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January 27, 2025

Mr. Jeff Wu Acting Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1785-P P.O. Box 8013 Baltimore, MD 21244-8013

Dear Acting Administrator Wu:

Re: Medicare and Medicaid Programs; Contract Year 2026 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

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled "Medicare and Medicaid Programs; Contract Year 2026 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," 89 Fed Reg. 99340 (December 10, 2024), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 159 U.S. medical schools accredited by the Liaison Committee on Medical Education; 14 accredited Canadian medical schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 201,000 full-time faculty members, 97,000 medical students, 158,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers International broadened participation in the AAMC by 70 international academic health centers throughout five regional offices across the globe.

Enrollment in Medicare Advantage (MA) plans continues to rise year over year. In 2024, 54 percent of Medicare-eligible beneficiaries were enrolled in an MA plan, up from 19 percent in 2007. This is a dramatic shift in the make up of the healthcare payer landscape and impacts

¹ KKF, Medicare Advantage in 2024: Enrollment Update and Key Trends. (August 2024)

providers as well as beneficiaries. Medicare Advantage plans present new opportunities for beneficiaries to access supplemental benefits not offered in FFS and to manage healthcare costs. However, the uptick in MA enrollment has also presented its challenges with narrow provider networks, utilization management tools like prior authorization, and misguided marketing practices. AAMC member teaching health systems and hospitals remain committed to supporting efforts to ensure patients maintain access to care as coverage can directly impact where beneficiaries receive their care. As Medicare beneficiaries continue to move from Traditional Medicare fee-for-service (FFS) plans to MA plans, we hope to continue working in partnership with policymakers to ensure access to high quality care.

The following summary reflects the AAMC's key recommendations on CMS' proposals and requests for information (RFIs) regarding MA and Part D plans in the Contract Year (CY) 2026 Medicare Advantage and Part D Policy and Technical Changes Proposed Rule.

- *Prior Authorization*: Prohibit restrictive uses of prior authorization and strengthen reporting of prior authorization metrics by reporting at the plan level.
- *Use of AI by MA Plans:* Finalize proposed guardrails for safe, equitable use of artificial intelligence (AI) by MA plans.
- *Network Adequacy:* Improve transparency in network adequacy standards by evaluating at the plan level, rather than the organization level.
- *Provider Directories:* Improve beneficiary access to accurate and complete provider directories without increasing provider burden.
- **Supplemental Benefits**: Ensure transparency by including supplemental benefit providers in provider directories and finalize guardrails for supplemental benefits to protect enrollees' access to services.
- *Marketing:* Finalize policies to minimize deceptive marketing practices for MA and Part D Plans to ensure beneficiaries are matched with plans best suited to their health needs.
- *Transparency in Coverage Information*: Finalize requirements for agents and brokers to discuss eligibility for Part D low income subsidies (LIS), resources to assist with costs including Medicare saving Programs, and the impact of MA enrollment on Medigap plan eligibility and cost.
- **Behavioral Health Services**: Finalize proposal to ensure affordability and access of behavioral health services for MA beneficiaries by aligning cost sharing with Medicare FFS.
- *Medical Loss Ratio (MLR):* Finalize changes to improve medical loss ratio reporting and calculations to ensure accuracy.
- *Vertical Integration Request for Information:* Monitor impact of consolidation in the insurer market, including PBMs, and how it may affect the availability of services and providers, and quality of care.
- *Part D Plans:* Prohibit utilization management practices in Part D plans that are more stringent than corresponding clinical guidelines and increase access to prescription drugs by limiting cost sharing and adopting policies that improve beneficiary affordability.

• **Dual Special Needs Plans (D-SNPs):** Streamline enrollment and encourage integration of dual eligible special needs plans.

CHANGES TO THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS

Prohibit Restrictive Uses of Prior Authorization That Depart from Traditional Medicare FFS

The use of prior authorization by MA plans continues to impact patient access to timely care. In contract year (CY) 2024, the agency adopted regulations explicitly requiring plans to adhere to original Medicare coverage criteria and limiting plans from adopting their own coverage policies unless Medicare policies were not fully established.² CMS is building on these regulations by proposing to broaden the definition of the phrase internal coverage criteria and prohibit the adoption of internal policies that automatically deny individuals coverage or are without clinical benefit. Additionally, these policies must be made publicly available such as through a plan's website. (P. 99457). The AAMC supports CMS' proposals for additional transparency and to ensure coverage criteria used in prior authorization determinations support clinical benefit. We have previously commented on the additional burden prior authorization in MA plans places on providers,³ and the detrimental impact on their patients, and we are encouraged by the agency's efforts to standardize coverage criteria and regulate the use of prior authorization.

