AMERICA'S PHYSICIAN GROUPS

January 5, 2024

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

Submitted via https://www.regulations.gov/commenton/CMS-2023-0187-0001

Re: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4205-P)

Dear Administrator Brooks-LaSure:

America's Physician Groups (APG) appreciates the opportunity to respond to the proposed rule from the Centers for Medicare & Medicaid Services (CMS) on Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications. APG welcomes your agency's openness to stakeholder input and ongoing commitment to improving health care for all Americans.

Below, APG will first provide (I) a brief description of our organization, followed by (II) a summary of CMS's proposals, (III) a summary of APG's recommendations, and then (IV) our fuller comments and recommendations. Together they reflect the voice of APG's membership and the commitment to working with the agency to ensure that all Medicare beneficiaries have consistently accessible, highquality, equitable, person-centered health care. This commitment pertains to all Medicare beneficiaries, regardless of whether they receive their benefits through the traditional, fee-for-service program or through a Medicare Advantage or Medicare Prescription Drug Benefit Program plan.

I. About America's Physician Groups

APG is a national association representing more than 360 physician groups that are committed to the transition to value, and that engage in the full spectrum of alternative payment models and Medicare Advantage (MA). APG members collectively employ or contract with approximately 195,000 physicians (as well as many nurse practitioners, physician assistants, and other clinicians), and care for approximately 90 million patients, including roughly 30 percent of all Medicare beneficiaries who are enrolled in MA.

APG's motto, "Taking Responsibility for America's Health," underscores our physician groups' preference for being in risk-based, accountable, and responsible relationships with all payers, including MA health plans, rather than being paid by plans on a fee-for-service basis. Delegation of risk from payers to providers creates the optimal incentives for our groups to provide integrated, coordinated care; make investments in innovations in care delivery; advance health equity; and manage our populations of patients in more constructive ways than if our members were merely compensated for the units of service that they provide.

II. CMS's Proposed Rule

CMS's proposed rule aims to help people with Medicare select and enroll in coverage options that best meet their health care needs. A key goal is to prevent plans from engaging in anti-competitive steering of prospective enrollees based on excessive compensation to agents and brokers, rather than ensuring that the plans selected meet enrollees' best interests. If finalized, the proposed guardrails will protect people with Medicare and promote a competitive marketplace in MA.

The proposed rule also aims to improve access to behavioral health care by adding to MA network adequacy requirements a new facility type that includes several behavioral health provider types. CMS is also proposing policies to increase the utilization and appropriateness of supplemental benefits to ensure that taxpayer dollars provide meaningful benefits to enrollees. Additionally, the proposed rule would improve transparency on the effects of prior authorization on underserved communities and proposes more flexibility for Part D plans to substitute lower cost biosimilar biological products more quickly for their reference products.

III. Summary of APG's Recommendations

A. Recommendations Related to Behavioral Health Access and Network Adequacy

- APG recommends that CMS finalize the proposed policy to (1) add Outpatient Behavioral Health as a new specialty type category required for inclusion in MA plan networks and (2) allow MA organizations the flexibility to choose among individual provider types that comprise this category.
- APG recommends that CMS finalize the proposed policy to add the Outpatient Behavioral Health specialty type category to the list of those that receive a 10-

percentage point credit if the MA organization's network includes one or more providers of this type who provide telehealth.

- B. Recommendations Related to Supplemental Benefits
 - APG recommends that CMS set a short-term goal of collecting detailed information from MA organizations (MAOs) about the following:
 - \circ the supplemental benefits they offer,
 - \circ the evidence supporting the inclusion of these supplemental benefits,
 - enrollees' utilization of supplemental benefits, and
 - evidence of the impact of supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs.
 - APG recommends that CMS (1) analyze and report data on the impact of MA supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs, and (2) make the dataset available to researchers who have data use agreements in place and are qualified to access CMS data.
 - APG recommends that CMS finalize the proposed requirement that MAOs notify beneficiaries at mid-year of unused supplemental benefits.
 - APG recommends that CMS finalize the proposed requirements that MAOs follow policies for determining enrollee eligibility for special supplemental benefits for the chronically ill (SSBCI) and document denials of eligibility.
 - APG recommends that CMS finalize the proposed requirement that MA organizations expand disclaimers regarding special supplemental benefits for the chronically ill (SSBCI) eligibility to MA marketing materials.
 - APG recommends that CMS temporarily delay adoption of the proposal to require MA organizations to provide the agency with evidence of the efficacy of services provided under special supplemental benefits for the chronically ill (SSBCI). The proposal should be adopted, however, after the agency also finalizes and adopts policies to collect, analyze, and report data on the impact of all supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs, and makes the dataset available to researchers who have data use agreements in place and are qualified to access CMS data.
- C. Recommendations Related to Agent and Broker Compensation
 - APG recommends that CMS finalize the proposal to establish a single fixed compensation amount for MA plan brokers, which will be updated each year by an inflationary factor.
 - APG recommends that CMS finalize the proposal to prohibit contract terms between MAOs and marketing middlemen, such as field marketing organizations, that result in incentives, such as volume-based bonuses for enrollment into certain plans.
 - APG recommends that CMS require that no other special incentives outside of the single fixed MA plan broker compensation amount be permitted.
 - APG recommends that CMS monitor the impact of any new MA plan agent and broker

compensation policies on beneficiaries to inform future rulemaking.

