerged as major forces in promoting integration of Medicare and Medicaid, in improving health outcomes and simplifying the experience of care for dual eligible enrollees. In 2022, 295 MA plans are offering D-SNPs serving over 4 million dual eligibles in 48 states.

AHIP and its member plans are long-term advocates for the integration of Medicare and Medicaid through integrated service delivery models. AHIP member plans have participated as MMPs in the Financial Alignment Demonstrations and have been persistent supporters of permanent authorization for D-SNPs. We commend CMS for its leadership on dual eligible

[14] Another aspect of this renegotiation process that is difficult to quantify but deserves acknowledgement, is how the loss of DIR use as a tool for plans to negotiate with pharmacies will impact the bargaining dynamics between these two parties—significantly in favor of the latter. By eliminating contingent discounts based on performance, this proposal, when combined with pharmacy geo-access requirements plans must meet when assembling their provider networks, shifts significant bargaining power to pharmacies that are likely to manifest in higher "base" reimbursement rates. Neither the preamble or the Regulatory Impact Statement sections of the Proposed Rule address this potential behavioral change and the cost impacts it will have in addition to the projected cost increases already identified and described within.

issues and recognition of the value that these integrated models provide, and we appreciate that CMS has devoted considerable portions of this rule to proposals that it views as further advancing the integration of Medicare and Medicaid. Following are our comments and recommendations relating to various proposals.

A. Enrollee Participation in Plan Governance (§ 422.107)

CMS proposes that MA organizations (MAOs) offering one or more D-SNPs in a State must establish and maintain one or more enrollee advisory committees (EACs) to solicit direct input on enrollee experiences. The EAC must include a reasonably representative sample of D-SNP members, based on parameters such as geography, service area, and member demographics. The EAC must solicit input from members on topics such as ways to improve access to covered services, coordination of services, and health equity for underserved populations. CMS is not proposing federal requirements regarding the frequency, location, format, participant recruiting and training methods, or other parameters for these committees, and is providing MAOs with flexibility in how they structure their EACs. CMS audit protocols for D-SNPs would include documentation of EAC meetings.

Discussion and Recommendations: We support the principles of member engagement and input, as AHIP members already use a variety of methods including EACs to actively solicit and incorporate input from their D-SNP enrollees to improve enrollee experience. However, we are concerned that EACs may not always provide the most effective or valuable means for obtaining enrollee input. While we appreciate that CMS' proposal offers MAOs the flexibility to structure their EACs to best meet their members' needs, we urge CMS to consider additional flexibilities if this requirement is included in the final rule.

In particular, it could be difficult for SNPs that have low enrollment and/or operate in rural service areas to solicit participation of enough members to operate an EAC effectively and with a representative sample of SNP enrollees, especially given potential variations in members' ability to participate given their health status and access to communications. In January 2022, CMS' SNP Comprehensive Report[15] indicates a total of 730 D-SNPs in operation. Of the 730 total D-SNPs, 59 (7.9%) have fewer than 100 enrollees; 166 (22.7%) have fewer than 500 enrollees; and 252 (34.5%) have fewer than 1,000 enrollees. We are concerned that it could be challenging for D-SNPs with low enrollment to engage enough enrollees to ensure sustained participation and a reasonable representation of membership.

In light of these considerations, **we recommend that CMS adopt a reasonable D-SNP enrollment threshold of 1,000 or more members in applying the EAC requirement.** This would increase the likelihood of good representation of a reasonable cross-section of D-SNP

[15] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.

enrollees. **D-SNPs with fewer than 1,000 members should be permitted to obtain enrollee input through focus groups, surveys, or other reasonable methods.**

In addition, if the EAC proposal is finalized sometime in 2022, many D-SNPs will need time to assess the requirement, develop outreach strategies and ensure effective cross-sectional representation. It could be extremely challenging to do this by January 2023. **Therefore, we recommend that the compliance date be no earlier than 2024.**

Finally, if the EAC proposal is finalized, we request that the final rule or other CMS guidance address a number of operational/compliance questions. For example:

- Can operation of the EAC be delegated to a first tier, downstream or related entity (FDR)?
- Can D-SNPs compensate their enrollees for participation on an EAC (e.g., through a meeting stipend, reimbursement of expenses, or lunch and transportation)?
- What specific EAC documentation requirements will be added to the CMS audit protocols?

B. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (HRAs) (§ 422.101)

CMS proposes to require that all SNPs (C-SNPs, D-SNPs, and I-SNPs) include one or more standardized questions on housing stability, food security, and access to transportation as part of their HRAs, with specific questions to be specified in sub-regulatory guidance. Enrollee responses would support the comprehensive risk assessments SNPs are required to conduct through HRAs, results of which are used in developing enrollee comprehensive individualized plans of care. CMS considered proposing to require that HRAs address the domains (for example, housing) without specifying standardized questions, but concluded that the benefit of flexibility was outweighed by purported difficulties for interoperability, comparability and reporting if different questions were used by SNPs across the country. This requirement would not be enforced until contract year 2024, but CMS said it is considering a later date, such as contract year 2025, to allow more time for the new questions to be incorporated into existing SNP HRAs.

Discussion and Recommendations: We strongly agree that access to data on enrollees' social needs can better inform care, remove barriers to care and healthy living, reduce disparities, and advance health equity. We also recognize that standardization of social needs data can make it easier for CMS and others to aggregate and analyze data and make "apples to apples" comparisons across organizations and programs. **However, we recommend CMS consider alternatives to standardized questions that could achieve CMS' goals, be more effective in addressing enrollee needs, and reduce burden on a wide range of stakeholders.**

- **Standardized Coding of Responses Rather than Standardized Questions.** For years, many states, health providers, and health plans have been investing resources to collect standardized data on their members' social needs, drawing on social determinants of health (SDOH) screening tools and toolkits such as PRAPARE (National Association of

Community Health Centers and Association of Asian Pacific Community Health Organizations), WellRx, We Care, American Academy of Family Physicians EveryOne Project, Accountable Health Communities SDOH Tool, or others. These tools focus on similar SDOH domains (including food insecurity, housing instability, and transportation issues) but the questions may differ slightly. An organization may use one of these tools in its entirety or select certain questions from one tool and other questions from another tool, as CMS appears to be suggesting they might do in the sub-regulatory guidance. Accordingly, a robust data collection environment has already developed. In addition, payers and providers may have interoperable systems that encode social needs questions in HRAs and electronic health records (EHRs). The CMS proposal could therefore require multiple organizations to modify data collection and IT systems and have significant spillover impacts into provider EHRs. It could disrupt the continuity of existing assessments; jeopardize linkages to historical data and related analytics; and prevent organizations from using validated questions they have determined work best to elicit information that is most effective in developing individualized plans of care for their enrollees.

Another key consideration is that SNP enrollees speak multiple languages. Given the nuances of translations to ensure cultural appropriateness and the many varied dialects inherent within languages, it may be difficult to ensure standardized questions remain the same across different translated languages.[16] Accordingly, not only are we concerned about the burdens and effectiveness of requiring standardized questions, we question whether the questions themselves could truly be considered "standardized" given these translation considerations.

While we acknowledge the value of standardization, CMS should consider an alternative that would require SNPs to report to CMS specific, standardized interoperable codes for social needs identified through their HRAs. This would place the focus on *standardized enrollee responses* to questions, rather than the questions themselves. This would align with CMS' process to "allow each SNP to develop its own HRA as long as it meets the statutory and regulatory requirements" (see discussion on page 1858 of the Proposed Rule). This approach could be more easily scaled by utilizing existing systems and infrastructure. It would allow organizations to focus on needs and person-centered approaches that best meet the needs of their members. And crucially, it would still promote standardization and interoperability for data analysis and comparisons on social needs.

Recommendation: If CMS finalizes a proposal to require HRAs to focus on housing stability, food security, and access to transportation, we recommend that CMS consider approaches that focus on standardizing how SNPs characterize enrollees' *needs* rather

[16] Cultural appropriateness of translations may require both a qualified professional translation company to do the initial translations and a community-engaged review process where native speakers for each language review and field test the translations, score the translations in terms of accuracy, appropriateness, and ease of understanding, and provide revisions to ensure translations use colloquial or conversational language rather than "high" or formal language. See., e.g., the PRAPARE SDOH tool's translation process (https://prapare.org/the-prapare-screening-tool/).

than the *questions.* As an example, CMS could look to the Gravity Project[17] for standardized value sets, interoperable codes, and HL7 technical standards to document standardized data on social needs. Interoperable codes could include codes from ICD-10 Z codes, LOINC codes, and/or SNOMED code sets, among others. For additional safeguards, CMS could specify which SDOH screening tools are permissible to ensure SNPs use questions from validated and vetted tools that have been tested by different communities to ensure they are person-centered and sensitive.

- **Include Questions on Enrollee Choice.** Some individuals with social needs may be reluctant to answer questions about those needs or not welcome assistance to address them. They may not feel comfortable sharing information with SNPs about these types of personal circumstances; for example, they might question their relevance in addressing specific health conditions. Requiring that enrollees answer these questions as part of their health plan enrollment could have unintended consequences and require diversion of limited resources. Even in the absence of HRA questions, SNPs may be able to obtain this information from other sources, such as reports from caregivers and observations from in-home assessments.