Additionally, CMS is proposing policy changes for MA plans related to inpatient coverage for CY 2026. One proposal would expand notice requirements to ensure providers who have made coverage determination requests on behalf of enrollees, or when otherwise appropriate, receive notice of the MA organization's determination in addition to the enrollee. (P. 99467). Improving communication channels between plans, patients, and providers has the potential to decrease the burden of prior authorization on both patients and providers. This added communication allows for providers to work with patients and respond to plan decisions as needed to guarantee patients receive the medically necessary care they need. Additionally, CMS' inpatient coverage proposals would clarify enrollee awareness of appeal rights so that an enrollee's liability to pay for services cannot be determined until a Medicare Advantage organization (MAO) has made its determination on a request for payment. This proposed change would eliminate confusion regarding whether an organizational determination is appealable or not due to enrollee financial liability. Having no liability to pay means that a beneficiary's financial liability will not be affected by whether a payment determination is upheld or overturned. The proposals would also address after-the-fact overturns by prohibiting MAOs from utilizing additional clinical information received after an initial determination is made and removing the discretion of MAOs to reopen an approved authorization for an inpatient hospital admission. (P. 99461). The AAMC supports CMS' efforts to protect patients by strengthening beneficiary appeal rights and preventing plans from retroactively denying coverage for care. CMS should continue to use

² 88 FR 22120

³ AAMC Comments on the <u>CY 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program</u> (February 2023)

future rulemaking to address prior authorization-related issues and hold payers accountable for decisions that fail to allow care that physicians judge necessary and appropriate.

Strengthen Reporting of Prior Authorization Metrics by Reporting at the Plan Level

Further, on prior authorization, CMS is proposing to revise required metrics for the annual health equity analysis on the use of prior authorization conducted by a plan's utilization management committee. This revision would require metrics be reported by each item or service, rather than aggregated for all items and services. (P.99423). MAOs also would be required to issue an executive summary of the analysis results in a way that ensures the public and plan enrollees can navigate and understand the data. The agency is also seeking comment on adherence to plain language principles and accessibility standards as well as consumer centered design standards used in these reports. (P.99424). The annual health equity analysis requires plans to conduct a review of the use of prior authorization that evaluates the number of requests, approvals/denials, timeframe for review and is focused on enrollees that are recipients of low-income subsidies, are dually eligible for Medicare and Medicaid, or have a disability. The analysis is also required to compare metrics for these groups to other MA enrollees without these social risk factors. The AAMC supports these proposals and urges CMS to finalize them. As the number of beneficiaries enrolled in MA increases, so does the use of prior authorization. In 2022, more than 46 million prior authorization requests were submitted to MA plans on behalf of MA enrollees. This rise in prior authorization requests was accompanied by an increase in denial rates, up to 7.4 percent in 2020 compared to 5.7 percent in 2019. Shifting the analysis requirements to be reported by each item or service, rather than aggregated for all items and services would provide greater transparency for beneficiaries, policymakers, researchers, and other stakeholders. This level of granularity will provide a greater understanding of what types of services are subject to prior authorization and how utilization management tools are applied by MA plans. Reporting at the plan level will also allow CMS and other stakeholders to identify and address any concerns with health equity that may arise plan to plan due to the use of utilization management tools.

As discussed in our response to CMS' request for information (RFI) on MA data,⁵ we continue to urge CMS to require additional reporting related to prior authorization, including on timeliness of determinations and reasons for denials, claims and payment requests denied after a service has been provided, beneficiary out-of-pocket spending, and disenrollment patterns stemming from these denials. These data points will allow policymakers and regulators to adequately oversee the program and create potential reforms as needed. Transparency from plans to provide this data is important so that researchers, regulators, and lawmakers can evaluate MA plans and assess whether plans are complying with CMS requirements. Lastly, the AAMC urges CMS to explore policy proposals to require adherence to plain language principles and accessibility standards as

⁴ KFF, Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022 (August 2024) https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/

⁵ AAMC Comments on Medicare Advantage Data RFI (May 2024)

this will ensure beneficiaries are able to not only access the data but understand and interpret how it may impact their care.