- D. Recommendations Related to Utilization Management and Health Equity
 - APG recommends that CMS finalize the proposal to require that MA organizations add a member with health equity expertise to their utilization management committees in 2025.
 - APG recommends that CMS finalize the proposal to require MA organizations to publish their utilization management committees' health equity studies on prior authorization, if the requirement applies to the first-year study and the due date is July 2026.
 - APG recommends that CMS convene a technical expert panel in the second half of 2026, following the release of the MA organizations' utilization management studies, to assess the findings in aggregate and consider options for addressing any issues that are identified.
 - APG recommends that CMS incorporate the technical expert panel findings in future rulemaking 1) regarding MA organization policies for utilization management and other aspects of MA plan operations, and 2) in refining expectations for the proposed annual MA organization studies.
- E. Recommendations Related to Star Ratings
 - APG recommends that CMS finalize the proposals that move toward adoption of Universal Foundation quality measures and accelerate the timeline for adoption of these measures.
 - APG recommends that CMS finalize the proposal moving medication therapy management completion rate changes to display-only for two years due to substantial changes in methodology.
 - APG recommends that all proposed Star Rating changes be described in detail in the proposed rule in the same year that they are adopted in the final rule to provide adequate opportunity for stakeholder feedback.
- F. Recommendations Related to Enrollment and Appeals
 - APG recommends that CMS finalize the proposal to align fast track appeals in MA with those in traditional Medicare. To avoid potential bias, quality improvement organizations – rather than MA organizations – should review "untimely" fast-track appeals of an MA plan's decision to terminate services provided in a skilled nursing facility, in a comprehensive outpatient rehabilitation facility, or by a home health agency.

- G. Recommendations Related to Dual-eligible Beneficiaries
 - APG recommends that CMS keep the dual-eligible special enrollment period available quarterly, rather than monthly.
 - APG recommends that CMS establish a special enrollment period for dually eligible beneficiaries who are not already enrolled in an integrated dual eligible special needs plan (D-SNP), such as a fully integrated dual eligible special needs plan (FIDE SNP); a highly integrated dual eligible special needs plan (HIDE SNP); or an Applicable Integrated Plan (AIP), that will allow them to enroll into such a plan during any month, only once per year.
 - APG requests that CMS clarify the effective date of any special enrollment period changes adopted in the final rule.
 - APG recommends that CMS finalize the proposed policies to limit new D-SNP enrollment by 2027 – and limit all D-SNP enrollment by 2030 – to individuals also enrolled in the D-SNP's affiliated Medicaid managed care organization (MCO) when MA organizations offer both D-SNPs and MCOs in the same service area. However, APG also recommends that the agency monitors the impact and aids affected beneficiaries these policies should apply only.
 - APG recommends that CMS finalize the proposal to lower the D-SNP look-alike threshold from 80 percent to 70 percent in 2025 and to 60 percent in 2026.
 - APG recommends that CMS finalize the proposal to cap out-of-network cost sharing for certain benefits beginning in 2026, such as for professional services, including primary care providers, specialists, inpatient hospitalization, inpatient psychiatric care, partial hospitalization, and inpatient rehabilitation.
- H. Recommendations Related to Encounter Data for Medicare and Medicaid
 - APG recommends that CMS finalize the proposal to release MA encounter data to states to improve care coordination for dually eligible beneficiaries, if the agency also continues to improve the completeness of MA encounter data.
- I. Recommendations Related to RADV Appeals Process
 - APG recommends that CMS finalize the proposal to require MA organizations to request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time.
 - APG recommends that CMS propose requirements that would ensure that recovery audit data validation (RADV) monetary penalties be applied to providers or other actors that contributed to a negative RADV finding as part of the 2026 MA rulemaking process.
- J. Recommendations Related to Part D Formulary Changes

- APG recommends that CMS finalize the proposal to treat Part D formulary substitutions of "interchangeable biological products" as "maintenance changes" that do not require prior approval by CMS.
- APG recommends that CMS finalize the proposal to require Part D sponsors to comply with updated Part D e-prescribing program software and transaction standards, per ONC regulations.
- APG recommends that CMS finalize the proposal to replace Part D drug management program regulation language that refers to "active cancer-related pain" with "cancer-related pain" to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options.
- APG recommends that CMS finalize the proposal to require Part D plans to send a second notice within three days to enrollees originally identified as "at risk" as part of drug management programs but later identified as exempt, even if that occurs less than 30 days from the initial notice to ensure that treatment is not unduly interrupted.

IV. APG's Detailed Comments and Recommendations

CMS includes multiple proposals to improve the functioning of the MA and Part D programs in the proposed rule. APG provides feedback on proposals that are pertinent to our members, including those related to:

- Behavioral Health Access and Network Adequacy
- Supplemental Benefits
- Agent and Broker Compensation
- Utilization Management and Health Equity
- Star Ratings
- Enrollment and Appeals
- Dual-eligible Beneficiaries
- Encounter Data for Medicare and Medicaid
- RADV Appeals Process
- Part D Formulary Changes

A. Behavioral Health Access and Network Adequacy

Currently, MA networks are required to include in their networks the following types of providers: 1) psychiatrists, 2) clinical psychologists, 3) clinical social workers, and 4) inpatient psychiatric facilities. CMS proposes to add Outpatient Behavioral Health as a new specialty type category required for inclusion in MA plan networks. As MA organizations (MAOs) design their plan networks, this category could be comprised of providers who are: 1) Marriage and family therapists (MFTs), 3) Mental health counselors (MHCs), 3) Opioid Treatment Programs (OTPs), and 4) Community Mental Health Centers. This proposed change will align the MA behavioral health provider types with traditional, fee-for-service Medicare, as the Consolidated Appropriations Act of 2023 added MFTs and MHCs as a new Part B benefit and provider type, and the other two types of providers were already included. These four types of behavioral health providers will join the existing types who do or may choose to provide behavioral health care services: 1) physician assistants (PAs), 2) nurse practitioners (NPs), 3) clinical nurse specialists (CNSs), 4) addiction medicine physicians, and 5) outpatient facilities mental health and substance use treatment facilities.