  Recommendation: In the interest of enhancing the actionability of social needs data and minimizing potential enrollee concerns, **we recommend that CMS revise its proposal to allow SNPs to ask whether the individual wants help or assistance with any of their social needs.** Additionally, CMS could include a "I choose not to respond" answer choice to each of the proposed questions. This would allow the person to maintain personal autonomy and choose not to disclose their personal information while also allowing SNPs to record their choice in a standardized response.

- **Limit Number of Questions.** CMS states that it would require "one *or more*" questions on each of the three social risk factors. We are concerned about the potential burdens on key stakeholders if too many questions are mandated. As further addressed below in the discussion on effective dates, States, SNPs, and other organizations will need to design, align, implement, test, evaluate, and revise their processes. If CMS focuses its proposal on housing, food security and access to transportation, and limits the number of questions that could be required on these topics, it will enhance the likelihood that the provisions could be successfully implemented.

  Recommendation: CMS should start small with just a few social needs questions and/or interoperable codes relating to housing, food, and transportation. Consideration should be given to potentially adding additional questions, or expanding to other social needs topics, only when the new social needs questions or codes have been implemented successfully in normal operations.

[17] https://thegravityproject.net/.

- **Convene Expert Panel to Consider Use of Social Needs Pre-Screeners.** We agree with CMS that food insecurity, housing instability, and lack of access to transportation are common social risk factors that can directly influence an individual's physical, psychosocial, and functional status. However, some populations may not have those specific needs depending on individual circumstances or geographic location. At the same time, an exclusive focus on these three social needs could miss other critical social needs that are more relevant. The relevance of different social needs questions will vary depending on individual circumstances, geographic location, populations served, and resource availability, among other factors. Focusing on just three SDOH domains could lead to unnecessary data burden on populations who may not have those specific needs while also missing other critical social needs.

  Rather than focusing on just three SDOH domains that may or may not have as much relevance for a SNP, an inclusive one-to-two question pre-screener could ask individuals about their needs or challenges across a wider range of social needs (covering topics such as social isolation, employment, safety, legal needs, assistance with utilities, issues with a person's living or home environment, material security, and digital access, in addition to housing, food and transportation). While we recognize that social needs pre-screeners have not been widely used or vetted, pre-screeners could allow for a more holistic assessment of member needs, which can then be followed up by additional questions if needed and be used to better inform care. This approach is similar to the process for depression screening with a "first-step" approach that involves administering a shorter PHQ-2 pre-screener, followed by a more detailed PHQ-9 version if individuals answer affirmatively to the two-question pre-screener. An inclusive social needs pre-screener could include the most relevant health related social needs (including housing, food, transportation, social isolation, work situation, safety, legal needs, assistance with utilities, issues with living or home environment, material security, digital access, among others). Individuals who indicate that they are struggling in certain areas can be flagged for follow-up to ask additional questions to inform care on those specific areas. It should be noted that a social needs pre-screener has not been widely used or vetted.

  Recommendation: Apart from CMS' proposal to require HRAs include standardized questions or responses on housing, food and transportation, we recommend that CMS also convene a technical expert panel of relevant stakeholders, such as MA plans, SNPs, SDOH screening tool developers like the PRAPARE team or Accountable Health Communities technical expert panel, and others to consider research on the comparative effectiveness of existing social needs screening tools, and develop and test a social needs pre-screener as a way to operationalize social needs screening at scale in a less burdensome and more efficient and actionable way.

- **Effective date/implementation timeline.** Once CMS' proposals are finalized, SNPs and state Medicaid agencies (in the case of D-SNPs) will need adequate time to assess the federal requirements, take steps to align state and federal requirements with the HRA questions and response codes, modify HRA-related software, and potentially modify state MCO contracts where needed. SNPs and states will need additional guidance from CMS on specific details,

including clarity relating to the documentation and reporting requirements. In the long run, this will help minimize additional assessment burdens on SNP members, providers, and plans. Accordingly, we agree with CMS that 2023 is too soon to apply the requirement. In addition, while additional time would be required even if the final rule adopted our recommendation for standardized coding of responses combined with plan flexibility on questions, even more time would be needed if CMS instead were to require standardized questions. That approach would require time to obtain input from multiple stakeholders on the specific questions, address concerns about clarity and usability, develop translations into multiple languages, etc., and then require the types of implementation and IT work referenced above. And the more questions that are required, the more time that will be needed to prepare and implement the process.

Recommendation: If CMS finalizes a requirement relating to the three social needs topics on HRAs, we would support a 2024 effective date if the rule focused on standardized response codes and the domains of questions to be included in HRAs while allowing SNPs some flexibility as discussed above. If CMS moves forward with the standardized question requirement, we urge an effective date no earlier than 2025, with the specific date dependent on the scope and complexity of questions developed in final guidance.

- **Responsibility of SNPs to Address Social Needs.** While the purpose of HRAs is to inform care, SNPs may be limited in their ability to address social needs identified in their HRAs. An organization's ability to address its members' social needs depends on many factors, including their geographic location, resource availability in their communities, the extent and complexity of needs in the populations served by the organization, whether the organization is allowed and has capacity to offer benefits and services to address social needs of all beneficiaries with those needs, and various levels of policy (whether local, state, or federal) that contribute to social needs, among others.

  Recommendation: Notwithstanding the proposal to require SNPs to include questions on social barriers in their HRAs, we request that CMS clarify that SNPs are not required to address all of the social needs potentially identified in HRAs, given that much that contributes to social needs lies outside the control of health plans. SNPs are one part of the overall solution to addressing social needs but meeting those challenges requires a much broader initiative and investments across many local, state, and federal stakeholders.

C. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)

CMS proposes to revise the definitions of *fully integrated dual eligible SNPs* (FIDE SNPs) and *highly integrated dual eligible SNPs* (HIDE SNPs) on the basis that such changes would help people with Medicare and Medicaid differentiate among the various types of D-SNPs and clarify their coverage options. The revised definitions would become effective beginning in 2025.

- FIDE-SNPs would be required to have exclusively aligned enrollment and cover Medicaid primary and acute services, long-term services and supports (LTSS), Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the state Medicaid agency. In addition, FIDE SNPs would cover all Medicare cost-sharing for full-benefit dually eligible enrollees.
- The capitated contract between a FIDE or HIDE SNP and its state Medicaid program would have to apply to the D-SNP's entire service area.
- CMS also proposes to codify limits on benefit carve-outs relating to LTSS and behavioral health for FIDE and HIDE SNPs. In general, the proposal would allow such carve-outs if they: (1) apply "primarily to a minority of beneficiaries eligible to enroll in the D–SNP" who use the LTSS or behavioral health benefit, or (2) constitute a small part of the total scope of LTSS or behavioral health provided to the majority of beneficiaries eligible to enroll in the D–SNP.

Discussion and Recommendations: AHIP understands that the proposed revisions to the definitions are intended to enhance the level of integration in FIDE and HIDE SNPs. We have consistently supported legislative and CMS efforts to increase integration in ways that improve the SNP experience for dual eligibles. We also have supported CMS proposals that provide flexibility to states in order to minimize disruption and account for different state resources and capabilities. In this regard, we request that CMS consider accommodating certain conditions that vary across states, and provide additional clarifications regarding the capitation requirement, if these elements of the Proposed Rule are finalized.

For example, we are aware that some states impose an enrollment cap or limit on the number of Medicaid enrollees (including dual eligibles) who receive LTSS. In such states, a HIDE or FIDE SNP's enrollment likely would consist of a mix of dual eligibles who receive Medicaid LTSS and those who do not receive Medicaid LTSS due to a state-imposed limit. **CMS should clarify how such limits would apply under the carve-out language of the proposal.**

Further, in some cases a capitated contract with a state Medicaid agency is held by a D-SNP's parent company or sister company, while in other cases the D-SNP entity itself may hold the contract. In the latter situation, Medicaid rules are not as clear as they should be about the application of the Medicaid actuarial soundness requirements at 42 CFR §438.4 to the Medicaid benefits covered by those capitated contracts. Specifically, 42 CFR §438.4 applies to managed care organizations (MCOs) with comprehensive Medicaid contracts, prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs). Neither that rule nor the current CMS *Medicaid Managed Care Rate Development Guide* refer to dual eligible SNPs or provide guidance on the applicability of Medicaid actuarial soundness standards to Medicaid services provided by D-SNPs. **We therefore request that CMS formally clarify that capitation rates developed pursuant to state Medicaid agency contracts (SMACs) with D-SNPs are subject to the actuarial soundness requirements of 42 CFR §438.4.**

- **Capitated Medicare Cost-Sharing for All D-SNPs.** CMS requests feedback on the feasibility, implementation, estimated time to enact, and impact of requiring Medicaid coverage of Medicare cost-sharing in capitated contracts with states for all D-SNPs, to inform future rulemaking.

  Discussion and Recommendations: We appreciate that there would be potential benefits to enrollees in D-SNPs that are not FIDE SNPs, and to their providers, if states made capitation payments for Medicare cost sharing to all D-SNPs. Potential benefits would include streamlined claims processing and limiting potential erroneous balance billing of enrollees.