Finalize Guardrails for Safe, Equitable Use of Artificial Intelligence (AI) by Medicare Advantage Plans

Additionally, in response to comments received in response to CMS' RFI on Medicare Advantage Data. 6 the agency is proposing guardrails for the use of AI in MA plans to ensure equitable access to MA services. Specifically, this proposal will require plans to ensure services are provided equitably, irrespective of delivery method, either human or AI. (P. 99397). The AAMC shares similar concerns with CMS as we expressed in our response to CMS' RFI on MA data and encourages the agency to finalize polices to guarantee equitable access to care is preserved when utilizing algorithms and AI. Moreover, additional transparency into the use of AI is needed. The unmonitored use of algorithms and AI in MA plans is highlighted in news reports calling out the harmful effects AI use has on patient care. 8 As reported, AI-powered decision-making tools have been observed prompting plans to make more restrictive decisions regarding prior authorization and continuation of care than Medicare coverage guidelines. CMS has clarified that if a plan does use AI, it may not discriminate based on any factor related to the enrollee's health status and must remain in compliance with internal coverage criteria rules. (P. 99397). CMS' proposals related to coverage criteria also seek to prevent more restrictive decisions regarding prior authorization and continuation of care than Medicare coverage guidelines. However, limited transparency regarding the inputs, performance, and AI usage creates a difficult environment for ensuring equity, access, and accountability. The AAMC urges CMS to improve transparency by collecting data and requiring public reporting on the use of algorithms and AI used by MAOs for the purpose of prior authorization as well as any additional uses that may negatively impact patient access.

Improve Transparency in Network Adequacy Standards by Evaluating at the Plan Level

Beyond the use of prior authorization by MA plans, the AAMC shares concerns with CMS regarding enrollees' ability to obtain information about MA plans that can be used to make informed choices about coverage. Enrollees' coverage can have a direct impact on where and how an enrollee receives care. To improve plan transparency efforts, CMS is soliciting comment on whether the agency should begin assessing network adequacy at the plan level, rather than the contract level. Currently, CMS conducts network adequacy reviews of an MAO's network at the contract level by county type, which is less granular. (P. 99426). The AAMC urges CMS to

^{6 89} FR 5907

⁷ AAMC Comments on Medicare Advantage Data RFI (May 2024)

⁸ STAT News, "How UnitedHealth's acquisition of a popular Medicare Advantage algorithm sparked internal dissent over denied care" (July 11, 2023) by Casey Ross and Bob Herman, available at: https://www.statnews.com/2023/07/11/medicareadvantage-algorithm-navihealth-unitedhealth-insurance-coverage/; STAT News, "Denied by AI: How Medicare Advantage plans use algorithms to cut off care for seniors in need," (March 13, 2023) by Casey Ross and Bob Herman, available at: https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/

expand data collection efforts related to provider networks and network adequacy at the plan level, rather than the organization level, to ensure adequate beneficiary access and oversight of plans. The number of plans offered by MAOs continue to expand as MAOs generally offer multiple plans within the same service areas. However, not all providers may be in-network plan to plan, even if a plan is under the same MAO. Tracking at the organization level can mask these differences in plans. The additional granularity in network adequacy data would allow for greater transparency so that beneficiaries may more effectively compare plans and so that policymakers and stakeholders may better monitor plans compliance with regulatory requirements.

This increased transparency is essential for beneficiaries in need of specialty care as MA plans are less likely than FFS plans to include an adequate number of providers for certain services such as cancer centers and geriatricians, endocrinologists, and psychiatrists. Additionally, certain MA plans use narrow networks that often exclude teaching health systems and hospitals and their associated providers who furnish primary, specialty and subspecialty care, and behavioral health services. Teaching health systems and hospitals and their associated physicians and other providers are an integral part of ensuring access to high-quality, cutting-edge treatments. To ensure access and the availability of primary, specialty and subspecialty care and behavioral health care, and to teaching health systems and hospitals, it is imperative that network adequacy standards be met at the plan level as well as the contract level, so beneficiaries have the most accurate information to access and identify necessary providers in their network.

Improve Beneficiary Access to Accurate and Complete Provider Directories

Further, to aid Medicare beneficiaries in the enrollment process, CMS is proposing changes to the Medicare Plan Finder (MPF) for the 2026 Annual Enrollment Period. These changes will allow MA provider directories to be viewable on the MPF and would require MA plans to attest to the accuracy of the provider directory data being submitted. Plans would also be required to update provider directory data made available to CMS within 30 days of receiving the information from providers about a network status change. (P. 99431). The AAMC shared comments in support of complete and up-to-date provider directories and networks in our May 2024 response to CMS' RFI on MA Data and we echo these comments here. We also continue to support the development of a centralized solution to improving health plan directories that improves patient experience and reduces administrative burden for providers. 11

Complete and sufficient data related to beneficiary access to care is needed to provide greater oversight of plans, support beneficiaries' informed decision-making, and improve beneficiaries' ability to access care. These provider directories are often the first source patients utilize to identify health care providers and check whether a clinician is within their health plan's network and accepting new patients. Specific to MA, beneficiaries are more likely to utilize their plan's

