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January 2, 2024

Ms. Chiquita Brooks-LaSure
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 Administrator Brooks-LaSure:

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

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled "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," 88 *Fed. Reg. 78476* (November 15, 2023), 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 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 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 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

CHANGES TO THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS

Expand Network Adequacy Standards for Behavioral Health in MA Networks

In a continued effort by CMS to strengthen network adequacy standards for Medicare Advantage (MA) and improve access to mental and behavioral services, the agency is proposing to create a new facility-specialty type to add to the existing list of facility-specialty types that are evaluated for network adequacy review. This new specialty type, referred to as Outpatient Behavioral Health, would include Marriage and

Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Programs (OTPs), Community Mental Health Centers (CMHCs), and other behavioral and addition medicine specialty providers (P. 78484).

The AAMC supports the Administration's efforts to expand access to mental and behavioral health services by building on network adequacy standards. Further, we thank CMS for listening and responding to stakeholders' concerns that patients struggle with accessing behavioral health providers. Ensuring that insurers have robust mental and behavioral health provider networks will safeguard patients' access to a greater number and type of providers, to meet their health care needs. Patients suffering from medical conditions who lack access to needed medical care, including mental health care, often present to emergency departments with advanced disease that requires acute, more expensive medical care. Individuals suffering from mental and behavioral health issues are no different. Further, mental health and physical health are closely connected; individuals with chronic medical conditions tend to also struggle with mental health issues.[1] Patients experiencing complex health issues often find limited support for providing mental health care, exacerbating mental health access and increasing disparities. The Departments' efforts to ensure that health insurance products include robust mental and behavioral health benefits that do not present burdensome barriers to access care is an important step toward addressing the mental health crisis.

However, provider inclusion in a network does not guarantee access. Low reimbursement rates limit access to in-network providers, including behavioral health specialists. Reimbursement rates should reflect the time and resources needed to provide care to ensure access. The 2022 AAMC Consumer Survey of Health Care Access[2] revealed that 35 percent of respondents who reported they needed mental or behavioral health care in the previous 12 months were not always able to access that care. CMS should monitor MA beneficiaries' access to all providers, including behavioral health providers. Further, behavioral health specialists included in the network must be accepting new patients. If behavioral health specialists are listed on a network but are not accepting new patients, this will do little to expand access moving forward. Additionally, CMS and other payers should implement policies that increase reimbursement rates for mental and behavioral health services in order to improve and ensure access to care.

Lastly, the agency is also proposing to add the Outpatient Behavioral Health specialty type to the list of specialty types that will receive a 10 percentage point credit toward the percentage of beneficiaries residing within published time and distance standards if the MA organizations contracted network includes one or more telehealth providers of that specialty type that provide additional telehealth benefits for covered services. (P. 78486). The Association is supportive of the expansion of telehealth services by plans to better serve their enrollees. This allows patients to access needed specialty and sub-specialty care from AAMC-member providers. However, we believe it would be premature to provide time and distance credit for telehealth services at this time. There are still barriers to the use of telehealth, such as the availability of broadband and access to the required equipment. Specific to this proposal, we are concerned that this may inadvertently weaken network adequacy standards. This could potentially leave beneficiaries without in-person options for those who require them, even in areas that appear to have strong provider networks. Therefore, we urge CMS not to implement this provision.

[1] https://mhanational.org/conditions/co-occurring-mental-health-and-chronic-illness
[2] https://www.aamc.org/about-us/mission-areas/health-care/workforce-studies/datasets

Finalize Proposals to Ensure SSBCI Improve or Maintain Health

In order to ensure that Special Supplemental Benefits for the Chronically Ill (SSBCI) offered by MA plans have a reasonable expectation of improving or maintaining the health and overall function of a chronically ill enrollee, CMS offers new policy proposals that shift responsibility from the agency to the plans. The agency is proposing for MA plans that utilize SSBCI in their bids, that they complete the following: 1) establish a bibliography of relevant acceptable evidence related to the item of service for the applicable coverage year, 2) require MA plans to follow their written policies based on objective criteria for determining eligibility for SSBCI, 3) require MA plans to document denials of SSBCI eligibility rather than approvals, and 4) codify CMS's authority to deny a bid due to the SSBCI included in the bid. (P.78536). The agency cited that they believe these proposals will improve the experience of MA plans, enrollees, and CMS in managing and oversight, including in the case of denials. (P.78538).