  However, we also agree with CMS that there are complications in extending this requirement beyond FIDE SNPs. For example, we are concerned that some states that authorize non-FIDE SNPs may lack the resources and/or expertise to implement capitation for cost sharing. This would increase the risk that such states would reject SNPs altogether or retain dual eligibles in their FFS programs in reaction to the requirement. **We recommend that CMS very carefully evaluate these risks before moving forward with such a proposal in the future.**

  We also recommend that CMS consider several policy and operational issues and the need for additional guidance before proposing to expand this proposal beyond FIDE SNPs:

  - CMS should consider developing a set of **informational materials** that would anticipate and help address state questions and concerns with capitating D-SNPs for Medicare cost sharing. These materials would likely be needed in a number of states, e.g., so Medicaid staff can educate other stakeholders in state government.
  - States would likely need **technical assistance and a model playbook** to follow. Some states already capitate SNPs for Medicare cost sharing but in different ways. CMS could consider using a demonstration or pilot program in development of the model playbook.
  - **Guidance will be needed on the actuarial soundness of cost-sharing capitation** CMS should ensure consistency between capitation payments and D-SNP cost-sharing projections and experience as reflected in MA bids. Without clarity on this issue, states may not offer capitation rates that are adequate to fund the D-SNPs' cost sharing obligations. For example, a plan's payments of Medicare cost sharing would be projected and valued in the plan bid according to the Medicare bid rules, but the state's capitation or reimbursement to the SNP could be calculated using the Deficit Reduction Act of 2005 (DRA) "lesser of" methodology.
  - States may need substantial lead time to design, test, and implement their approaches. As part of any such proposal, **CMS should allow at least three years for implementation following publication of a final rule.**

- **State Medicaid Data Exchanges with D-SNPs.** CMS requests feedback on the pros and cons of requiring state Medicaid data exchanges to provide real-time Medicaid FFS program

and Medicaid managed care plan enrollment data with D-SNPs, and the impact of such a requirement on states, Medicaid managed care plans, D-SNPs, providers, and enrollees.

Discussion and Recommendations: Improved access to real-time Medicaid enrollment information would support further operational integration of Medicare and Medicaid benefits and coordination of services for dual eligible enrollees. We recognize that this could be a significant incremental requirement for some states in terms of IT system enhancements and project prioritization. **We therefore recommend that CMS convene a technical expert panel of states and plans to further develop the concept and identify considerations, obstacles and design and implementation solutions**.

D. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)

CMS proposes to codify new options that states can use in their state Medicaid contracts to require that certain D-SNPs with exclusively aligned enrollment: (a) integrate enrollee plan materials and notices; and (b) establish MA contracts that only include one or more D-SNPs within a state. CMS also would provide new mechanisms to improve coordination of state and CMS monitoring and oversight of certain D-SNPs when a state has elected these options, including granting the state access to certain CMS information systems.

- **Integrated Member Materials**. In the preamble, CMS notes that D-SNPs with exclusively aligned enrollment must comply with all MA, Part D, and Medicaid plan rules for communicating information to enrollees and potential enrollees. Enrollees in D-SNPs with exclusively aligned enrollment benefit from receiving one set of plan communications that integrate all required content. For states that elect to have D-SNPs with exclusively aligned enrollment, CMS is proposing to codify a pathway for coordination of federal and state processes for SNP Summaries of Benefits, Formularies, and combined Provider and Pharmacy Directories that integrate Medicare and Medicaid content. CMS indicates its activities could include coordination with states on potential template materials, identification of potential conflicts between federal regulatory requirements and state law, and establishment of a process for joint or coordinated review and oversight of the integrated materials. CMS also indicates it is considering including the Evidence of Coverage and Annual Notice of Change (ANOC) documents as part of the minimum scope of integrated materials but says it may be better to assess integration of these materials at a later date.

  Discussion and Recommendations: Before formalizing this proposal as an option for states, we recommend that CMS work through and provide adequate lead time and additional guidance on practical operational considerations, such as:

  – How should states and SNPs address differences in timing of changes in MA program and Medicaid benefits and processes? For example, in states with July to June Medicaid contract years (e.g., Ohio and North Carolina), a D-SNP potentially would have to revise,

retranslate, reprint, and redistribute integrated member materials twice a year to appropriately reflect Medicare and Medicaid benefit and process changes: once for the January 1 Medicare plan year and again for the July 1 Medicaid plan year.

- How and on what schedule would states and SNPs be required to modify integrated materials to account for impacts of new state legislation or significant changes in Medicaid enrollee coverage groups and benefits? For example, a new state law could be passed in January requiring the Medicaid program to begin providing dual eligibles with managed LTSS benefits beginning on September 1.
- CMS should also clarify that changes in Medicaid benefits would not be regarded as mid-year benefit changes for purposes of Medicare bids.

Additionally, we request that CMS work with states that elect to require integrated member materials to ensure that those states are aware of and committed to the federal MA schedule and deadlines for review and approval of plan member materials. We also strongly encourage CMS to provide model integrated materials and guidance to states to maximize consistency and uniformity across state programs.

- **"D-SNP Only" Medicare Contracts.** The discussion in the preamble suggests that the primary driver for the "D-SNP only" contract proposal is to allow states to evaluate SNP performance separately from other MA plans. At the same time, CMS requests comments on consequences that would result from the proposal in terms of benefits and problems for MAOs, states, and dually eligible individuals. CMS believes that few states would elect the "D-SNP only contract" contract option but that there is no guarantee that would be the case.

  Discussion and Recommendations: We have very serious concerns with this proposal.

  - **Uncertainty about Ability to Use Existing Entities.** CMS' current policy limits the number of MA contracts a legal entity can hold to one contract for each product type (e.g., local HMO, local PPO, regional PPO). We assume that CMS would make an exception to its "one contract" policy for D-SNPs with exclusively aligned enrollment that would become subject to this proposal, but the proposal is not explicit on that point. Without such an exception, the repercussions of the proposal would be substantial and potentially limit the viability of some D-SNPs. A state could require a small MAO with a state FIDE SNP contract to house the FIDE SNP in a new MA contract, meaning that the MAO would have to create a new legal entity. The costs for a new entity would be significant, including legal expenses for incorporation, a new state insurance license, meeting state risk-based capital deposit requirements, obtaining new or modifying existing IT systems to ensure data integrity of the new entity, and applying to CMS for a new MA contract. In addition, the MAO's entire current provider network and ancillary vendor arrangements likely would have to be re-contracted with the new entity. Further, some MA plans currently have a single MA contract that includes multiple D-SNPs operating in multiple states; the costs of standing up new entities and contracts for those plans would be multiplied.

- **Star Ratings Data Issues.** Star Ratings are reported at the MA contract level. As CMS references in the preamble, D-SNPs in "D-SNP only" contracts could experience sample size issues. Many D-SNPs with low enrollment could be prevented from reporting on many of the Star Ratings measures due to minimum sample size requirements for CAHPS, Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) data. This would result in reliability and volatility impacts and produce even less visibility into D-SNPs' local performance than with the current system. If FIDE SNPs were removed from the current Star Ratings system as a result of this proposal, baselines and cut points would need to be recalculated, and a new set of baselines and cut points may need to be established for the "D-SNP only contract" group. Impacts of CMS' proposal on other methodological issues such as the Categorical Adjustment Index (CAI) must also be assessed. In summary, the implications for the current MA Star Ratings system would be significant.

- **Potential Impacts on Rebate Amounts.** A likely consequence of placing D-SNPs with exclusively aligned enrollment in "D-SNP only" contracts is that their Star Ratings would decrease. Lower Star Ratings can reduce benchmarks and rebate percentages under the MA quality bonus program, thereby reducing the funding available for MA supplemental benefits that can be offered to enrollees. It could also increase premiums or reduce the supplemental benefits that the MA plans will cover through Medicare benefits, thereby raising costs for state Medicaid programs.

We urge CMS to withdraw this proposal. We also recommend that CMS evaluate other available options that would be more effective and less obtrusive. We believe that the objectives CMS seeks to achieve with the "D-SNP only" contract proposal may be better accomplished through other means with fewer negative collateral impacts.

- We are aware of certain states that already require enhanced reporting from their D-SNPs with exclusively aligned enrollment. **CMS should evaluate the extent to which the goals of the "D-SNP only contract" proposal could be accomplished through supplemental reporting at the state level rather than separate contracts.** This could accomplish the objectives of the proposal in a much more straightforward manner and with fewer collateral impacts.
- Alternatively, CMS currently captures three SNP-only Star Ratings measures: Special Needs Plan Care Management and two Care for Older Adults measures: Medication Review and Pain Assessment measures at the PBP level (as opposed to the MA contract level) based on HEDIS data.[18] **CMS could consider the feasibility of expanding the number of SNP-only measures reported at the PBP level to gain insights into D-SNP performance without implementing the separate D-SNP contract proposal.**

[18] https://www.cms.gov/files/document/2022-star-ratings-technical-notes-oct-4-2022.pdf.