CMS proposes that MAOs be allowed to include contracted individual providers, group practices, or facilities under the Outpatient Behavioral Health specialty type category to meet network adequacy requirements. CMS also proposes adding this specialty type category to the list of those that receive a 10-percentage point credit if the MAO's network includes one or more providers of this type who provide telehealth. Because MAOs will be able to select among the individual specialty types that comprise the new Outpatient Behavioral Health category, CMS will monitor the impact of the proposed policy if finalized, including the choice to include OTPs with other specialty types in one category.

APG is grateful for CMS's ongoing efforts to ensure that there is an adequate supply of behavioral health care providers to provide Medicare beneficiaries with adequate access to these essential services. Given the behavioral health care access crisis in America, it is essential to deploy all viable options to draw upon the expertise of all qualified members of the behavioral health care workforce while striving to expand the overall supply of these providers to address unmet demand.

Furthermore, APG appreciates the design of CMS's proposal to create a category of Outpatient Behavioral Health that will allow MAOs the flexibility to design their plans' network to make the best use of the mix of behavioral health care providers available in each local market. APG supports CMS's proposal to add this specialty type category to the list of those that receive a 10-percentage point credit if the MAO's network includes one or more providers of this type who provide telehealth. Telehealth has proven to be an essential tool for ensuring adequate access to health care services and is especially well-suited to behavioral health care services.

In summary:

- APG recommends that CMS finalize the proposed policy to (1) add Outpatient Behavioral Health as a new specialty type category required for inclusion in MA plan networks and (2) allow MA organizations the flexibility to choose among individual provider types that comprise this category.
- APG recommends that CMS finalize the proposed policy to add the Outpatient Behavioral Health specialty type category to the list of those that receive a 10percentage point credit if the MA organization's network includes one or more providers of this type who provide telehealth.

B. Supplemental Benefits

CMS proposes three new key requirements for MA plans that offer supplemental benefits:

- MAOs must notify beneficiaries at mid-year of unused supplemental benefits.
- MAOs must provide CMS with evidence of the efficacy of services selected to include as

special supplemental benefits for the chronically ill (SSBCI), following policies for determining enrollee eligibility, and documenting denials of eligibility.

• MAOs must expand disclaimers regarding SSBCI eligibility to MA marketing materials.

CMS proposes that beginning January 1, 2026, MAOs must mail a mid-year notice between June 30 and July 31 to each enrollee with information on each supplemental benefit that the enrollee has not begun to use or has started to use but has not yet exhausted. MAOs must use information, including claims data, that is as up-to-date as possible for the purpose of generating these letters. The letters must include all pertinent information about these benefits, such as eligibility criteria, cost sharing, instructions on how to access the benefits, limitations, and scope of covered items and services. MAOs must also list a point of contact either via the customer service line or a separate dedicated line with trained staff who can help enrollees with the SSBCI eligibility process and any other questions.

Currently, CMS is responsible for determining if there is reasonable evidence of efficacy for the SSBCI that MAOs plan to offer. CMS proposes to shift this responsibility to the MA plans. MAOs would be required, as part of plan bids, to provide CMS with a bibliography of "relevant and acceptable evidence" that demonstrates that an item or service is reasonably expected to improve or maintain the health or overall function of a chronically ill enrollee. The bibliography must include working hyperlinks.

Under the proposed policy, "relevant and acceptable evidence" will be interpreted to include large randomized controlled trials or prospective cohort studies with clear results, published in a peerreviewed journal, designed to investigate the item or service's impact on health or overall function. If these types of studies are unavailable, "relevant and acceptable evidence" could include large systematic reviews or meta-analyses summarizing literature of the same. In the absence of publications that meet these standards, bibliographies may include case studies, federal policies or reports, internal analyses, or any other investigation of the items/service's impact. MAOs must include all relevant acceptable evidence published within 10 years of the preceding month in which the bid is submitted, not just supportive evidence.

CMS proposes to apply the required evidence of efficacy proposed policy only when MAOs opt to offer SSBCI, not when they opt to reduce cost sharing. CMS will also not apply the proposed policy to the Value-base Insurance Design (VBID) model. CMS proposes to codify that the agency can deny plan bids that fail these new requirements. CMS proposes to specify that MA plans must apply their written policies based on objective criteria to determine enrollees' eligibility for SSBCI. CMS proposes to require MA plans to document that a chronically ill enrollee is ineligible rather than eligible for SSBCI.

CMS proposes expanding the currently required SSBCI disclaimers in MA marketing materials. This expansion would clarify eligibility requirements: 1) that the enrollee must have the required chronic condition(s), 2) that they must meet the statutory definition of a "chronically ill enrollee" and 3) the MAO must determine that the enrollee is eligible for a particular SSBCI under the plan's coverage criteria.

Given the importance of MA supplemental benefits and the lack of transparency about their effects on enrollees' outcomes and quality of life, APG lauds CMS's efforts to ensure that supplemental benefits deliver value to enrollees. In fact, given this importance and lack of transparency, APG supports many of CMS's proposals and urge CMS to consider even bolder efforts. APG proposes that CMS set a short-term goal of collecting detailed information from MAOs about the following:

- 1. the supplemental benefits they offer,
- 2. the evidence supporting the inclusion of these supplemental benefits,
- 3. enrollees' utilization of supplemental benefits, and
- 4. evidence of the impact of supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs.