⁹ MedPAC, (March 2024). Report to Congress: Medicare Payment Policy
https://www.medpac.gov/wpcontent/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf
¹⁰ AAMC Comments on Medicare Advantage Data RFI (2024)

¹¹ AAMC Comments on CMS RFI on National Directory of Healthcare Providers and Services (2022)

directories (compared to other sources) to find a new doctor in comparison to Medicare FFS beneficiaries, with one third of MA beneficiaries using their directory to find a new doctor in the past twelve months. ¹² Having up-to-date provider directories can assist not only beneficiaries in identifying and accessing providers, but can also assist in facilitating care coordination, health information exchange, and advance public health data reporting and research. ¹³

For provider directory data to be made available in the MPF for the 2026 Annual Enrollment Period, which occurs in fall 2025, CMS is proposing an applicability date of July 1, 2025. (P.99432). The agency has noted that if finalized, they intend to release a provider directory data submissions guide with additional guidance including how the attestation process will be implemented. Currently, CMS is considering requiring one attestation when data is initially submitted and then annually thereafter. (P.99432). However, if the agency plans to operationalize this policy for the 2026 Annual Enrollment Period, then CMS must ensure the additional guidance clarifying the attestation requirements and other operational elements are made available to plans well before summer 2025. The AAMC agrees that requiring an attestation with each data update and rushing implementation would be administratively burdensome for plans, which has the potential to translate into additional administrative work for providers. CMS should be mindful in considering positive incentives to encourage updates and reporting on provider directories rather than negative incentives that will only frustrate stakeholders and detract from the agency's intent to improve access to meaningful information.

Lastly, on CMS' provider directory proposals, the agency is proposing a change in definition that will expand MA plan provider directories to include all providers of supplemental benefits. Specifically, CMS is proposing to utilize a definition for a "direct furnishing entity" that includes any individual or entity that delivers or furnishes covered benefits to the enrollee, including all types of supplemental benefits. (P.99399). The AAMC continues to express support for increased transparency in supplemental benefits offered to MA enrollees and urges CMS to move forward with its proposal. In addition to understanding what benefits are offered and from whom, the availability of utilization data and out-of-pocket spending associated with these additional benefits is imperative to understanding the affordability, availability, and impact of these additional benefits for beneficiaries. The agency should continue to monitor reporting efforts and work swiftly to ensure public access to accurate information.

Finalize Guardrails for Supplemental Benefits to Protect Enrollees Access to Services

Additionally, related to supplemental benefits, CMS is proposing to codify current guidance and impose additional guardrails on the use of debit cards as a supplemental benefit. Most notably, the agency is proposing to prohibit MAOs from marketing the dollar value of a supplemental

¹² Gretchen Jacobson et al., What Do Medicare Beneficiaries Value About Their Coverage? Findings from the Commonwealth Fund 2024 Value of Medicare Survey (Commonwealth Fund, Feb. 2024) https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage

¹³ 87 FR 61018

benefit or the method by which a supplemental benefit is administered. (P.99390). Often supplemental benefits are used as a marketing tool to entice beneficiaries, subsequently giving these benefits a significant role in beneficiary enrollment decisions. Utilizing a monetary value to advertise supplemental benefits fails to ensure beneficiary health and wellbeing are at the forefront when contemplating these additional benefits. The use of supplemental benefits as a marketing tool may inadvertently steer beneficiaries away from plans best suited for their needs that offer broad, inclusive provider networks or less prohibitive utilization management tools. We agree with CMS that marketing the dollar value of a supplemental benefit and the method of administration, such as a debit card, could mislead beneficiaries and does not significantly aid in enrollee's decision to select a plan most suitable for their health needs. We urge CMS to finalize this policy. The AAMC also supports enhanced transparency in supplemental benefits. Improving the understanding of associated premiums and conditions or limitations may combat misleading marketing practices that rely on advertising supplemental benefits offered by MA plans.