We urge CMS to fully evaluate the implications for quality measurement and reporting before finalizing the proposal, and we recommend that CMS engage with AHIP, our members, and states in that evaluation and to consider other solutions for ensuring that quality reporting needs for D-SNPs are met.

In the alternative, if CMS determines that "D-SNP only" contracts are the only way to gain greater visibility into D-SNP performance, CMS should revise its "one contract of a type per entity" policy to establish D-SNPs as a separate contract type generally, or at least make an exception to the current policy.

E. Requirements to Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634)

CMS proposes to codify existing sub-regulatory guidance requiring applicable integrated plans (AIPs) to unify certain aspects of their Medicare and Medicaid appeals and grievance processes, for example, continuation of benefits, integrated notices, guiding enrollees on presenting evidence, the roles of assignees and representatives, and time frames for processing payment requests and issuing authorizations.

Discussion and Recommendations: We support the proposal as a key component of integrated service delivery for dual eligible enrollees. However, 2023 would be too soon for states and AIPs to understand and modify their administrative systems and processes to meet the requirements. Additionally, even with the codified guidance, we believe states and D-SNPs would benefit from additional explanatory materials and other information given the complexities involved in moving toward greater integration on appeals and grievances.

We therefore recommend that CMS delay this requirement until CY 2024 to allow time for states and AIPs to understand and modify their administrative systems and processes to meet the requirements.

In addition, we recommend that CMS develop a "Unified Appeals and Grievances" guide or playbook. It could explain the general requirements of the proposal and explore operational issues and best practices for aspects of integrated appeals and grievances such as continuation of benefits, integrated notices, guiding enrollees on presenting evidence, integration with state Medicaid representation rules, the roles of assignees and representatives, proper handling of appeals involving episodes of care that combine services contracted through the plan with services provided outside the plan, time frames for processing payment requests and issuing authorizations, and integration of requests for reconsideration. This would be a valuable resource for both states and D-SNPs to ensure a streamlined enrollee experience and promote a common understanding of and compliance with the requirements.

F. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)

CMS proposes to revise the regulations on MOOP limits for MA plans, beginning in 2023. The proposal would require that all costs for Medicare Parts A and B services *accrued* under the plan benefit package count towards an enrollee's MOOP limit. CMS explains that the proposal would require MA plans to apply toward the enrollee's MOOP limit: 1) cost-sharing paid by any applicable secondary or supplemental insurance (e.g. Medicaid, employer(s), and commercial insurance) and 2) any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing. Those Medicaid cost-sharing limits include state Medicaid "lesser-of" secondary payment policies (which cap state cost-sharing payments to providers for certain Medicaid beneficiaries when Medicare and other payments exceed the Medicaid payment rate for a particular service); and cost-sharing protections that prohibit providers from billing unpaid Medicare cost-sharing to certain dually eligible individuals. In addition to tracking each enrollee's accrued out-of-pocket spending, MA plans would also be required to alert the enrollee and contracted providers when an enrollee's MOOP limit is reached.

This proposal would apply to all MA plans. Moreover, while the focus of the preamble discussion is on dual eligible enrollees, the language of the proposal would apply to all MA enrollees and cover all circumstances in which cost sharing is accrued but not actually incurred by the enrollees.

Discussion and Recommendations: Counting unpaid cost sharing amounts toward the MOOP limit will speed up the point in the plan year after which the MA plan pays 100 percent of the cost of covered Part A and B services for each enrollee. CMS' primary goals in putting forward the proposal appear to be: (1) reducing State Medicaid costs since the state agency would no longer be billed for any Medicare cost-sharing once an enrollee reaches the MOOP; and (2) allowing providers to increase their revenue as they would no longer be limited in their ability to collect cost sharing under a state's Medicaid "lesser-of" payment policy. CMS also provides additional justifications, such as providing "equal treatment" under the MOOP for dual eligibles and other MA enrollees; potentially increasing the willingness of providers who treat dual eligibles to participate in plan networks; and having a more uniform approach to calculating the MOOP across plans.

For the reasons discussed below, **we have very serious concerns with this proposal and we strongly urge CMS not to finalize it.** It could have adverse cost impacts on all MA plans, but those impacts would be particularly significant for D-SNPs. Those costs would result in higher premiums and/or reduced supplemental benefits that enrollees have come to rely on, including supplemental benefits that may not be available through an enrollee's Medicaid program and that can help overcome social barriers to health, provide adult dental coverage, etc. We also have serious questions about CMS' authority for imposing this requirement. In the following discussion, we provide detailed comments on the implications of the proposal for MA enrollees, providers, state Medicaid programs, MA plans and D-SNPs. **Again, we strongly urge CMS not to finalize it.**

- **Implications for MA Enrollees.** CMS estimates presented in Table 12 of the preamble project that implementation of the MOOP proposal would increase MA bids by $12.4 billion over ten years. The agency projects that it would increase Medicare program costs by $3.98 billion while creating estimated savings of approximately $2.7 billion for the federal share of Medicaid funding.

  Based on input from our members, we are concerned this may underestimate the actual impact on MA plans. As noted, the proposal is not limited to D-SNPs, nor is it limited to Medicaid cost sharing. It is broadly written, applying to all secondary or supplemental insurance that pays cost sharing for all enrollees.[19] We have significant concerns about the unknown risks and the range of potential unintended consequences that may result from such a broadly worded proposal. The result could be higher bids that reflect greater uncertainty about the cost of providing Medicare coverage because enrollees could progress more rapidly than expected to the MOOP limit. This would reduce rebate amounts available to all MA plans to fund supplemental benefits and reduce member cost sharing, with the result that all Medicare beneficiaries enrolled in MA plans would likely experience increases in their premiums and cost sharing and/or reductions in supplemental benefits. Also, the proportion of dual eligibles and MA enrollees with other secondary coverage in an MA-only plan can vary, so national averages could mask significant adverse impacts for certain plans serving larger populations of dual eligibles in certain geographies.

  The impacts on D-SNPs would be even more pronounced. Wakely Consulting Group analyzed the impacts of the CMS proposal on a sample of 2022 D-SNPs and concluded that their costs of Medicare Part A and B benefits in 2022 alone would increase by $23.90 PMPM (2.3%).[20] As with regular MA plans, the proposals would increase the cost of Part A and B benefits relative to a D-SNP's service area benchmarks, thereby reducing rebate savings. In D-SNPs, the reduction in rebate savings would decrease the amount and value of supplemental benefits available to enrollees. In addition, the Wakely analysis points out that the reductions in rebate savings would also make it more difficult for D-SNPs to reduce their Part D premiums. Many MA plans and most D-SNPs apply rebate savings to reduce their Part D premiums to an amount less than the Low-Income Premium Subsidy Amount (LIPSA), which ensures that their dual eligible enrollees do not have to pay a Part D premium. A D-SNP that could not achieve enough rebate savings to reduce its Part D premium to the LIPSA level would have to charge a premium, which would make that SNP unviable as a plan choice for dual eligibles from a competitive standpoint. It is not clear from the preamble that CMS has taken this impact into account.

  As noted above, CMS supports the proposal by indicating it would provide dually eligible MA enrollees with equal treatment as compared with how MOOP limits apply to Medicare-

[19] CMS indicates that its estimate in Table 12 was based on an analysis of data for dual eligible enrollees.
[20] Wakely Consulting Group analysis of CMS MOOP proposal conducted for AHIP; February 2022.

only enrollees. However, dual eligibles in MA plans are in fact treated differently than other MA enrollees under federal law. For dual eligibles, Medicaid pays for the cost sharing that other MA enrollees are required to pay and holds dual eligibles harmless from balance billing for amounts not paid by the state or its delegates. Given their lack of cost sharing obligations, dual eligibles receive little or no direct benefit from the MOOP provision. Accordingly, we see no reason why "equal treatment" with respect to the MOOP limit justifies the proposal.

- **Implications for Providers.** As noted, a key goal of the proposal is to increase revenue for providers that serve dual eligible enrollees by increasing services covered exclusively under a SNP's Medicare benefit and thereby reducing services for which providers cannot collect enrollee cost sharing due to state Medicaid limits. CMS says that it believes the result will "mitigate existing provider payment disincentives related to serving dually eligible MA enrollees." The agency speculates that this could "improve access to providers, including specialists, who currently limit the number of dually eligible MA enrollees they serve or decline to contract with D-SNPs."

  We have several concerns with this justification for the proposal.

  – D-SNPs and MA-only plans must meet CMS' MA network access and adequacy requirements on an ongoing basis. CMS does not present any data or other evidence in the Proposed Rule to support their concern that dual eligible enrollees are experiencing problems with access. Given the significant potential impacts on D-SNP costs and the availability of supplemental benefits, CMS should provide factual support for this proposal.
  – CMS primarily claimed authority for establishing MA plan MOOP limits in the April 2011 rule referenced in the preamble based on the provisions of SSA section 1852(b)(1). Those provisions prohibit plan designs and benefits that would substantially discourage enrollment by certain individuals. Again, CMS presents no evidence that provider revenues are having any impact on enrollment in D-SNPs, and certainly no evidence that they are "substantially" discouraging enrollment. Accordingly, it is not appropriate for CMS to use the MOOP rule to increase provider payments.
  – We are concerned that the proposal creates an incentive for providers to render an increased number of services at the beginning of the plan year so as to hasten an enrollee's progress toward the MOOP limit, after which the provider will receive 100% of the Medicare contracted rate. As a result, some percentage of those services could be duplicative or not medically necessary. This would not only exacerbate the cost impacts of the proposal on Medicare but could also jeopardize federal, state, and MA plan initiatives to increase the number and financial impact of value-based arrangements in place with providers.