CMS should then analyze and report these data, as well as make the dataset available to researchers who have data use agreements in place and are qualified to access CMS data.

In summary:

- APG recommends that CMS set a short-term goal of collecting detailed information from MA organizations (MAOs) about the following:
 - the supplemental benefits they offer,
 - \circ the evidence supporting the inclusion of these supplemental benefits,
 - enrollees' utilization of supplemental benefits, and
 - evidence of the impact of supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs.
- APG recommends that CMS (1) analyze and report data on the impact of MA supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs, and (2) make the dataset available to researchers who have data use agreements in place and are qualified to access CMS data.
- APG recommends that CMS finalize the proposed requirement that MAOs notify beneficiaries at mid-year of unused supplemental benefits.
- APG recommends that CMS finalize the proposed requirements that MAOs follow policies for determining enrollee eligibility for special supplemental benefits for the chronically ill (SSBCI) and document denials of eligibility.
- APG recommends that CMS finalize the proposed requirement that MA organizations expand disclaimers regarding special supplemental benefits for the chronically ill (SSBCI) eligibility to MA marketing materials.

As physician groups who take responsibility for the quality and total cost of care for the patients that they serve, APG members recognize the unparalleled value that supplemental benefits can provide. For example, well-managed transportation benefits can ensure that patients with significant social determinants of health challenges, health-related social needs, and multiple chronic conditions, can readily have regular visits with their primary care providers, specialists, and diagnostic service providers. The support that transportation benefits provide can vastly improve patients' quality of life by allowing their providers to effectively manage their care and deliver high-quality outcomes. However, not all supplemental benefits necessarily yield improved outcomes, especially when they are poorly targeted to enrollees' needs. For example, over-the-counter benefits and flexible spending card benefits can serve as an important support for some enrollees, while simultaneously adding unnecessary spending for enrollees who are not in need to these benefits. In the latter cases, these spending cards are little more than a marketing tool for MAOs.

Once CMS collects, analyzes, and reports the impact of supplemental benefit utilization on

enrollees' quality of care outcomes and out-of-pocket costs, the agency could then address better supplemental benefit design through future notice-and-comment rulemaking. CMS and all MAO could learn from these results how to better design supplemental benefit choices to lead to better outcomes.

In the meantime, APG urges caution regarding CMS's proposal to apply the evidence of efficacy proposed policy only when MAOs opt to offer SSBCI, not when they opt to reduce cost sharing. The obvious choice for too many MAOs will be to opt to reduce cost sharing in lieu of offering SSBCI. This outcome will be premature.

At this point, policymakers and other stakeholders have concerns that not all SSBCI are optimally designed to support better outcomes. Yet they lack the data to discern which SSBCIs achieve optimal outcomes for MA enrollees. Abandoning SSBCIs before studying their impact will waste the learning opportunity afforded by the testing of the effects of these benefits. It would be far better to maintain these options and view the MA plans that provide SSBCI – combined with data collection, analyses, and reporting – as a much-needed experiment in the relative value to enrollees of various supplemental benefits.

In summary:

APG recommends that CMS temporarily delay adoption of the proposal to require MA organizations to provide the agency with evidence of the efficacy of services provided under special supplemental benefits for the chronically ill (SSBCI). The proposal should be adopted, however, after the agency also finalizes and adopts policies to collect, analyze, and report data on the impact of all supplemental benefit utilization on enrollees' quality of care outcomes and out-of-pocket costs, and makes the dataset available to researchers who have data use agreements in place and are qualified to access CMS data.

C. Agent and Broker Compensation

Many beneficiaries rely on agents and brokers to help navigate complex Medicare choices as they comparison shop for coverage options. The Medicare statute requires that CMS's marketing standards and consequent guidelines ensure that compensation arrangements for brokers through third party marketing organizations and field marketing organizations create incentives for agents and brokers to enroll individuals in the MA plans that best meet their health care needs. However, financial incentives to agents and brokers, more readily paid by large plans, can result in beneficiaries being steered to some MA plans over others based on excessive broker and agent compensation and other bonus arrangements, rather than to plans best suited to prospective enrollees.

Specifically, CMS is proposing to redefine "compensation" to set a clear, fixed amount that agents and brokers can be paid regardless of the plan the beneficiary enrolls in. This proposal addresses loopholes in existing regulation that result in commissions above this amount that, in turn, create anticompetitive and anti-consumer steering incentives. The proposal is intended to ensure that the payment of agent and broker compensation reflects only the legitimate activities required of agents and brokers. It does so by broadening the scope of the regulatory definition of "compensation" so that it is inclusive of all activities associated with the sales to and enrollment of a beneficiary into an MA plan or Part D plan.

The proposed national agent/broker fixed compensation amount for MA is \$642 for 2025, and the amount will be updated annually to reflect inflation and include associated costs such as training and travel. This proposed fixed amount for MA compensation, compared to the existing national compensation cap of no more than \$611, would eliminate the current variability in payments and improve the predictability of compensation for agents and brokers. The proposed fixed compensation amount would eliminate any special bonuses or other a la carte compensation.

Additionally, the proposed rule would generally prohibit contract terms between MAOs and marketing middlemen, such as field marketing organizations, that result in arrangements such as volume-based bonuses for enrollment into certain plans. Such arrangements may interfere with the ability of agents or brokers to assist enrollees in finding the plans best suited to their needs.