The AAMC supports CMS's effort to ensure access to SSBCI and ensure beneficiary health and well-being are at the forefront when plans are considering these additional benefits and urges CMS to finalize their proposal. As more MA plans offer both these primarily health-related supplemental benefits and non-primarily health-related supplemental benefits, it is essential that CMS establishes a precedent that these supplemental benefits are included with the goal of improving beneficiary health and function. As a great pool of research is available on the correlation between addressing primary health needs or other social needs and its effects on health outcomes, it is vital that this knowledge be leveraged. In this case that knowledge can be leveraged in the implementation of SSBCI by selecting benefits that plans know will lead to stabilization or improvements in beneficiaries' health. Additionally, this proposal will assist in CMS oversight of eligibility for these supplemental benefits which will allow CMS to monitor plans eligibility determinations to ensure they are done in an equitable manner. However, as CMS notes in the rule, it is also crucial that the agency work together with MA organizations to continue offering these supplemental benefits without placing too much burden onto Medicare Advantage organizations (MAOs) that there is a drop in SSBCI offerings.

In addition to these policy changes related to SSBCI, CMS is also proposing changes to the SSBCI disclaimer that MA plans are required to provide in their advertising and marketing materials. CMS proposes to require plans to specify that not all individuals are eligible for SSBCI and clarify which conditions are necessary to qualify for these benefits (P.78550). We agree with CMS that polices should be adopted that increase transparency for beneficiaries and limit misleading advertising. We urge CMS to finalize these policies and continue to monitor misleading marketing and advertising practices that may harm beneficiaries.

Finalize Proposal to Give Mid-Year Notice of Unused Supplemental Benefits to MA Enrollees

CMS is proposing to require MA plans to provide notification to enrollees of supplemental benefits that have not yet been accessed. Specifically, CMS is proposing that beginning January 1, 2026, that MA plans must mail a mid-year notice to each enrollee between June 30 and July 31 of a plan year that includes information on supplemental benefits available to the enrollee that have not yet been used during that plan year. The notice would include the following information: the scope of supplemental benefits, applicable cost sharing, instructions on how to access the benefits, applicable information on the use of network providers for each available benefit, list benefits consistent with evidence of coverage, and a toll-free customer service number. (P.78540).

The AAMC supports the proposal for a mid-year notification of unused supplemental benefits to MA plan enrollees. We echo CMS's sentiments within the proposed rule, that beneficiaries may be making enrollment decisions based on the supplemental benefits advertised to them during the annual election period but may be missing out by not be utilizing them during the plan year. We agree that a mid-year reminder containing information on the scope of the supplemental benefits, cost sharing, instructions on how to access benefits, etc. would encourage and remind beneficiaries to take advantage of these additional benefits offered as they could address additional health needs that may otherwise go unmet.

Ensure Agent and Broker Compensation Align with MA Enrollee Needs

CMS is proposing several changes to better align agent and broker behaviors and compensation with MA enrollee needs. The first proposal would prohibit contract terms between MA organizations and agents, brokers, and other third party marketing organizations (TPMOs) that may interfere with the agent's or broker's ability to objectively access and recommend the plan that best fits the health care needs of a beneficiary. The second proposal would set a single rate for agents and broker compensation for all plans and revise the scope of what is considered compensation. Lastly, CMS is proposing to eliminate the regulatory framework that allows for a separate payment to agents and brokers for administrative fees, and instead administrative fees would be baked into the single rate for compensation. (P. 78554)

The AAMC agrees that agents and brokers should steer MA beneficiaries to plans that best suit their individual health needs. Any incentives that encourage agents and brokers to deviate from this should be eliminated, such as the use of increased administrative fees for certain plans. It is imperative that beneficiaries are matched with plans that best address their individual health needs to ensure that they receive coverage and access to the care that they need. As mentioned previously, we strongly advise CMS to continue to monitor for and take action against misleading tactics, including marketing and advertising, that prevent or interfere with a beneficiary's ability to enroll in the best plan suited for them. Therefore, we urge CMS to move forward with finalizing their proposals to revise agent broker compensation.