- **Implications for State Medicaid Programs.** As noted above, one of the explicit goals of the proposal is to shift costs from Medicaid to Medicare by speeding up the point at which D-

SNPs would be obligated to cover 100% of Part A and Part B costs. In other words, the proposal by its terms is designed to provide a net subsidy of Medicaid by the Medicare program. CMS notes that, if implemented, the MOOP proposal would create estimated savings of $2.7 billion for the federal share of Medicaid. Based on that number, we infer that state Medicaid programs would also realize an estimated savings of $1.7 billion. CMS concedes that these amounts would be considered transfers from the Medicare Trust Fund to the states. However, it's unclear whether those estimates adequately account for the reductions in rebate savings available to MA plans, making it more difficult for them to reduce cost sharing, provide supplemental benefits, and reduce Part D premiums to the LIPSA level.

Under federal law, Medicaid coverage of Medicare cost sharing for dual eligibles is the responsibility of Medicaid. Consistent with that fact, policies governing disbursement of Medicaid funds to pay Medicare cost sharing for dual eligible enrollees should be determined by states in their discretion within the 42 CFR 438 regulatory framework under Title XIX. States that decide to adopt the flexibilities provided by the DRA to use the "lesser of" methodology in calculating Medicaid payments for Medicare cost sharing make that decision in the context of a state legislative and political environment in which providers and other stakeholders could advocate with the state legislature and/or state administration for changes in the state's payment policy if desired. However, the CMS proposal interferes with those decisions in the Medicaid program and instead shifts the resulting costs of the proposal to the Medicare program and MA plans, especially D-SNPs.

D-SNPs operate under both federal authority as MA plans and under state authority, as each D-SNP is required to contract with the state Medicaid agency. As CMS describes in the Proposed Rule:

> "Section 164 of MIPPA amended section 1859(f) of the Act to require that each D-SNP contract with the State Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. Implementing regulations are codified at § 422.107. Notwithstanding this State contracting requirement for D-SNPs, section 164(c)(4) of MIPPA does not obligate a State to contract with a D-SNP, which therefore provides States with significant control over the availability of D-SNPs in their markets. The State's discretion to contract with D-SNPs, combined with the State's control over its Medicaid program, creates flexibility to require greater integration of Medicare and Medicaid benefits from the D-SNPs that operate in the State."

Through the authority established under MIPPA, Congress gave states the discretion and ability to contract with D-SNPs and implement state payment policies through D-SNPs, and authority to direct D-SNPs as to how they should administer payments of Medicaid-covered services, including at the state's option, payment of Medicare cost sharing. Under the SMAC or "MIPPA agreement" required of each D-SNP, the state has the ability to specify the methods a D-SNP will use in administering Medicaid payments of Medicare cost sharing. Given the deference that CMS generally affords to states in structuring the details of the SMACs, we believe that acknowledging state authority over administration of Medicaid

payments for Medicare cost sharing would be consistent with the authority granted states under MIPPA. We question whether CMS can propose a change in Medicare regulations that would supersede the authority granted to states by MIPPA.

As we noted in our comments on the request for comments on "Capitated Medicare Cost-Sharing for All D-SNPs", should the MOOP proposal be applied to D-SNPs, there is also a concern that many D-SNPs would be subject to a reimbursement gap, in which their payments of Medicare cost sharing would be projected and valued in the plan bid according to the Medicare rules, but the state's capitation or reimbursement to the D-SNP would be calculated using the DRA "lesser of" methodology.

- **Regulatory Authority.** MA plans appreciate that MOOP limits are an important benefit for their enrollees. It is one of the key features in which the MA program distinguishes itself from the Original Medicare program, which has no MOOP limits. The fact that MA plans can offer MOOP limits while still providing 98% of Medicare beneficiaries[14] with access to $0 premium MA plans, and provide $123.36 PMPM[21] in supplemental benefits on average, demonstrates the value and cost effectiveness of the MA program.

  That said, the authority for CMS to impose a mandatory MOOP limit on all MA plans is questionable. There is no statutory mandate that requires MOOP limits for most MA plans. Moreover, the statute is not merely silent on MOOP limits in MA; it actually applies MOOP limits only to MA regional plans (SSA section 1858(b)(2)) while not applying MOOP limits to local MA plans. The fact Congress applied MOOP limits to one type of MA plan and not to other types suggests that CMS authority to impose MOOP obligations on these other types of MA plans is limited, at best. Any changes – like the proposal here – that build additional costs and obligations around a MOOP limit with such questionable authority make it more important to assess whether such a requirement is consistent with statutory requirements.

  Further, we note again that the key objectives of the MOOP proposal relate to increasing provider payments and reducing Medicaid costs. By contrast, the primary statutory basis under which CMS has justified the application of a MOOP limit to MA plans is avoiding plan designs or benefits that discourage enrollment. CMS does not present any data or other evidence to support the notion that current MOOP policies discourage enrollment by MA-only or dual eligible individuals in MA plans (the criteria set forth in SSA section 1852(b)(1)(A)). This raises further questions about the authority for this particular proposal.

Discussion and Recommendations: For the numerous reasons noted above, we urge CMS to abandon its proposal to revise the basis for calculation of MOOP limits. The circumstances do not warrant the change and the change is not supported by the authorities granted CMS in the SSA. The proposal would use the Medicare program to subsidize Medicaid

[21] Avalere analysis, October 2021; accessed at https://avalere.com/insights/more-medicare-advantage-plans-will-offer-non-medical-benefits-in-2022.

costs, increase Medicare expenditures at a time in which there is significant concern about the long-term solvency of the program, and increase the costs of the MA program for enrollees, threatening benefits and stability for dually eligible enrollees. Furthermore, given that the objective of the proposal is to improve practices relating to Medicaid coverage of Medicare cost sharing, it would be more appropriate for CMS to consider changes to the Medicaid program regulations instead of in MA. **However, if CMS decides to implement the amendment despite the significant concerns discussed above, states and MA plans will need additional time to work through the operational and contractual details of the amendment and consider the impacts on bid development, so we request that CMS not require compliance earlier than plan year 2025.**

G. Comment Solicitation on Coordination of Medicaid and MA Supplemental Benefits

CMS seeks comments on several different approaches to coordinating Medicaid services with MA plan supplemental benefits. While any of the approaches is potentially workable, most involve significant levels of data exchange, particularly when Medicaid benefits are administered through FFS arrangements.

Recommendation: We conclude that the most efficient and effective model for coordination is through a state capitation contract that integrates both Medicare and Medicaid services through D-SNPs. Through such arrangements, the state and D-SNPs can align and agree on the relationship and precedence between MA supplemental benefits and related Medicaid benefits. However, it is important that the value of benefits such as capitation for coverage of Medicare cost sharing be adequately projected and reflected in the capitation rates consistent with principles of actuarial soundness.

H. Converting MMPs to Integrated D-SNPs

CMS indicates that if it finalizes its proposals regarding D-SNPs, it plans to engage with the states participating in the Financial Alignment Demonstrations during CY 2022 to develop a plan for eventually converting MMPs to integrated D-SNPs.

Recommendations: We support the eventual phase-out of MMPs and a thoughtful, deliberate transition to a more far-reaching D-SNP program. Over the long term, we believe this proposal ultimately will help streamline integrated models and will eliminate the "demonstration" status of integrated plans for dual eligibles. **However, we recommend that CMS provide additional details on this proposal**, including a timeline that allows states, MMPs and D-SNPs a sufficient runway for conversion of operations and membership, and integration of lessons learned from the demonstrations into the SNP model. CMS should require existing MMP states to establish end dates for their MMP demonstrations that reflect an adequate transition period of at least two years to ensure that MMP enrollees experience seamless and easy transitions from their MMP model to a successor FIDE or HIDE SNP model. In some cases, we note that states may need the flexibility to extend their demonstrations to achieve that

objective. **In addition, workgroups consisting of CMS, state, MMP and D-SNP staff would provide an opportunity for collaborative discussion, planning and implementation of the transformation.** With significant planning and coordination, CMS, states and plans can align on a transition path that (1) ensures appropriate outreach and education, (2) minimizes discrepancies in messaging to enrollees and providers, (3) resolves operational and administrative issues that could delay or complicate transitions; and 4) ensures a smooth and successful transition.

III. Special Requirements During a Disaster or Emergency (§ 422.100(m))

CMS proposes to clarify the period of time during which MAOs must comply with special regulatory requirements (e.g., waiver of gatekeeper referrals, required coverage for services provided by non-contracted providers) that apply during (and for a 30-day transition period, after) a disaster or emergency period, including a PHE. CMS also proposes to specify that there must be a disruption in access to health care, in addition to a disaster or emergency declaration, in order to trigger the special requirements. Under the proposal, the special requirements would apply for 30 days after the later of the end of the disruption of access to health care, and the end of the disaster or emergency. In general, a disruption in access to health care would be defined as an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MAOs to fail to meet the prevailing patterns of community health care delivery in the service area.