APG recognizes that, as MA plans have become more complex, in part because of the increasing adoption of various supplemental benefits, brokers have become an essential part of explaining the difference in plan options to beneficiaries and assisting them in selecting plans most suitable to their needs. The consolidation of plans in the markets has led to larger plans being able to accommodate more substantial special broker incentives than smaller regional plans can afford, potentially leading to anticompetitive activities.

APG therefore supports simplifying the broker standard compensation formula to include all administrative costs and fees under a single fixed amount to eliminate potential bias in brokers' recommendations to beneficiaries. APG also supports revising the definition of compensation to prevent volume-based bonuses that can be based on the practice of generating leads to receive additional leads, thus fueling a cycle that harms beneficiaries through unnecessary plan churn. In fact, APG believes that all other special incentives should be eliminated from the broker's compensation – in addition to administrative and lead generating – to eliminate incentives that introduce the opportunity for bias in brokers' guidance to beneficiaries in their selection of appropriate MA plans.

In summary:

- APG recommends that CMS finalize the proposal to establish a single fixed compensation amount for MA plan brokers, which will be updated each year by an inflationary factor.
- APG recommends that CMS finalize the proposal to prohibit contract terms between MAOs and marketing middlemen, such as field marketing organizations, that result in incentives, such as volume-based bonuses for enrollment into certain plans.
- APG recommends that CMS require that no other special incentives outside of the single fixed MA plan broker compensation amount be permitted.

APG welcomes CMS's proposed policies to address marketing and enrollment practices that cause harm to beneficiaries through selection of inappropriate MA plans, churn, and other problems. In addition to finalizing and expanding the proposed policies, APG asks that CMS closely monitor the impact of any new policies on beneficiaries to inform future rulemaking.

In summary:

• APG recommends that CMS monitor the impact of any new MA plan agent and broker compensation policies on beneficiaries to inform future rulemaking.

D. Utilization Management and Health Equity

Prior authorization policies and procedures may have a disproportionate impact on underserved populations and may delay or deny access to certain services. The proposed rule is intended to ensure that MAOs analyze their utilization management (UM) policies and procedures from a health equity perspective. UM committees have been added as a new requirement, effective January 1, 2024.

CMS is proposing updates to the composition of and responsibilities for the committees, to require, effective January 1, 2025, the following: 1) a member of the UM committee to have expertise in health equity; 2) the UM committee to conduct an annual health equity analysis of prior authorization policies and procedures used by the MAO, using contract-level data that is scored using specified social risk factors (SRFs) and 3) MAOs to make the results of these analyses publicly available on their websites by July 2025. The goal of the health equity analyses is to create additional transparency and identify disproportionate impacts of UM policies and procedures on enrollees who receive the Part D low-income subsidy, are dually eligible, or have a disability. CMS requests stakeholder comments on the question of whether additional populations (e.g., LGBTQ+, limited English proficiency, rural) should be included in the study as well.

APG appreciates CMS's consideration of the impact of implementation of prior authorization policies and procedures on underserved populations. We recognize that in some instances beneficiaries experience tremendous difficulty in navigating the complex prior authorization system, but the prevalence of this situation is uncertain. 2024 will be the first year in which all MAOs are required to have a UM committee review all policies and procedures to ensure consistency with Medicare rules and regulations. APG supports CMS's proposal to require MAOs to add a member with health equity expertise to the UM beginning in 2025.

In summary:

APG recommends that CMS finalize the proposal to require that MA organizations add a member with health equity expertise to their utilization management committees in 2025.

APG also supports requiring MAO's UM committees to conduct a health equity analysis of prior authorization policies and procedures used by the MAO, using contract-level data that is scored using specified social risk factors (SRFs). However, APG suggests two modifications to this proposed policy.

First, requiring MAOs to publish health equity analysis studies of their UM activities within seven months of appointing health equity experts is too quick of a turn-around time and is likely to result in superficial analyses that are not detailed enough to accurately assess the extent to which MAO's prior authorization policies and procedures may have a differential impact on various populations. To allow adequate time for meaningful studies that include robust data collection and analysis, and that

incorporate the additional populations that CMS requests stakeholder feedback on, APG suggests that the first report be published by July 2026.

Second, APG supports the concept of ongoing vigilance about any potential differential impact on various populations, but establishing a requirement for an annual study without also determining what CMS is prepared to do with the results, risks creating a situation in which problems are repeatedly identified without any required actions to address the root causes. For example, studying prior authorization appeals in the underserved population may not lead to the root cause of any identified problems, which could be differences in access to health care services or other elements such as lack of provider engagement.

APG thus recommends that CMS convene a technical expert panel (TEP) in the second half of 2026, following the release of the MAO's UM studies, to assess the findings in aggregate and consider options for addressing any issues that are identified. The TEP should be comprised of representatives of MAOs, provider groups that contract with MAOs, patient advocates, and health equity experts. APG also recommends that CMS then incorporate the TEP findings in future rulemaking regarding MAO policies for UM and other aspects of MA plan operations, and in particular, in refining expectations for the annual MAO studies.

In summary:

- APG recommends that CMS finalize the proposal to require MA organizations to publish their utilization management committees' health equity studies on prior authorization, if the requirement applies to the first-year study and the due date is July 2026.
- APG recommends that CMS convene a technical expert panel in the second half of 2026, following the release of the MA organizations' utilization management studies, to assess the findings in aggregate and consider options for addressing any issues that are identified.
- APG recommends that CMS incorporate the technical expert panel findings in future rulemaking 1) regarding MA organization policies for utilization management and other aspects of MA plan operations, and 2) in refining expectations for the proposed annual MA organization studies.