Finalize Policies to Minimize Deceptive Marketing Practices for Medicare Advantage and Part D Plans

Moreover, CMS is continuing to revise its marketing policies for MA plans beyond supplemental benefits. To keep up with the evolving MA landscape, CMS is proposing a change to the definition of 'marketing' and 'advertisement'. CMS' proposal would eliminate the content standard and rely solely on an intent standard to determine whether communications material and activities are considered marketing. (P.99433). If finalized, this would broaden the scope of communication materials and activities defined as marketing and would be subject to regulatory review. We agree with CMS and support the adoption of additional policies to protect beneficiaries from misleading or predatory marketing and advertising practices. A 2023 report from the Senate Finance Committee explored themes of beneficiary complaints in response to open enrollment advertisements and marketing. Examples of beneficiary complaints included promising an increase in a beneficiary's Social Security checks, targeting marketing to beneficiaries with cognitive impairments, and instances of provider network confusion where beneficiaries were encouraged to switch plans without understanding the change could mean their current providers would then be out-of-network. ¹⁴ As the number of MA plans offered increases and more Medicare eligible beneficiaries choose to enroll in MA, it is imperative beneficiaries receive accurate information on the plans available. The AAMC is concerned if these practices are left unchecked and unregulated that beneficiaries may be misled and steered towards plans without their trusted providers due to narrow provider networks and increased barriers to care due to utilization management tools. This mismatch can negatively impact beneficiary access to care and worsen health outcomes. We urge CMS to finalize these policies

¹⁴ Majority Staff of the U.S. Senate Committee on Finance, Deceptive Marketing Practices Flourish in Medicare Advantage (November 2023)

 $[\]underline{https://www.finance.senate.gov/imo/media/doc/Deceptive\%20Marketing\%20Practices\%20Flourish\%20in\%20Mediacne\%20Advantage.pdf}$

and continue further oversight of MA marketing and advertising practices to ensure beneficiaries are matched to a plan best equipped to meet their health needs.

Ensure Beneficiaries Have Access to All Relevant Coverage Information Prior to Enrollment

Beyond broadening the definition of marketing, CMS is proposing to expand the required list of topics agents and brokers must discuss with Medicare eligible beneficiaries prior to enrolling them in a MA plan. The expanded list of discussion topics includes eligibility for Part D Low Income Subsidies (LIS), resources to assist with costs including Medicare Saving Programs, and the impact of MA enrollment on Medigap plan eligibility and cost. CMS is also proposing to require agents and brokers to pause and ask if the beneficiary has any outstanding questions prior to an enrollment decision being made. (P. 99427). The AAMC agrees that agents and brokers should provide clear information about available MA plans prior to enrollment by providing information on all aspects of a plan, including costs and eligibility for other programs. It is imperative that beneficiaries select a plan that is best suited to meet their own individual health needs. This requires access to all the relevant information regarding a plan prior to making an enrollment decision. This information could also increase access to additional resources to assist with costs such as LIS or Medicare Savings Programs, creating greater affordability for enrollees.

Specific to Medigap plans, it is essential that eligible beneficiaries understand the impact enrolling in a MA plan may have on future eligibility. In 2022, 90 percent of MA enrollees did not have guaranteed issue protections to purchase Medigap beyond the initial MA trial period. 15 The guaranteed issue protections allow beneficiaries to purchase Medigap coverage within the first six months after signing up for Medicare Part B, within the MA 'trial rights' period (initial 12 months of enrollment), or if their MA plan terminates coverage in their area. Outside of the guaranteed issue protections timeframe beneficiaries may be denied enrollment in a Medigap plan or face higher premiums. A limited number of states offer continuous enrollment or other exceptions to the enrollment timeframe. The goal of limiting enrollment eligibility for Medigap plans is to ensure that risk pools for these plans include a mix of both healthier and sicker enrollees subsequently lowering plan premiums. However, this also has the unintended consequence of locking out Medicare beneficiaries that may need to switch from a MA plan to Traditional FFS at a later date. Concern for this issue had increased as beneficiaries may consider switching to Traditional FFS due to narrow provider networks, increased use of utilization management tools such as prior authorization, and changes to supplemental benefits in MA plans. Lastly, Medigap plans may deny coverage for beneficiaries with pre-existing conditions, which heightens concerns around health equity and beneficiary access to care. Providing information on eligibility prior to enrollment in a plan can prevent enrollees from selecting a plan that may incur higher costs or hinder access later.

¹⁵ KFF, Medigap May Be Elusive for Medicare Beneficiaries with Pre-Existing Conditions (October2024) https://www.kff.org/medicare/issue-brief/medigap-may-be-elusive-for-medicare-beneficiaries-with-pre-existing-conditions/

Ensure Affordability and Access of Behavioral Health Services for Medicare Eligible Beneficiaries

Within this proposed rule, the AAMC is pleased to see CMS continue its commitment to ensuring access to behavioral health services across Medicare programs. CMS is proposing for CY 2026 to require cost-sharing for behavioral health services in MA and Cost plans, which are managed care plans that compliment FFS plans by offering additional benefits, to be no greater than cost-sharing in Traditional Medicare FFS plans. This would limit coinsurance for mental health specialty services, psychiatric services, partial hospitalization/intensive outpatient services, and outpatient substance abuse services to 20 percent. This would also limit cost sharing for inpatient hospital psychiatric services to the estimated Medicare FFS cost sharing for all length of stay scenarios and limit cost sharing for opioid treatment program services to zero dollars. (P. 99407). Finally, CMS is considering a transitional period for these new proposals. (P. 99420). The AAMC supports the administration's continued efforts to expand access to mental and behavioral health services and urges CMS to finalize its proposals. We agree that aligning cost sharing among Medicare programs will assist in eliminating onerous financial barriers that may limit patients' access to mental and behavioral care. We encourage CMS to work with plans to ensure that these changes do not inadvertently impact access to behavioral health and services offered.