Discussion and Recommendations: We appreciate CMS' plans to clarify the period of time during which MAOs must comply with special requirements to ensure access for enrollees to covered services throughout a disaster or emergency period. We support the proposal to explicitly limit application of the special requirements to disruptions in access to health care, and the 30-day transition period for enrollees to return to in-network providers.

We also have the following special coverage related recommendations:

- CMS should ensure that the final regulations support good faith, reasonable assessments made by plans related to the provision of special coverage. We agree with CMS that MAOs are in the best position, due to their knowledge and understanding of their enrollees and service areas, to reasonably assess whether a disaster or emergency is disrupting access to health care.
- CMS should engage with plans on considering alignment of events that trigger special coverage rules with Star Ratings disaster relief adjustments that take into account the effects of extreme and uncontrollable circumstances, which occur during the Star Ratings measurement period.
- We also appreciate and support CMS' intention to issue sub-regulatory guidance for MAOs on this topic. We ask CMS to provide sub-regulatory guidance in draft form with a meaningful opportunity for review and comment.

- To promote common understanding about CMS' expectations and future development of more objective criteria, the agency should engage with MA plans about their experiences and consider other factors such as Federal Emergency Management Agency (FEMA) and state declaration criteria.

IV. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

Beginning with the CY 2024 application cycle, CMS proposes to require applicants for new and expanding MA service areas to demonstrate that they meet network adequacy standards for the service areas as part of the application. CMS also proposes to provide the applicants with a 10-percentage point credit toward the percentage of beneficiaries residing within published time and distance standards for the proposed network. The 10-percentage point credit would apply only for the duration of the application review; MAOs would need to be in full compliance with network adequacy requirements at the beginning of the applicable contract year. The proposal changes current rules that require applicants to attest to the adequacy of networks at the time of application for a new or expanding service area, and then have CMS evaluate compliance through a triggering event or triennial network review process. CMS indicates the proposal is needed to address bidding-related and compliance issues. CMS also indicates that plans would have the opportunity to submit exception requests from the network adequacy standards, as provided under current rules.

Discussion and Recommendations: We appreciate and support CMS' proposal to automatically apply a 10-percentage point credit towards an applicant meeting the network adequacy requirements for the pending service area, at the time of application and for the duration of the application review. However, we are concerned that even with the 10-percentage point credit, there may be circumstances, particularly in rural and medically underserved areas, where it will be challenging for an applicant to have a full network in place in a new service area almost one year prior to the beginning of the contract year. As noted below, we have longstanding concerns about the ability of the current exceptions process to address legitimate network challenges in certain geographies. Accordingly, if CMS moves forward with this proposal, plans will need more flexibility and time to build their provider networks and/or seek exceptions under certain circumstances before the start of the contract year. **We therefore strongly recommend that in addition to the automatic 10-percentage point credit, CMS should create a process to allow plans to submit letters of intent to meet network adequacy requirements with their application along with a request to apply for additional time and credits.** Additional time and credits may be necessary, especially in cases when meeting the network adequacy requirements for all provider types at the time of or during the application process is challenging due to provider/facility shortages, ongoing negotiations with a provider that has large market share, as well as other factors including those considered under the exceptions process.

We also ask CMS to engage with AHIP and our members to consider improvements to the current network adequacy exceptions criteria and process. We believe the exceptions criteria

and process should be modified to better accommodate increased use of high-value provider networks, integrated care delivery systems, and personalized care access options, especially for rural and underserved service areas. We request that CMS consider the above-mentioned factors as well as others including cases where good faith negotiations have been attempted, but the provider is unwilling to negotiate on reasonable terms.

V. Part C and Part D Quality Rating System

Due to the impacts of COVID-19, CMS proposes to make a technical change to the disaster relief policy by eliminating the 60 percent rule for 2023 Star Ratings for the three Health Outcomes Survey (HOS) measures: Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control. CMS also notes it intends, in a future final rule, to address Star Ratings changes and comments the agency received in response to the March 31, 2020 COVID-19 IFC and the September 2, 2020 COVID-19 IFC.

Discussion and Recommendations: We support CMS' proposed change to the Star Ratings disaster relief methodology for the three HOS measures to enable the agency to calculate these measures for the 2023 Star Ratings and include them in the 2023 reward factor calculation.

We note however, that on August 5, 2021, CMS decided to move two HOS outcome measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, to the display page for 2022 and 2023 Star Ratings due to data integrity issues related to COVID-19. We remain concerned about the impact of COVID-19 on all of the Star Ratings measures, including the three HOS measures addressed in this Proposed Rule**. We urge CMS to closely review potential data anomalies for these three HOS measures, and if any are uncovered, we recommend these measures also be removed from the 2023 Star Ratings.**

In addition, we appreciate CMS' statement that it intends additional rulemaking in response to comments submitted to the March and September 2020 IFCs. We believe such guidance is critically important given some of the key issues we and others raised in our comments. For example, the COVID-19 PHE has still not ended. During the 2021 measurement year the country experienced the spread of the Delta variant and the surge of the Omicron variant, both of which impacted patients' desire to seek care and/or access to care. As a result, provider and plan performance on a variety of measures including those focused on health care delivery, utilization, patient experience, and outcomes have been affected. And these impacts vary due to geographic differences in COVID-19 infections rates and restrictions as well as other factors including stay-at-home recommendations, provider and staff shortages and office closures, rescheduling or delay of services, suspensions of elective procedures, and supply chain issues. **We therefore continue to urge CMS to extend its COVID-19 disaster relief policy and special rules through an IFC to all applicable measures for 2023 Star Ratings.** This policy extension would provide needed stability to ensure plans, their network providers, and the affordable benefit offerings and options they provide to their enrollees are not adversely affected.

Our members have also seen reductions in patient experience survey response rates throughout the pandemic. Lower response rates could adversely affect plan and provider performance on patient experience survey measures. Virtual visits may also have an impact on CAHPS survey results, as beneficiaries completing CAHPS surveys may not consider telephone and video services with clinicians when answering the survey questions. Although the initial instructions for the CAHPS survey do ask responding beneficiaries to consider health care services received through a variety of methods, including by video or telephone, these instructions are fairly new. We are concerned that unlike other CAHPS surveys, not all questions for the MA survey have been updated to align with the initial instructions on virtual visits. This new instruction and method for receiving care combined with the lack of consistency in language about virtual visits throughout the survey could be confusing or misleading to Medicare beneficiaries and impact the reliability of their survey responses. While we appreciate CMS adding in telehealth as a modality for health care services, we have concerns about interpretation and alignment across CAHPS survey versions.

We also remain concerned about other aspects of the CAHPS methodology such as the impact of the tight clustering of CAHPS measure cut points. MA contracts with marginally different performance can receive measure scores that are several star levels apart.[22] **Because of concerns about lower response rates, other methodological issues and negative impacts of the pandemic we have raised above, we urge CMS through an IFC to maintain the weighting of patient experience/complaints and access measures at 2 (including for the improvement measure calculation) for 2023 Star Ratings.** We also ask CMS to closely review the comments submitted by AHIP members that describe in more detail the impacts of COVID-19 on CAHPS and other measures for 2023 Star Ratings.

We would like to take this opportunity to highlight our previous recommendations for improving the Star Ratings program:

- **COVID-19 Stars Data Analysis**. We ask that CMS analyze and share data and findings on the impact of COVID-19 on plan performance across the categories of Star Ratings measures (e.g., HEDIS, HOS, CAHPS) to promote transparency and inform additional Star Ratings changes.

- **CAHPS Methodology Improvements**. AHIP and our members welcome the opportunity to collaborate with CMS to improve the CAHPS methodology including changes that would ensure meaningful differences between cut points, appropriate weighting of measures, and improvements to survey response rates.

[22] For example, the difference between a 1 Star rating and a 5 Star rating for the CAHPS customer service measure in the 2022 Star Ratings was only 5 percentage points (a score of less than 88 percent for 1 Star and greater than or equal to 92 percent for 5 Stars).

- **Disaster Relief Policy Considerations**. We support consideration of enhancements to the disaster relief policy including extending the policy to cover a wider range of local and federal disaster or emergency declarations and providing relief for plans subjected to a disaster than spans more than one year and for new plans impacted by a disaster or emergency during their first year of ratings, while not adversely impacting unaffected plans.

- **CAI Methodology Support and Improvements**. We continue to support the use of the Categorical Adjustment Index (CAI) methodology and welcome engagement with CMS to address volatility some plans have experienced in their scores from year to year and consider other changes to ensure this adjustment is more impactful.

- **Health Equity Measures and Measurement**. AHIP and our members look forward to ongoing engagement with CMS on initiatives to advance health equity for Medicare beneficiaries. We have provided feedback to CMS on future health equity measures and concepts for the Star Ratings program in our comments on the CY 2023 Advance Rate Notice.