E. Star Ratings

The proposed rule indicates that CMS continues to move toward adopting Universal Foundation measures to align quality measures across all programs, including MA, traditional FFS Medicare, accountable care organizations (ACOs), and others. Notably, CMS indicated the agency's interpretation of rulemaking authority that proposals included in previous years' proposed rules can be finalized in subsequent final rules. CMS indicated that if the Medication Therapy Management (MTM) completion rate for the Comprehensive Medication Review (CMR) MA Star Rating is finalized in a subsequent final rule from the 2022 proposed rule, it will be displayed for two years due to substantive measure updates. Additionally, the proposed rule would include 10 chronic diseases for MTM.

CMS proposes a more expanded data review process for MAOs and Part D sponsors before Star Rating calculations are completed. CMS also proposes technical changes to the calculations of

Categorical Adjustment Index (CAI) and Health Equity index (HEI) when plan contracts are consolidated.

APG appreciates CMS's efforts to move toward Universal Foundation measures to align all programs and minimize burden for providers. Moving to a standardized group of quality measures will not only decrease provider burden but will also facilitate CMS ability to measure and compare quality differences across different Medicare populations, such as traditional Medicare, ACOs, and MA.

APG has concerns about CMS's comment that policies included in previous proposed rules can be finalized in subsequent, nonconsecutive years without updating them. Any changes in Star Ratings measures and methodology require providers to modify their workflow processes to support the new data collection and process requirements, including implementing EHR changes, which typically take 12 to 18 months to finalize. As a result, APG believes that all proposed Star Rating changes should be described in detail in the proposed rule in the same year that they are adopted in the final rule to provide adequate opportunity for stakeholder feedback.

In summary:

- APG recommends that CMS finalize the proposals that move toward adoption of Universal Foundation quality measures and accelerate the timeline for adoption of these measures.
- APG recommends that CMS finalize the proposal moving medication therapy management completion rate changes to display-only for two years due to substantial changes in methodology.
- APG recommends that all proposed Star Rating changes be described in detail in the proposed rule in the same year that they are adopted in the final rule to provide adequate opportunity for stakeholder feedback.

F. Enrollment and Appeals

CMS proposes modifying the initial coverage election period (ICEP) for MA to begin three months before and end two months following a beneficiary's enrollment in Medicare Part A and B. The goal is to allow more time than at present for the beneficiary to make an informed decision on plan choice. In addition, CMS proposes that when a beneficiary is eligible for more than one election period, such as a special enrollment period (SEP), then the MAO or Part D sponsor must allow beneficiaries to choose which election period is more appropriate for their situation.

Currently, Medicare beneficiaries enrolled in an MA plan under current regulations do not have the same access to Quality Improvement Organization (QIO) review of a fast-track appeal as do traditional Medicare beneficiaries. CMS is proposing to (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in a skilled nursing facility, comprehensive outpatient rehabilitation facility, or by a home health agency; and (2) fully eliminate the provision requiring forfeiture of an enrollees' rights to appeal a termination of services decision when they leave the facility. These proposals would bring MA plan regulations in line with the parallel reviews available to beneficiaries in traditional Medicare and expand the rights of MA plan beneficiaries to access the fast-track appeals process. APG recognizes that due to health issues or confusion surrounding appeals process, beneficiaries can inadvertently miss the deadlines for appeal, resulting in adverse impact on them. In these situations, the only avenue is the application of the "untimely" appeal process. However, as opposed to traditional Medicare, MA beneficiaries can only use the MAO as the review entity during the "untimely" appeal, which may introduce a biased perspective. Modifying the regulation to allow the QIO to serve as the review entity in these situations will better align the appeals process between the two Medicare programs and address beneficiaries' concerns of a potentially biased approach.

In summary:

 APG recommends that CMS finalize the proposal to align fast track appeals in MA with those in traditional Medicare. To avoid potential bias, quality improvement organizations – rather than MA organizations – should review "untimely" fast-track appeals of an MA plan's decision to terminate services provided in a skilled nursing facility, in a comprehensive outpatient rehabilitation facility, or by a home health agency.

G. Dual-eligible Beneficiaries

CMS proposes to replace the quarterly dual-eligible special enrollment period (SEP) with a new dual/low-income subsidy (LIS) SEP that would allow dually eligible and LIS-enrolled beneficiaries to enroll once per month in any standalone prescription drug plan. The agency also proposes to create a new SEP for enrollment into integrated D-SNPs, including fully integrated D-SNPs (FIDE SNPs), highly integrated D-SNPs (HIDE SNPs), and applicable integrated plans (AIPs), for those who qualify for these plans. Together, these two proposals would allow dually eligible beneficiaries to have a monthly election opportunity to elect any of the following options:

- Leave an MA-PD plan for Medicare FFS by enrolling in a stand-alone prescription drug plan (PDP);
- Switch between stand-alone PDPs;
- Enroll in an integrated D-SNP, such as a FIDE SNP, HIDE SNP, or AIP.

It is unclear from the proposed rule when these proposed changes would go into effect.

CMS proposes that, beginning in 2027, when an MAO, its parent organization, or an entity that shares a parent organization also contracts with a state as a Medicaid managed care organization (MCO) that enrolls dually eligible individuals in the same service area, the D-SNP offered by that entity must limit new enrollment to individuals enrolled in the D-SNP's affiliated Medicaid MCO. CMS proposes that, beginning in 2030, such D-SNPs must only enroll individuals enrolled in the affiliated Medicaid MCO. Thus, integrated D-SNPs would be required to disenroll individuals who are not enrolled in both the D-SNP and MCO offered under the same parent organization, except in cases of temporarily lost Medicaid coverage.