Plans that offer limited benefits such as high cost sharing for mental and behavioral health services impede beneficiaries' ability to access care. Lack of care for mental health needs may also exacerbate physical health conditions given how interconnected mental health and physical health are. Individuals with chronic medical conditions tend to also struggle with mental health issues. 16 Patients experiencing complex health issues are often limited when seeking support for mental health care, worsening mental health access and increasing disparities. The agency's efforts to ensure that health insurance products include robust mental and behavioral health benefits that limit financial barriers for beneficiaries are an important step toward addressing the mental health crisis. In addition to patient affordability, low reimbursement rates for mental and behavioral health exacerbates patients' ability to access care and disincentivizes providers from accepting patients with certain insurance coverage. A 2022 KFF analysis found that 40 percent of psychiatrists are not accepting new Medicare patients.¹⁷ Commercial insurance generally set rates as a percentage of Medicare rates which frequently do not cover the costs of furnishing services to beneficiaries. Beyond lowering out-of-pocket costs for beneficiaries, the agency should focus on ways to increase reimbursement rates for mental and behavioral health services to improve access to care.

Finalize Changes to Improve Medical Loss Ratio Reporting and Calculations to Ensure Accuracy

¹⁶ Mental Health America, Co-occurring: Mental Health and Chronic Illness (2024) https://mhanational.org/conditions/co-occurring-mental-health-and-chronic-illness

¹⁷ Kimberly Lankford, AARP, Does Medicare cover mental health? (February 2023) https://www.aarp.org/health/medicare-qa-tool/does-medicare-cover-mental-health.html

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The medical loss ratio (MLR) provisions require insurers to spend a minimum percentage of total premiums on medical costs. Currently, MA and Part D plans are required to maintain a minimum MLR of 85 percent. This percentage depicts the amount of revenue spent on incurred claims and health care quality improvement activities. The remaining 15 percent represents the portion of premiums that can be put towards administrative costs and profits, combined. To calculate the MLR, a numerator that includes incurred claims and quality improvement activities is divided by a denominator that includes revenue after the removal of certain taxes and fees. In this proposed rule, CMS is seeking to better align MLR standards and requirements with those for commercial and Medicaid plans. The agency looks to achieve this through several different policy changes.

First, CMS is proposing to require incentive and bonus arrangements be tied to clinical or quality improvement standards to be included in MLR numerator. The agency believes this change will limit plans from inflating their MLRs by including these payments solely for the purpose or meeting the MLR threshold without any clinical or quality improvement purposes. (P 99447). Similarly, CMS is proposing to exclude administrative costs from quality improvement activities used in the numerator for calculating a plan's MLR. (P 99449). The AAMC agrees that the MLR should include only costs directly applicable to improving health care quality that can be measured and verified. Activities that are associated with improving clinical and quality outcomes for the purpose of the MLR calculation must lead to quantifiable improvements in patient outcomes or patient safety. Without this standard, MLR calculations may artificially increase plans' MLRs, inaccurately reflecting plans' premium revenue, care costs, and clinical and quality activities. Additionally, CMS should continue to verify quality improvement activities included in the MLR calculation do not include costs that are primarily focused on improving the quality of the insurance plan itself or activities associated with cost containment to primarily benefit the insurance plan over beneficiary care.

In addition to these changes, CMS is proposing enhancements to reporting requirements consistent with commercial and Medicaid MLR reporting practices. Specifically, plans would be required to provide detailed descriptions of expense allocation methodologies, including incurred claims, quality improvement activity expenditures, and tax-related costs. (P. 99450). Additionally, CMS proposed to collect additional details on plan expenditures categorized by provider payment arrangements, including FFS, alternative payment models, and population-based payments. (P. 99454). The AAMC supports CMS' effort to improve reporting activities for MA and Part D plan sponsors. Improved transparency and clear reporting of all activities with related expenses ensures that plan sponsors accurately account for claims, quality improvement activities, and other costs. Further, the AAMC continues to support the collection of data related to provider payment arrangements. ¹⁸ Obtaining a clearer understanding of provider payment arrangements in these plans will allow policymakers and stakeholders to compare and evaluate plan expenditures among the various arrangements to inform future rulemaking and program improvements.