- **Cut Points Methodology Improvements**. To ensure more predictability and stability in the Star Ratings program, we continue to recommend CMS consider setting cut points for Star Ratings measures well in advance of the measurement period. Additionally, we ask that CMS delay implementing a change to the cut point methodology scheduled to take effect for 2024 Star Ratings that would exclude performance "outliers" when setting cut points. Such a change should not be considered until concerns with the methodology are addressed and the agency ensures cut points reflect meaningful differences.

We appreciate CMS' consideration of our recommendations for improving the Star Ratings program. AHIP continues to strongly support the overall design of the Star Ratings program, which incentivizes plans to achieve high performance on quality and plays a vital role in helping millions of diverse individuals continue to have access to high-quality, coordinated care, affordable benefit offerings, and options they deserve and rely on. We look forward to working with CMS to support and improve this important program for Medicare consumers.

VI. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505)

CMS proposes to add three additional bases for denial of applications for new contracts or service area expansions based on past performance reviews. Those new bases are low Star Ratings (2.5 or below), bankruptcy issues, and thirteen or more compliance action points. While CMS is not yet considering including civil money penalties (CMPs) as a basis for an application denial, the agency is soliciting input on how to factor CMPs into the past performance methodology.

Discussion and Recommendations: We oppose adding more reasons for application denials into the past performance methodology. The proposed changes regarding Star Ratings may be

unfair and unnecessary; there are a number of important questions not addressed in the proposal; and if adopted, the proposal would potentially have adverse and uneven impacts on plans, including possibly high-performing plans, and the beneficiaries they serve.

As CMS notes, in the January 2021 final rule, the agency considered but did not finalize a proposal to include low Star Ratings as a basis for rejecting applications. CMS concluded at that time it was unnecessary to deny applications based on one year of low Star Ratings given the agency's other enforcement tools. We believe that rationale is still correct. We also note that one year of low performance does not necessarily equate to a low performing organization. Low Star Ratings scores could be the result of recent changes to the Star Ratings measures and methodologies or events not under the control of the plan, including the impacts of COVID-19. Furthermore, plans that receive Star Ratings of 2.5 are already incented to improve performance for their beneficiaries, quality bonus payments and a better rating on Medicare Plan Finder to retain and attract more beneficiaries. Accordingly, **while we recommend CMS reject this proposal as it did in 2021, if CMS were to finalize low Star Ratings as a basis for an application denial, we urge the agency at a minimum to consider low overall Star Ratings (2.5 or lower) at the contract level for two consecutive years for the past performance review.**

We also have critical methodological questions and concerns which would impact application of all three additional denial reasons that CMS proposes to adopt. **We further recommend the following issues be addressed in additional rulemaking if CMS were to move forward with the proposal.**

- It is unclear whether CMS will consider the three additional bases for an application denial at the contract, legal entity, or parent organization level. The higher the level of application, the greater the potential ramifications to beneficiaries and their plan choices, including access to high-performing plans.
- The effective date of the proposal should be prospective, i.e., cover performance review periods after the proposal is finalized. If CMS were to finalize its proposal for CY 2023, the twelve-month look back period for performance reviews would be 2022. As a general matter CMS should always implement proposals only on a prospective basis, consistent with the requirements of SSA section 1871(e)(1)(A). A retrospective application of this proposal is also problematic since a 2022 performance period would be adversely affected by the ongoing pandemic.

Finally, given these concerns, if CMS were to move forward with any of the bases the agency is proposing, we recommend that CMS provide plans with a mitigation/remediation opportunity (e.g., implementation of a corrective action plan) and incorporate an appeals process as part of its plan performance review process.

VII. Marketing and Communications Requirements on MA and Part D Plans to Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267, and 423.2267)

CMS proposes to codify several pre-existing sub-regulatory requirements, including provisions relating to Member ID cards, preferred pharmacy disclaimers, and website information related to appointing a representative.

CMS also proposes to reinstitute a previous requirement to include a multi-language insert regarding the availability of free interpreter services for specified required materials. The required statement must be provided in the top fifteen languages spoken in the United States, as specified by CMS, plus additional languages that are the primary languages of at least 5 percent of individuals in a plan's service area.

The proposal further applies new requirements related to TPMOs used by MA or Part D plans. They include:

- A new standardized disclaimer on websites, marketing materials, and in interactions with beneficiaries;
- New TPMO oversight requirements for MA and Part D plans, including: mandated TPMO disclosures to plans regarding subcontracted relationships used for marketing, lead generation, and enrollment; TPMO recording of calls with beneficiaries; and monthly reports to plans of staff disciplinary actions associated with beneficiary interactions; and
- New beneficiary notification requirements for TPMOs when conducting lead generating activities.

In addition, under the proposal plans doing business with a TPMO (either directly or through a downstream entity) would be responsible for ensuring TPMO compliance with any requirements that apply to the plan. CMS indicates this obligation extends to instances where a plan (or its downstream entity) does not contract with the TPMO but merely "purchases leads or otherwise receives leads directly or indirectly from a TPMO."

Discussion and Recommendations:

- **Multi-Language Insert Document. We appreciate and support CMS' goal to improve beneficiary materials and make them more accessible to all beneficiaries.** We believe the multi-language insert document that informs beneficiaries about interpreter services in multiple languages is helpful. However, sending the document every time a beneficiary receives CMS required material may prove redundant for the beneficiary and create unnecessary costs. **We ask CMS to consider limiting the requirement for plans to send the document to once per year with the ANOC. If CMS finalizes its proposal on the multi-language insert document for CY 2023, we recommend the final model document and related requirements be provided to plans no later than May 2022 to provide plans with sufficient lead time to operationalize this change prior to the 2023 annual open**

enrollment period. To promote efficiencies, we also ask that CMS consider permitting plans to continue using their existing multi-language notice/insert document for CY 2023, subject to CMS review and approval.

- **TPMOs. AHIP supports CMS' goal to protect beneficiaries from misleading advertising and to reduce consumer confusion and abrasion.** We also support CMS' proposal to require the use of a disclaimer by TPMOs, although we recommend CMS provide flexibility for plans to modify the standardized disclaimer to improve readability and understanding, subject to CMS approval. However, we are concerned with the proposal to require plan oversight of TPMOs, and to otherwise hold plans responsible for TPMO compliance with marketing rules, when the plans or their downstream entities do not contract with the TPMOs. Plans are already responsible for ensuring compliance with CMS' marketing and communications regulations. This includes monitoring and overseeing the activities of their subcontractors, downstream entities, and/or delegated entities.[23] Without a contractual relationship, plans would have difficulty monitoring or ensuring compliance of a third party with CMS' rules. **As such, we recommend CMS not finalize the proposed plan oversight requirements for TPMOs for CY 2023. As an initial step, we recommend CMS engage with AHIP, MA plans, the States, agents and brokers, TPMOs, and beneficiary advocates to discuss and address marketing-related concerns before proposing specific requirements related to plan oversight obligations.** If CMS were to finalize its proposed oversight requirements, we ask that they be limited to TPMOs that plans have a direct relationship with that conduct marketing and, potentially, enrollment activities on their behalf.

VIII. Proposed Regulatory Changes to Medicare Medical Loss Ratio Reporting Requirements and Release of Part C Medical Loss Ratio Data (§§ 422.2460, 422.2490, and 423.2460)

CMS proposes to modify the medical loss ratio (MLR) reporting requirements for MA and Part D plans to require more detailed reporting. For calendar years (CYs) 2014 through 2017, plans were required to report detailed information on components of medical costs (numerator) and plan revenues (denominator) using the MLR Reporting Tool, a CMS-developed tool. Beginning with CY 2018, CMS significantly reduced the number of elements plans were required to report. In this rule, CMS proposes to return to the more detailed reporting requirements in place prior to CY 2018, and to use the MLR Reporting Tool for such reporting, with some modifications.

CMS also proposes to expand reporting requirements for medical cost information. If this provision is finalized as proposed, plans will report medical cost information for services covered under Medicare Parts A or B, including amounts paid to reduce cost sharing for such services or enhance such coverage, Part D prescription drug costs, and separately report cost

[23] Medicare Communications and Marketing Guidelines. https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.

information for each of 18 categories of supplemental benefits. The supplemental benefit categories CMS proposes to include in the MLR Reporting Tool are:

Dental	Routine Foot Care
Vision	Out-of-Network Services
Hearing	Acupuncture Treatments
Transportation	Chiropractic Care
Fitness Benefit	Personal Emergency Response System
Worldwide Coverage/ Visitor Travel	Health Education
Over the Counter Items	Smoking and Tobacco Cessation Counseling
Remote Access Technologies	All Other Primarily Health Related Supplemental Benefits
Meals	Non-Primarily Health Related Items that are Special Supplemental Benefits for the Chronically Ill

Finally, CMS proposes to modify MLR regulations to specify that a plan may resubmit an MLR report or MLR data, at CMS' direction, in order to correct the prior MLR report or data submission.

Discussion and Recommendations: AHIP does not support the return to detailed MLR reporting requirements and does not believe requiring more detailed reporting will affect the likelihood a plan will fail to meet the MLR threshold in a particular year. MLR reporting takes place well after the end of a payment year and the way in which reporting takes place does not affect plan revenues or costs in any way. As CMS points out in the Proposed Rule, plans must already account for all revenues, medical claims and quality improvement activity costs, and administrative expenditures in order to track MLR performance. Requiring that detailed information be reported to CMS and publicly released will not affect the actual components of the MLR but as discussed below, will threaten the confidentiality of proprietary information and lead to confusion for users of CMS data.