Expand UM Committee Requirements to Include Health-Equity Related Requirements

Expanding on CMS's requirement for MA plans to establish a utilization management (UM) committee to review UM policies and procedures, CMS is proposing to add additional health-equity related requirements. CMS is proposing that beginning January 1, 2025, UM committees must include at least one member with expertise in health equity. In addition to this, the UM committee must conduct an annual health equity analysis of the use of prior authorization. Additionally, the analysis must be approved by the member of the committee with health equity expertise and a final report of the analysis must be posted on the plan's publicly available website. The analysis would focus on enrollees that are the recipient of the low-income subsidy or are dually eligible for Medicare and Medicaid and enrollees who have a disability. (P. 78541).

We support these proposals and urge CMS to finalize them. The AAMC supports adding a representative to the UM committee that understands the impact that prior authorization requirements can have on access and health equity to ensure equitable determinations of prior authorization requests. We also believe that the additional health equity analysis on the use of prior authorization has the potential to identify instances of inequity, which can then be reduced and eliminated. We agree that CMS should begin with evaluating the use of prior authorization for enrollees that are the recipient of the low-income subsidy or are dually eligible for Medicare and Medicaid and enrollees who have a disability. However, in future reports, CMS should consider expanding the populations evaluated as UM committees build

experience and knowledge. We also echo our previous recommendations, that if the UM committee does not have the specific expertise to properly decide on a prior authorization request, it should be required to seek outside assistance from an entity or entities with expertise in the subject.[3] This will ensure that prior authorization requests are not denied strictly because of the committee's lack of clinical knowledge or expertise.

Allow MA Enrollees Additional Options to Challenge the Termination of Services When an Appeal Deadline is Missed

CMS is proposing to align MA requirements with Original Medicare requirements that allow QIOs to hear appeals from enrollees who make an untimely request for a fast-track appeal from an Independent Review Entity related to services in a skilled nursing facility, home health, or comprehensive outpatient rehabilitation facility. This would allow MA enrollees another option to challenge the termination of services from a provider where they have missed a deadline for an appeal. (P. 78544).

As stated in our February 2023 comments to CMS in response to the Contract Year 2024 proposed rule, the AAMC supports efforts to ensure that beneficiaries receive the necessary post-acute care in the correct setting.[4] According to the Kaiser Family Foundation, in 2021, more than 35 million prior authorization requests were submitted to MAOs on behalf of MA beneficiaries. Just 11 percent of prior authorization denials were appealed, but of those a whopping 82 percent resulted in the initial prior authorization denial being fully or partially overturned.[5] If the beneficiary is required to follow-up on the denial, they often forego care due to the complexities of filing an appeal. Additionally, some beneficiaries that are discharged early from the post-acute care setting before they are healthy enough to go home decompensate and return to the emergency department sometimes necessitating an inpatient admission to stabilize the patient. This unnecessarily leads to a cycle of being transferred among acute and post-acute settings. If a patient returns to the emergency department within 30 days of discharge and requires an inpatient admission, this may also negatively impact a hospital's readmission rate. Therefore, we urge CMS to finalize their proposal to align MA requirements with Original Medicare requirements that allow QIOs to hear appeals from enrollees who make an untimely request for a fast-track appeal from an Independent Review Entity.