 $^{^{18}}$ AAMC Comments on $\underline{CMS\ Medicare\ Advantage\ Data\ RFI}$ (May 2024)

Vertical Integration – Request for Information

Lastly, related to MLR reporting, the agency is exploring requiring greater transparency in transactions involving vertically integrated systems. CMS is requesting additional information to determine if the agency should include additional parameters for transfer payments included in the MLR numerator, adopt a stricter definition of incurred claims that include indirect remuneration to a plan, and adopt a refined definition of vertical integration as it relates to the health insurer market. (P. 99454). The AAMC appreciates CMS' interest in vertical integration in the health insurer market and remains concerned about how vertical integration within these markets may affect patient care. The impact of consolidation in the insurer market may affect the availability of services and providers, and quality of care.

Increases in insurer consolidation leaves consumers and providers vulnerable to harm due to the increased potential to exercise market power. A recent study found that 73 percent of the metropolitan statistical area (MSA)-level markets were considered highly concentrated according to federal guidelines, 90% of MSA-level markets had at least one insurer with a commercial share of 30% or greater, and in 48% of markets, a single insurers share was at least 50%. PAnother recent study showed that the top three large-group insurers hold an average of 82.2% of the market share in each state, far exceeding the market share of health systems. Mergers and acquisitions involving health insurers raises antitrust concerns as CMS has raised in their concerns related to MLR. With so much market share, insurers could be enabled to increase health insurance premiums above competitive levels and reduce reimbursement rates to providers below competitive levels, ultimately harming consumers. This lower reimbursement may result in a reduction in the type of services offered by physician practices and hospitals, or even closure. Related to MLR, this increase in market power and shift in premiums, reimbursement, and cost can skew calculations and without proper safeguards may encourage bad actors to manipulate calculations to meet MLR requirements.

Within the rule, CMS cites concerns about vertical integration among plans, pharmacy benefit managers (PBMs), and pharmacies. (P. 99454) The AAMC shares the agency's concerns about the effects this type of vertical integration has on drug prices and patient access. As the number of pharmacies and PBMs that insurers have acquired has increased so have anticompetitive practices. Currently, five of the largest six PBMs are vertically integrated with top health insurers in the country.²² One key function of PBMs is to negotiate discounts with drug manufacturers to reduce the costs for payers and consumers. Having the plan, the PBM, and the pharmacy

¹⁹ American Medical Association. Competition in health insurance: A comprehensive study of U.S. markets, 2023. (amaassn.org). https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf

²⁰ Association of American Medical Colleges Research and Action Institute. Why Market Power Matters for Patients, Insurers, and Hospitals (May 1, 2024). https://www.aamcresearchinstitute.org/our-work/data-snapshot/why-marketpower-matters

²¹ Id.

²² Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (July 2024) https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

consolidated under one entity may raise health spending by driving patients to use higher-priced drugs in exchange for discounts from the drug manufacturers and preferred placement on the plan's formulary. Additionally, PBMs and payers often will steer patients to their own pharmacies in their network, limiting patient access and contributing to higher out of pocket costs. These networks often exclude hospital-operated retail and specialty pharmacies, restricting the ability of patients to have their prescriptions filled at locations most convenient and accessible to them. Requiring additional transparency on plan consolidation and vertical integration and the resulting effects on patient access will shed light on these practices.

PERSCRIPTION DRUG COVERAGE AND PAYMENT

Prohibit Utilization Management Practices in Part D Plans That are More Stringent Than Corresponding Clinical Guidelines

Continuing the theme of protecting patient access to prescription medications, CMS has included proposals that impact Part D plans and prescription drug costs. Related to drug costs, CMS is proposing to add a revision to its formulary review process to check that Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs. Specifically, CMS would holistically review whether a plan's formulary and utilization management practices are "costeffective," "reasonable and appropriate," and inclusive of "incentives to reduce cost" as well as evaluate if fewer utilization controls are used on brand drugs and reference products. (P. 99470). The AAMC supports reductions in drug costs. The inclusion of generics and biosimilars in a formulary creates cost savings across the entire health system. Specific to biosimilars, in the last 10 years \$36 billion in biosimilar spending was associated with saving \$56 billion compared to estimated spending without biosimilars.²³ However, CMS should be cautious when evaluating a plan's formulary and utilization management practices not to approve step therapies and utilization management practices that are more stringent than corresponding clinical guidelines. The AAMC urges CMS not to allow plans to utilize overly stringent utilization management practices to avoid over steering patients away from preferred medications for the sake of promoting cost effectiveness. Prior authorization and step therapy requirements are routinely used by insurers to steer patients to less expensive medications.²⁴ While these practices do assist in continuing health care costs, they may also increase administrative burden and stress on patients and providers.²⁵