The proposed rule would change contracting standards for D-SNP look-alike plans. CMS adopted

contracting limitations for D-SNP look-alike plans to ensure full implementation of requirements for D-SNPs, including minimum integration standards as required by the Bipartisan Budget Act of 2018. CMS is proposing to lower the D-SNP look-alike threshold from 80 percent to 70 percent in 2025 and to 60 percent in 2026. This proposal is designed to help address the continued proliferation of MA plans that are serving high percentages of dually eligible individuals without meeting the requirements to be a D-SNP.

The proposed rule would limit out-of-network cost sharing for D-SNP preferred provider organizations (PPOs) for specific services, beginning in 2026. CMS's proposal is driven by concerns with high out-of-network cost sharing in D-SNPs, which can lead to effective payment cuts for providers when cost-sharing amounts are not paid and increased financial burden for state Medicaid programs that do reimburse for these cost-sharing amounts. The proposed rule is designed to reduce cost shifting to Medicaid, increase payments to safety net providers, expand dually eligible enrollees' access to providers, and protect dually eligible enrollees from unaffordable costs. The proposed rule would cap out-of-network cost sharing for certain benefits, such as professional services, including primary care providers, specialists, inpatient hospitalization, inpatient psychiatric care, partial hospitalization, and inpatient rehabilitation, beginning in 2026.

APG appreciates CMS's consideration of policies to address the issues that arise due to the lack of coordination of benefits for dually eligible beneficiaries who are not enrolled in integrated D-SNPs. Coordination of benefits is a long-sought-after goal that remains frustratingly out of reach for too many dually eligible beneficiaries. Policymakers have tried multiple options for addressing this lack of coordination of benefits, including D-SNPs, Medicare-Medicaid plans, and others over multiple years.

APG shares with CMS a preference for options that coordinate benefits for dually eligible beneficiaries yet cautions that the proposed policies may result in perverse unintended consequences that offset the gains in benefit coordination. Such an outcome is especially concerning given that coordination of benefits, which seems inherently beneficial for enrollees, has not been proven to improve health outcomes for dually eligible beneficiaries despite multiple studies assessing impacts.

Given this lack of evidence of positive impact of benefits coordination, risking the potential negative impact of interruptions in access to prescriptions drugs, and adherence with drug regimens due to churn, may not be worth the trade-off. Specifically, a monthly election as opposed to a quarterly election to 1) leave an MA-PD plan for Medicare FFS by enrolling in a stand-alone prescription drug plan (PDP), 2) switch between stand-alone PDPs, or 3) enroll in an integrated D-SNP, such as a FIDE SNP, HIDE SNP, or AIP is excessively frequent.

APG thus recommends that CMS consider options that balance the preference for integration of benefits with protections against unnecessary churn, especially by establishing policies that expand dually eligible beneficiaries' options for enrolling in integrated D-SNPs when they are not already enrolled in such plans.

In summary:

- APG recommends that CMS keep the dual-eligible special enrollment period available quarterly, rather than monthly.
- APG recommends that CMS establish a special enrollment period for dually eligible beneficiaries who are not already enrolled in an integrated dual eligible special needs plan (D-SNP), such as a fully integrated dual eligible special needs plan (FIDE SNP); a highly integrated

dual eligible special needs plan (HIDE SNP); or an Applicable Integrated Plan (AIP), that will allow them to enroll into such a plan during any month, only once per year.

• APG requests that CMS clarify the effective date of any special enrollment period changes adopted in the final rule.

APG supports CMS's proposals that address how MAOs that offer both D-SNPs and Medicaid MCOs would be expected to coordinate these benefits, beginning in 2027 and 2030. However, given that these enrollment opportunities are not available in all markets, and it is unclear how this situation will evolve, APG is concerned about the potential for unintended consequences for beneficiaries, including churn.

APG requests that CMS monitor the potential and actual impact of these proposed policies, if finalized, on beneficiaries as these dates approach and pass. CMS should be prepared to offer assistance to dually eligible beneficiaries who may be confused by and possibly negatively affected by these policies.

In summary:

 APG recommends that CMS finalize the proposed policies to limit new D-SNP enrollment by 2027 – and limit all D-SNP enrollment by 2030 – to individuals also enrolled in the D-SNP's affiliated Medicaid managed care organization (MCO) when MA organizations offer both D-SNPs and MCOs in the same service area. However, APG also recommends that the agency monitors the impact and aids affected beneficiaries these policies should apply only.

APG supports CMS's proposal to lower the D-SNP look-alike threshold from 80 percent to 70 percent in 2025 and to 60 percent in 2026. We agree that doing so should help to encourage a greater focus on development and enrollment in actual D-SNPs.

In summary:

• APG recommends that CMS finalize the proposal to lower the D-SNP look-alike threshold from 80 percent to 70 percent in 2025 and to 60 percent in 2026.

APG shares CMS's concern with high out-of-network cost-sharing in D-SNPs, which can lead to effective payment cuts for providers when cost-sharing amounts are not paid, and to increased financial burden for state Medicaid programs that do reimburse for these cost-sharing amounts. APG supports the proposal to limit out-of-network cost sharing for D-SNP PPOs for specific services, beginning in 2026.

In summary:

- APG recommends that CMS finalize the proposal to cap out-of-network cost sharing for certain benefits beginning in 2026, such as for professional services, including primary care providers, specialists, inpatient hospitalization, inpatient psychiatric care, partial hospitalization, and inpatient rehabilitation.
- H. Encounter Data for Medicare and Medicaid

CMS proposes changes to the use of MA encounter data to improve care coordination for dually eligible beneficiaries, including permitting the agency to use and release MA encounter data – prior to reconciliation – for Medicare, Medicaid, or both. CMS anticipates that MA encounter data would generally be released to the states.

APG agrees that MA encounter data are a robust source of information and appreciates CMS's proposal to release these data to states to improve care coordination for dually eligible beneficiaries. However, APG is concerned that encounter data are not always as complete as they could be and requests that the agency continue to seek ways to improve the completeness of encounter data, including considering the MedPAC 2019 recommendation on MA encounter data completeness.^{1,2}

In summary:

• APG recommends that CMS finalize the proposal to release MA encounter data to states to improve care coordination for dually eligible beneficiaries, if the agency also continues to improve the completeness of MA encounter data.

I. RADV Appeals Process

The proposed rule addresses operational constraints included in existing Risk Adjustment Data Validation (RADV) appeal regulations. CMS proposes that MAOs may request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time. CMS also proposes that MAOs that request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process.

Additionally, the proposed rule clarifies that a revised audit report containing a recalculated payment error calculation will not be issued by the Secretary at each level of appeal but instead will be issued when a medical record review determination appeal or a payment error calculation appeal is final, as applicable. The proposed rule includes a requirement that if the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MAO's or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.

APG supports CMS's proposal to implement a sequence for RADV appeals processes. It is logical to adjudicate the steps in a sequential order.

In summary:

• APG recommends that CMS finalize the proposal to require MA organizations to request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time.

¹ <u>https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch7_medpac_reporttocongress_sec.pdf</u>

² https://www.medpac.gov/wp-content/uploads/2023/03/Tab-C-MA-workplan-Sept-2023.pdf

As physician groups that contract with MA plans, APG members have a significant concern with the RADV process that CMS would do well to address in future rulemaking.

Currently, when MAOs are subject to monetary recoveries as the result of RADV findings, there are no program rules governing how the MAO funds the monetary penalty. Affected MAOs are not precluded from distributing the resulting negative financial assessment across all provider groups that contract with the MAO – including provider groups who played no role in the inappropriate diagnosis coding along with bad actors who were responsible for the RADV finding. APG calls on CMS in next year's rulemaking process to propose requirements that would ensure that RADV monetary penalties be applied to providers or other actors that contributed to a negative RADV finding.

In summary:

• APG recommends that CMS propose requirements that would ensure that recovery audit data validation (RADV) monetary penalties be applied to providers or other actors that contributed to a negative RADV finding as part of the 2026 MA rulemaking process.

J. Part D Formulary Changes

CMS is proposing to employ a new term, "interchangeable biological product," to describe a specified category of products and to permit Part D sponsors to treat formulary substitutions of these biosimilar biological products other than the existing category of "interchangeable biological products" for their reference products as "maintenance changes" that would not require prior approval by CMS.

Under the agency's current guidance, plans must obtain explicit approval prior to substituting branded biological products with biosimilar biological products, other than interchangeable biological products. Such substitutions apply only to enrollees who begin therapy after the effective date of the maintenance change—delaying enrollees' access to cheaper options. Treating these substitutions as maintenance changes would also mean that any substitutions would apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice, so that enrollee access to equally effective, but potentially more affordable, options would be available sooner.

CMS also proposes updating electronic prescribing standards. Part D sponsors are required to support the Part D e-prescribing program transaction standards as part of their electronic prescription drug programs. The proposed rule would require Part D sponsors to comply with updated software and standards, per Office of the National Coordinator (ONC) regulations, by January 2027

In addition, CMS proposes drug management program improvements, including replacing regulation language that refers to "active cancer-related pain" with "cancer-related pain" to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options. CMS also would require Part D plans to send a second notice within three days to enrollees originally identified as "at risk" but later identified as exempt, even if that occurs less than 30 days from the initial notice to ensure that treatment is not unduly interrupted.

APG supports CMS's proposals to update Part D formulary policies to better serve beneficiaries, including 1) treating formulary substitutions of "interchangeable biological products" as "maintenance changes" that do not require prior approval by CMS; 2) requiring Part D sponsors to comply with updated Part D e-prescribing program software and transaction standards, per ONC regulations; 3) replacing drug management program regulation language that refers to "active cancer-related pain" with "cancer-related pain" to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options; and 4) requiring Part D plans to send a second notice within three days to enrollees originally identified as "at risk" as part of drug management programs but later identified as exempt, even if that occurs less than 30 days from the initial notice to ensure that treatment is not unduly interrupted.

In summary:

- APG recommends that CMS finalize the proposal to treat Part D formulary substitutions of "interchangeable biological products" as "maintenance changes" that do not require prior approval by CMS.
- APG recommends that CMS finalize the proposal to require Part D sponsors to comply with updated Part D e-prescribing program software and transaction standards, per ONC regulations.
- APG recommends that CMS finalize the proposal to replace Part D drug management program regulation language that refers to "active cancer-related pain" with "cancer-related pain" to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options.
- APG recommends that CMS finalize the proposal to require Part D plans to send a second notice within three days to enrollees originally identified as "at risk" as part of drug management programs but later identified as exempt, even if that occurs less than 30 days from the initial notice to ensure that treatment is not unduly interrupted.

V. <u>Conclusion</u>

APG appreciates and welcomes CMS's proposed policies in this proposed rule and supports the agency's ongoing efforts to ensure that the MA and Part D programs continue to evolve to better serve the needs of Medicare beneficiaries. APG encourages CMS to consider the modifications to the proposed policies described in this letter to further refine the proposed policies and help to avoid unintended consequences.

Sincerely,

Susan Dentys

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