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

Allow for D-SNP Enrollment Flexibilities While Ensuring Beneficiary Access to Appropriate Coverage is Not Limited

CMS is offering several proposals related to enrollment flexibilities for Dual Eligible Special Needs Plans (D-SNPs) aimed at increasing the number of beneficiaries receiving integrated Medicare/Medicaid services from the same plan. First, CMS is proposing to replace the current quarterly special enrollment period (SEP) with a one-time-per-month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone prescription drug plan. CMS would also create a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP monthly. In another proposal CMS would limit enrollment in certain D-SNPs to individuals who also enroll in an

[3] https://www.aamc.org/media/64986/download
[4] https://www.aamc.org/media/64986/download?attachment
[5] https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/

affiliated Medicaid managed care organization (MCO). This proposal would also limit the number of D-SNP plan benefit packages an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization can offer in the same service area as an affiliated Medicaid MCO to limit choice overload. (P.78567). Additionally, beginning in plan year 2027, CMS would require D-SNPs offered by an MA organization to limit enrollment to individuals enrolled in the D-SNP's affiliated Medicaid MCO when the MA organization also contracts with a state as a Medicaid MCO. MA organizations would only be allowed to offer one D-SNP in the same service area as the aligned Medicaid MCO. Lastly, beginning in plan year 2030, CMS would require that these D-SNPs only enroll individuals enrolled in the affiliated Medicaid MCO. By 2030, integrated D-SNPs would be required to disenroll individuals who are not enrolled in both the D-SNP and Medicaid MCO offered under the same parent organization, with the exception that D-SNPs be allowed to use a period of deemed continued eligibility to retain enrollees who temporarily lose Medicaid coverage. (P. 28572).

We appreciate CMS's concern within the proposed rule with predatory marketing practices and choice overload for dually eligible beneficiaries as it relates to D-SNPs. We agree with CMS that the duel eligible population historically been found to have lower levels of education and health literacy [6] and due to this, we do believe there is a need to simplify the enrollment process through a more streamlined approach. However, we are concerned that limiting the number of plans available could impact enrollment and access depending on beneficiary needs and coverage offered by a more limited number of plans available. This is especially true for states that may lack integrated D-SNPs. With this said, we urge CMS to consider and mitigate negative impacts on access prior to adopting policies that would limit the number of D-SNPs offered by MA organizations.

Finalize Proposal to Lower D-SNP Look-Alikes Threshold

In addition to D-SNP enrollment flexibilities, CMS is also looking to expand their policies on look-alike plans by proposing to lower the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026. CMS proposes that any plan that has the relevant percentage of dual eligibles enrolled but that is not a D-SNP would lose their MA contract and not be able to re-contract with CMS until they met the percentage threshold or become a D-SNP plan. (P.78581) Again, we believe that CMS should continue to limit misleading marketing and advertising to ensure that beneficiaries are selecting the plans that best meet their own individual health needs. With that said, we urge CMS to finalize their proposal to lower the D-SNP look-alike threshold and emphasize the need to continue to monitor and address potential loopholes in prohibiting D-SNP look-alike plans.

Ensure Providers are Adequately Reimbursed for Out-of-Network Services

CMS is proposing to require D-SNP PPOs to cap out-of-network cost sharing for professional services and out-of-network acute and psychiatric inpatient services at the cost sharing limits for services when furnished in network beginning January 1, 2026. For professional services this would include primary care services, physician specialist services, partial hospitalization services, and rehabilitation services. CMS also included a proposal to limit cost sharing for a plan to under the Medicare FFS cost sharing for chemotherapy administration services, skilled nursing facility services, home health services, and durable medical equipment. Finally, CMS is also considering an alternative proposal that would limit all D-SNP PPO out-of-network cost sharing to no greater than Medicare FFS or using an incremental approach to

[6] https://atiadvisory.com/wp-content/uploads/2022/06/A-Profile-of-Medicare-Medicaid-Dual-Beneficiaries.pdf

establish a limit specifically for physician services, including psychiatric and other mental health services. (P.78585).

While the AAMC supports limiting beneficiaries' financial obligation for out-of-network care, out-of-network providers should not be required to accept in-network reimbursement for their services from MAOs. The burden of payment should not fall on providers but rather it should fall on MA organizations to provide adequate reimbursement for services that will make providers whole regardless of if they are in or out of network. Teaching hospitals and their associated physicians and other providers are an important part of ensuring access to high-quality, cutting-edge treatments. However, teaching hospitals and their associated faculty physicians are sometimes excluded from insurer networks. Excluding these institutions and physicians limits patients' access to specialized and sub-specialized care that often is only furnished at teaching hospitals. Ensuring that MA plans have robust provider networks, including teaching hospitals and their associated providers, will safeguard beneficiaries' access to a greater number and type of providers, to meet their health care needs. However, in the case of out-of-network providers, MAOs should be required to reimburse providers at a rate that accurately reflects the services provided.

FORMULARY SUBSTITUTION OF BIOSIMILARS

Limit Negative Impacts on Beneficiaries Due to Formulary Substitutions for Part D Plans

CMS is providing updated policy proposals on additional changes to an approved formulary for Part D plans, specifically focusing on biosimilar biological product maintenance changes and the timing of substitutions. CMS is proposing to include substitutions of biosimilar products other than interchangeable biological for their reference products as maintenance changes. This would mean that all FDA-licensed biosimilar biological products, not just interchangeable biological products, that are highly similar to and have non clinically meaningful difference from the reference product in terms of safety and effectiveness may follow the pathway for formulary maintenance changes. CMS believes that this will allow for the promotion of utilizing more biosimilar biological products while still providing enough advance notice to Part D enrollees of formulary changes. (P. 78518). Additionally, CMS is proposing to update the definition of maintenance changes to include adding negative formulary changes when these biosimilar biological products are added to the same or lower cost-sharing tier and with the same or less restrictive prior authorization, step therapy, or quality limit requirements.

We appreciate CMS' efforts to advance the use of biosimilar biologic products and encourage an increase in their utilization. Increasing the use and availability of biosimilar biologic products creates cost savings for the entire health care system. In a report from IQVIA, it was found that in the last 10 years that $36 billion in biosimilar spending was associated with saving $56 billion compared to what spending would have been without biosimilars. IQVIA also found that over the next five years this savings will increase to $181 billion.[7] However, CMS should ensure beneficiary access in not impacted before finalizing their proposals.

Lastly, CMS is proposing to require a 30 day advance written notice prior to making any negative formulary change to the reference product. (P. 78520). Which would mean that if a new prescription is required for the enrollee to switch from the reference product to the biosimilar biologic product, then enrollees will have 30 days to do so before the change becomes effective. CMS notes that they have

[7] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

previously utilized 60 days for enrollees to obtain a new prescription due to formulary changes but have since changed this policy. (P.78519). While the 30-day notice that is proposed mirrors current policy under §423.120(b)(5)(i), we believe that additional time for beneficiaries to act would be warranted in this case. The additional time would allow beneficiaries ample time to receive a new prescription for the biosimilar biologic product or to work with their provider to determine if a different treatment is needed. We urge CMS to finalize the 60 day time frame for negative formulary changes to ensure enrollees have sufficient time to obtain a new prescription if needed. The additional time will help to prevent beneficiaries from facing gaps in treatment due to a prescription lapse.

UTILIZATION DATA IN MEDICARE ADVANTAGE PLANS

Building on the policies outlined in the proposed rule, we also urge CMS to consider expanding the utilization data available to relevant stakeholders related to MA plans. **Specifically, we urge CMS to include standardized costs in the Medicare Advantage encounter data that the agency provides, and if needed, explore additional pathways to collect such data.** As the portion of beneficiaries enrolled in Medicare Advantage surpasses the portion of beneficiaries enrolled in Traditional Fee-for-Service Medicare[8], it is important to ensure that data is available so that researchers, regulators, and lawmakers are able to evaluate Medicare Advantage plans and whether MA plans are complying with CMS requirements.

In addition to standardized costs in utilization data, access to publicly available data related to prior authorization would also increase transparency in Medicare Advantage plans and improve care for Medicare beneficiaries. Access to data on prior authorization requests by type of service, 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, will allow policymakers and regulators to adequately oversee the program and create potential reforms. While CMS currently does collect some data related to Medicare Advantage, this data is often used for internal purposes only or made available with a significant time delay, which hinders transparency efforts.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. 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

[8] https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/