AHIP is particularly concerned with CMS' proposal to require plans to report detailed cost information about different types of supplemental benefits. CMS' proposal assumes all plan designs structure supplemental benefits in a consistent way, which is not always the case. While

plans must track detailed information about the revenue and costs that affect MLR calculations, plans do not necessarily track the information according to the categories CMS is proposing to use. Plans may use financial accounting systems that track supplemental benefits generally. Converting these systems to mirror CMS' proposed reporting scheme would be expensive and time-consuming.

Additionally, requiring that such detailed information be reported to CMS and included in public release of MLR data will hinder competition in the MA market. Supplemental benefits are a key factor in driving competition among MA plans. Revealing detailed information about plan expenditures for such benefits threatens to compromise such competition by laying bare the distribution of plan spending across benefit categories. Furthermore, public release of data on CMS-defined categories of supplemental benefits suggests that such benefit categories represent comparable services or cost structures across plans, which may not be true. Rather than providing meaningful information to users, the data will create misunderstanding and confusion about supplemental benefits.

We therefore urge CMS to withdraw its proposal to return to detailed MLR reporting requirements and require more detailed reporting on supplemental benefits. If CMS does move forward with this proposal, we urge the agency to allow more time for plans to implement the necessary accounting changes to meet new reporting requirements. Finally, we recommend that CMS not include data on specific supplemental categories in publicly-released MLR data.

IX. Requests for Information

A. Request for Information: Prior Authorization for Hospital Transfers to Post-Acute Care Settings during a Public Health Emergency

CMS requests input from MAOs and other affected stakeholders regarding the effects of both the relaxation of and reinstatement of prior authorizations on patient transfers during a PHE.

Discussion and Recommendations: We thank CMS for the opportunity to provide input on this topic. Patients should receive clinically effective, evidence-based, high-value care. Prior authorization is a valuable tool to ensure that patients receive safe, affordable, effective care. We appreciate that CMS has repeatedly recognized prior authorization as an important tool to protect patients and has taken a number of actions to thoughtfully expand its use under Original Medicare. We believe that it is important to work together to ensure these processes work as effectively as possible, which is why health insurance providers are continually improving prior authorization programs to reduce physician and enrollee burdens and improve outcomes for patients.

AHIP and our members are committed to improving the prior authorization process for enrollees and their providers. In January 2020, AHIP launched its Fast Prior Authorization Technology

Highway (Fast PATH) initiative to better understand the impact of electronic prior authorization (ePA) on the prior authorization process.[24] In March 2021, AHIP publicly announced and shared the findings from our Fast PATH initiative.[25] AHIP's initiative demonstrated that providers who are high users of the ePA technology experience the greatest benefit. The benefits include faster time to a decision following a prior authorization request, greater transparency of information on what drugs or services require prior authorization, less time spent on phone calls and faxes related to prior authorization, and improved provider and patient experience. It is also clear that to maximize the efficiencies of ePA, strong provider adoption of the technology solution is critical.

To further realize the benefits of prior authorization, AHIP has recommended additional pathways be explored to increase provider adoption of ePA technology. These pathways could include a combination of: (1) increasing the availability of the technology enabling electronic prior authorization to providers; and (2) increasing the use of the technology where it is already available by identifying and addressing challenges, such as provider readiness and training, workflow integration, and incentives for providers to use the technology.[26]

AHIP recognizes that health care providers continue to be under enormous pressure and stress during the COVID-19 pandemic. And the infection rates and unpredictability of COVID-19 surges has only exacerbated hospital, health system and provider capacity. Throughout the COVID-19 pandemic, health plans have worked closely with their network providers to ensure that prior authorizations did not pose administrative and clinical concerns for providers and patients. Patient transfer delays have been caused by a number of factors including staffing shortages, lack of availability of post-acute beds as well as other factors outside the control of plans or providers.

AHIP members have partnered with hospitals to build capacity and have taken steps to simplify and accelerate the transfer and discharge of patients from hospitals to the safest, clinically appropriate setting of care. Patients who can be treated safely in alternate sites of care for post-acute care services have been quickly moved to those facilities. Plans have used a variety of approaches including temporarily suspending or relaxing prior authorization requirements where inpatient capacity is most compromised and most at risk. **AHIP's members continue to partner with their network providers to mitigate and resolve health care delivery impacts. To help support these efforts, we recommend CMS continue to provide MA plans with COVID-19 policy flexibilities, including those related to use of prior authorization and other tools for ensuring that patients receive safe and appropriate care.**

---

[24] AHIP FAST Path Initiative. January 2020. Available online at: https://www.ahip.org/new-fast-path-initiative-aims-to-improve-prior-authorization-for-patients-and-doctors/.
[25] AHIP FAST Path Key Findings. March 2021. Available online at: https://www.ahip.org/prior-authorization-helping-patients-receive-safe-effective-and-appropriate-care/.
[26] AHIP FAST Path Key Findings. March 2021. Available online at: https://www.ahip.org/prior-authorization-helping-patients-receive-safe-effective-and-appropriate-care/.

B. Request for Information: Building Behavioral Health Specialties within MA Networks

CMS seeks information on challenges MAOs face when building an adequate network of behavioral health providers and suggestions on how to address issues with building adequate behavioral health networks within MA plans.

Discussions and Recommendations: We appreciate CMS' dedication to ensuring that MA beneficiaries have access to behavioral health services. Health insurance providers are committed to ensuring access to quality, affordable behavioral health care, including both mental health care and treatment for substance use disorders in the context of whole-person care. Health insurance providers have been leaders in supporting access to telehealth, inclusive of tele-behavioral health services, the need for which has been accelerated by the pandemic. Health insurance providers have also increasingly implemented approaches to integrate behavioral health into primary care as a strategy to improve both access and quality.

Challenges exist for building behavioral health specialties within plan networks, the most significant of which is the national shortage of behavioral health providers. A March 2021 Government Accountability Office report[27] on patient access to behavioral health noted the longstanding workforce shortages and health system capacity issues that have only been exacerbated by an increased demand for services during the COVID-19 pandemic. The Health Resources & Services Administration also projects that by 2030, there will be a 20 percent decrease in the supply of adult psychiatrists.[28]

In addition to addressing the overall shortage of behavioral health providers, we also believe it is important to have diverse provider networks that reflect communities served so that individuals can find providers that meet their preferences and needs to receive culturally competent and patient-centered care. This not only includes provider and practitioner demographic diversity but also diversity of staff and care team members who have varied living experiences to build empathic relationships with patients. Many of the strategies to address the overall workforce shortage can be targeted also to increase diversity in the behavioral health workforce. These strategies include, for example, expansion of loan repayment and scholarship programs that help incentivize providers to enter the health care field and serve in underserved areas (such as National Health Service Corps or Nurse Corps). To help individuals know the demographic diversity of behavioral health providers available to them and find someone that they feel comfortable seeing for care, it is important to collect provider demographic data (on a voluntary basis). This voluntary provider data should be collected in a streamlined manner and securely stored in national or state databases to serve as "single sources of truth". Potential data collection vehicles for provider demographic data include state medical licensure boards or the CMS National Provider and Plan Enumeration System (NPPES).

---

[27] https://www.gao.gov/assets/gao-21-437r.pdf.
[28] Behavioral Health Workforce Projections | Bureau of Health Workforce (hrsa.gov).

In the face of this national shortage of behavioral health providers, health plans are using a range of strategies and approaches to promote access to behavioral health care and maximize the existing workforce. These include: active recruitment of behavioral health providers for their networks, use of health risk assessments and case managers to proactively identify members who may be at risk for behavioral health conditions and engage them in treatment before more serious conditions develop, leveraging tele-behavioral health to provide convenient access to treatment for patients, and promoting team-based care that leverages the full range of behavioral health provider types, including by integrating behavioral health with primary care to build on existing relationships most patients have with their primary care providers.[29]

To increase beneficiary access to behavioral health services, AHIP recommends that CMS support the following policies that provide incentives for individuals to enter the behavioral health field and improve both the supply and diversity of the behavioral health workforce.

- Increase of the number of graduate medical education (GME) slots allotted to behavioral health providers and expanding loan repayment and scholarship programs.
- Emphasis in training programs on behavioral health treatment specific to the Medicare population due to the chronic nature of the behavioral health illnesses and the changing physiology of people as they grow older.
- Support for team-based care to improve access and maximize the existing workforce by exploring alternative payment models through the Center for Medicare & Medicaid Innovation that support behavioral health integration.
- Expansion of the behavioral health provider types covered under Medicare who can help deliver care in integrated settings, such as certified peer support specialists, licensed professional counselors, and licensed mental health counselors.

We welcome the opportunity to engage with CMS and other stakeholders to identify additional avenues to increase and support the behavioral health work force.

[29] https://www.ahip.org/resources/issue-brief-integrating-behavioral-health-and-primary-care-2.