Increase Access to Prescription Drugs by Limiting Cost Sharing and Adopting Policies that Improve Beneficiary Affordability

²³ IQVIA, Biosimilars in the United States 2023-2027 (January 2023) https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

²⁴ See, for example, SP Pourali, et al., Out-of-pocket costs of specialty medications for psoriasis and psoriatic arthritis treatment in the Medicare population, JAMA Dermatol, 157:1239-1241 (2021), finding that 90 percent of Part D plans required prior authorization for the use of biologics in the management of psoriasis and psoriatic arthritis.

²⁵ Sachs RE, Kyle MA. Step Therapy's Balancing Act - Protecting Patients while Addressing High Drug Prices. *N Engl J Med.* 2022;386(10):901-904. doi:10.1056/NEJMp2117582

Lastly, the agency is proposing to codify three provisions from the Inflation Reduction Act (IRA) related to cost sharing and prescription affordability in Medicare Part D plans. For vaccines, CMS is proposing to codify IRA requirements beginning for plan years on or after January 1, 2023, to eliminate the application of the Part D deductible and cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Medicare Part D. (P. 99350). For insulin, CMS is proposing to codify IRA requirements to eliminate the application of the Part D deductible and limit the cost sharing for a one-month supply of each covered insulin product to \$35 or 25 percent of the product's negotiated price or maximum fair price (MFP), whichever is lower. (P. 99354). Lastly, CMS is proposing to codify the IRA provisions that establish the Medicare Prescription Payment Plan, requiring Part D sponsors to allow enrollees the option to pay their out-of-pocket prescription drug costs in monthly amounts over the course of the plan year. This differs from the current practice of requiring beneficiaries to pay out-of-pocket costs at the point of sale. (P. 99355).

The AAMC supports these proposals to improve access to medications for Part D enrollees through improved affordability. Eliminating out-of-pocket costs for Part D covered vaccinations through these IRA provisions have been associated with significant increases in vaccination rates. Further, addressing the affordability of prescription medications by limiting cost sharing for insulin products and managing point of sale costs can increase access and adherence to prescription drugs. Prescription nonadherence may be due to cost and could increase health care costs in the long-term for beneficiaries and providers, worsen health outcomes, and increase service utilization. Due to this, we urge CMS to move forward with these proposals and continue to evaluate policy options to improve affordability and access to prescription medications.

DUAL ELIGABLE SPECIAL NEEDS PLANS (D-SNP) PROPOSED POLICY CHANGES

Streamline Enrollment and Encourage Integration of Dual Eligible Special Needs Plans

Building on previous years, CMS is proposing two changes related to Dual Eligible Special Needs Plans (D-SNPs) aimed at increasing the number of beneficiaries receiving integrated Medicare/Medicaid services and eliminating confusing, misaligned, and duplicative aspects of D-SNPs. The first proposal would require plans to provide integrated member ID cards that serve as the ID cards for both the Medicare and Medicaid plans beginning in CY 2027. (P.99486). The second proposal would require plans to conduct an integrated health risk assessment for Medicare and Medicaid, rather than separate health risk assessments for each program. (P.99488). The AAMC supports CMS efforts to eliminate confusing, misaligned, and duplicative aspects of D-SNPs to simplify healthcare coverage for eligible beneficiaries. We believe there is a need to simplify D-SNPs by minimizing administrative barriers for beneficiaries so they may utilize their coverage and access care. We urge CMS to finalize these proposals and continue

²⁶ Qato DM, Romley JA, Myerson R, Goldman D, Fendrick AM. Shingles Vaccination in Medicare Part D After Inflation Reduction Act Elimination of Cost Sharing. *JAMA*. 2024;331(23):2043–2045. doi:10.1001/jama.2024.7348

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evaluating D-SNPs in future rulemaking for additional policy changes to further integrate MA and Medicaid plans.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We are committed to supporting improvements to transparency and access in MA plans as more Medicare eligible beneficiaries enroll in MA. The AAMC's concern for these issues has increased as our members and their patients grapple with the effects of plan's narrow provider networks, increased use of utilization management tools such as prior authorization and denials, and lack of transparency in supplemental benefits offered. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic community. If you have questions regarding our comments, please feel free to contact Katie Gaynor at kgaynor@aamc.org.

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.

Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer