AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

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:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2025 Policy and Technical Changes to the Medicare Advantage Program, issued on November 15, 2023.

In response to the CMS' proposed changes for CY 2025, the AMA provides the following detailed recommendations to enhance the Medicare Advantage Program. In summary, our key recommendations are as follows:

1. **Improving Access to Behavioral Health Providers**: The AMA supports the proposed requirement that Medicare Advantage (MA) plan networks include Outpatient Behavioral Health. We emphasize the need for timely and affordable access to evidence-based treatments for opioid and substance use disorders. The AMA also recommends enhanced monitoring of patient access to these treatments and ensuring team-based care is physician-led to maximize the effectiveness of the new Outpatient Behavioral Health facility-specialty.

2. **Standards for Electronic Prescribing**: The AMA commends CMS' efforts to update electronic prescribing standards to improve the prescription process. We support the adoption of the National Council for Prescription Drug Programs (NCPDP) SCRIPT and Real Time Prescription Benefit (RTPB) standards to provide real-time patient-specific prescription drug coverage information, enhancing the care delivery process.

3. **Health Equity in Utilization Management**: The AMA applauds CMS for its initiatives to integrate health equity into utilization management policies. We support the need for an annual health equity analysis of utilization management practices, especially prior authorization, to address the disparities and barriers in accessing medically necessary care.

4. **Biosimilar Requirements**: The AMA expresses concerns about CMS' proposal to allow biosimilar biological products to be substituted for their reference products. While recognizing the potential for cost savings, we highlight the importance of patient safety and physician autonomy and recommend appropriate regulatory standards for biosimilars.

5. **Enhanced Right to Appeal**: The AMA supports CMS' proposal to enhance the rights of MA beneficiaries in appealing decisions about service terminations. We support having a Quality Improvement Organization review untimely appeals, aligning MA beneficiaries' appeal rights with those of traditional Medicare.

6. **Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System**: The AMA highlights the importance of focusing the Star Ratings program on compliance, communication, and access and support CMS' proposals that ensure accuracy and completeness in the data used for determining ratings and further support the need for transparent quality metrics.

7. **Payment for Routine Costs Associated with Clinical Trials**: The AMA urges CMS to develop a coordinated payment policy for covering routine costs associated with participation in clinical trials and recommends that patients should not bear the upfront costs and physicians should receive direct payment for services, alleviating the financial and administrative burdens associated with clinical trials.

8. **Special Supplemental Benefits for the Chronically Ill (SSBCI)**: The AMA supports CMS' proposals to ensure that SSBCI items and services are appropriate for and benefit chronically ill enrollees. We support the requirement for plans to demonstrate evidentiary support for these benefits and suggest ongoing data collection to assess their effectiveness and utility.

Improving Access to Behavioral Health Providers

In comments responding to the 2022 Request for Information: Building Behavioral Health Specialties with MA Networks, the AMA recommended that CMS ensure that all provider networks include adequate access to physicians and other health professionals and organizations offering behavioral health care. We specifically urged CMS to require that MA networks be required to include timely and affordable access to those who offer evidence-based treatment for opioid use disorder (OUD) and other substance use disorders (SUD), including addiction medicine and psychiatry physicians who provide buprenorphine in-office for the treatment of OUD as well as Opioid Treatment Programs (OTPs).

The AMA appreciates and strongly supports the proposed requirement that MA plan networks must include Outpatient Behavioral Health. As proposed, the new Outpatient Behavioral Health combined facility-specialty type can include OTPs, addiction medicine physicians, Community Mental Health Centers, and other physicians, other health professionals, and facilities that regularly furnish behavioral health counseling or therapy services, including but not limited to psychotherapy or prescription of medication for SUD. The proposed regulation includes time and distance standards that MA plans would be required to meet for the new specialty type and indicates that CMS plans to monitor the appropriateness of the Outpatient Behavioral Health approach for network adequacy review purposes.

The Outpatient Behavioral Health requirement for MA networks is an important step forward in potentially improving access to behavioral health and OUD and SUD treatment and recovery

services for Medicare patients enrolled in MA. The AMA offers several recommendations to improve this proposal.

To help monitor the appropriateness and effectiveness of this approach, the AMA reiterates our recommendation that CMS require MA plans to report on the number of patients receiving medications for opioid use disorder (MOUD), including the type of medication—buprenorphine or methadone—and whether that care is being provided in- or out-of-network. In addition, the team-based care approach envisioned for the new Outpatient Behavioral Health facility-specialty needs to be physician-led. CMS' proposal suggests a high degree of flexibility as to the types of health professionals, organizations, and facilities to be included and in general it is appropriate to allow them to be organized to best meet the needs of the patients and communities they serve. Whereas an OTP must have a physician medical director, if an Outpatient Behavioral Health facility were to be established without including an OTP or addiction medicine or other physicians, it is possible that it would only have non-physician health professionals. Each Outpatient Behavioral Health facility should be required to have a physician lead the behavioral health care team.

There will be little benefit to having Outpatient Behavioral Health available in MA networks if the plans employ other utilization management tactics to prevent patients from accessing evidence-based treatment for OUD. The AMA recommends that:

- **MA plans should be prohibited from imposing prior authorization, step therapy or fail first requirements on medications for OUD.** The nationwide drug overdose epidemic has become increasingly lethal with more than 100,000 Americans dying annually, largely due to illicitly manufactured fentanyl and other illicit drugs, often manufactured in forms that are designed by criminal enterprises to deceive people into believing that these deadly products are safe pharmaceuticals. There is clear evidence in support of using buprenorphine or methadone to treat opioid use disorder. It is indisputable, however, that prior authorization, step therapy, and fail first protocols are barriers that many patients will not live to cross. When a patient who is experiencing the cravings and fear of withdrawal that typify OUD faces any type of delay in accessing treatment with medication, they may instead turn in the opposite direction to satisfy their craving and ward off withdrawal and never get the chance to recover.

- **MA plans should be required to include all forms of buprenorphine on their formularies and be prohibited from imposing quantity limits on dosages of buprenorphine.** A recent clinical considerations paper published by the American Society of Addiction Medicine discusses key factors in current treatment protocols for patients with OUD. It makes clear that treatment must be individualized to the patient and that one-dose-fits-all approaches will not be effective in addressing this epidemic. It discusses different formulations for buprenorphine and different doses. MA plans should make all forms available on formularies and in their network pharmacies. Doses should not be limited to 16-24 mg daily as this will often not be sufficient for patients to achieve long-term recovery from OUD. Some patients with high opioid tolerance may require buprenorphine doses greater than 24 mg per day, such as 32 mg per day, during treatment stabilization, and some patients will benefit from long-acting, injectable forms of buprenorphine. MA plans should not be allowed to cavalierly play with people's lives when they substitute their judgment for that of the addiction medicine physician.

- **MA plans should cover both prescription and over-the-counter naloxone and ensure that network pharmacies have naloxone available and have OTC naloxone available like other OTC products and not behind the counter.** Naloxone is a critical tool for preventing deaths due to drug overdoses. Individuals should not have to face the shame and stigma of asking a pharmacist for naloxone now that OTC naloxone products have been approved, yet these OTC products remain extremely difficult to locate in pharmacies. The AMA is deeply concerned by reports of pharmacies promoting their support for naloxone only to then keep these life-saving products from the easy access OTC is designed to bring. Thus, while we understand that the brand medication, Narcan, may no longer be eligible for coverage under Part D, there are other naloxone-containing, opioid overdose reversal agents that have not switched to OTC status. We urge, therefore, that the non-OTC products remain eligible for coverage under Part D. Coverage by MA plans and other payers could be extremely helpful in increasing access to this lifesaving medication.

Improving equitable access to SUD care must become a priority

Nearly 52,000 Medicare beneficiaries had an opioid-related overdose in 2022, but fewer than one in five Medicare beneficiaries with an OUD receives medications for their OUD, according to a recent Office of the Inspector General (OIG) Report.[1] Rates to receive medications for OUD varied considerably by state—from only six percent of beneficiaries in Florida with an OUD to 60 percent in Vermont. The OIG report also highlighted multiple inequities in OUD treatment that the AMA strongly urges CMS to forcefully address. Inequities included the fact that in 2022, only 15 percent of female enrollees received MOUD compared to 23 percent of male enrollees. In addition, White enrollees were more likely to receive MOUD than Black, Hispanic or Asian/Pacific Islander enrollees. When MOUD was provided, Black and Hispanic enrollees were less likely to receive buprenorphine from a community-based physician. While buprenorphine and methadone both are evidence-based MOUD options, methadone currently can only be accessed at Opioid Treatment Programs, which often require individuals to daily travel far distances, arrange for childcare and manage employment-related requirements.[2] The AMA strongly encourages CMS to require MA plans to conduct analyses where people with OUD get MOUD—to ensure that within the time/distance standards, there are adequate numbers of in-network OUD physicians who offer both medications.

Standards for Electronic Prescribing

The AMA sincerely appreciates CMS' ongoing efforts to address the significant challenges the prescribing process poses to Medicare beneficiaries and physicians. We encourage CMS to continue to

[1] U.S. Department of Health and Human Services Office of Inspector General. The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern. December 2023. Available at https://oig.hhs.gov/oei/reports/OEI-02-23-00250.pdf.

[2] To address these challenges, the AMA supports S. 644/H.R. 1359 - the Modernizing Opioid Treatment Access Act (the "M-OTAA"). This bipartisan, bicameral legislation would responsibly expand access to methadone treatment for opioid use disorder (OUD) in medical settings and areas where it is not available now. Letter available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfcsot.zip%2F2023-5-16-Signed-On-MOTAA-Stakeholder-Endorsement-Letter.pdf.

evaluate the MA and Part D programs for additional opportunities to improve the care delivery process when finalizing this rule and in future rulemaking.

Like CMS, the AMA is concerned by the current inefficiencies in the electronic prescribing process, notably the lack of access to real-time patient cost-sharing information at the point of prescribing and the often manual, labor-intensive prior authorization (PA) process (e.g., submitting PA requests via facsimile). We would like to highlight that although electronic PA (ePA) offers an opportunity for physicians to free themselves from these manual processes, the ePA systems offered today fail to provide physicians with critical pieces of coverage and benefit information. For example, in the 2022 AMA Prior Authorization Physician Survey, 64 percent of physicians reported that it is difficult to determine whether a prescription medication requires PA.[3]

We therefore commend CMS for recognizing these challenges and proposing much-needed updates to standards that play a crucial role in the electronic prescribing workflow. Providing accurate, real-time, patient-specific prescription drug coverage information at the point of prescribing is critical for obtaining the best patient outcomes, and the updates to the NCPDP Formulary and Benefit (F&B) and SCRIPT standards, as well as the implementation of the Real Time Prescription Benefit (RTPB) standard, will play a crucial role in ensuring patients can access the most cost-appropriate prescriptions in a timely manner.

The AMA appreciates CMS' proposed improvements to the electronic prescribing process, and the AMA urges CMS to finalize its proposal to adopt updated versions of the NCPDP SCRIPT and F&B standards, as well as its proposal to adopt the new NCPDP RTPB standard.

NCPDP SCRIPT standard version 2023011

The AMA supports CMS' proposals to require use of the NCPDP SCRIPT standard version 2023011 and retire the use of current NCPDP SCRIPT Standard Version 2017071 as the e-prescribing standard for transmitting prescriptions and related information, including electronic prescription drug PAs, effective January 1, 2027.

As CMS notes in the proposed rule, the NCPDP SCRIPT standard version 2023011 offers additional benefits over version 2022011, and version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, which should support a smooth transition process for the industry.

NCPDP RTPB standard version 13

The AMA commends CMS for addressing the need for real-time, patient-specific prescription drug coverage information at the point of prescribing in physicians' electronic health records (EHRs) via real-time benefit tools (RTBTs). The AMA also supports CMS' proposal to require the most current version, NCPDP RTPB standard version 13, as the exclusive standard for prescriber RTBTs beginning January 1, 2027.

As CMS has noted previously, formulary and benefit data must be reliable, seamlessly integrated within EHR systems, and sufficiently detailed (unlike currently available F&B batch files), to be widely adopted by physicians. To facilitate informed conversations between physicians and patients regarding drug selection, the AMA strongly supports adoption of the NCPDP RTPB standard version 13 for the

[3] 2022 Update: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

increased transparency it will bring to both physicians and patients at the point-of-care regarding PA requirements, formulary design, and patient financial responsibility. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of PA and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Enhanced transparency of coverage restrictions in EHRs can thus help prevent medication nonadherence and treatment abandonment.

The AMA has actively participated in the development of the NCPDP RTPB standard since its inception, and the AMA has full confidence in NCPDP's consensus-based decision-making process for developing and refining its standards. CMS noted in the proposed rule that several comments expressed concerns regarding potential limitations of the NCPDP RTPB standard (e.g., one commenter noted that version 13 of the RTPB standard may impede what the commenter referred to as "the industry standard" of sending four drugs or pharmacies in a single transaction). CMS also noted concerns about the potential impact of proprietary RTBT tools that have already been implemented on adoption of the standard. The AMA appreciates these concerns and recognizes the potential for some immediate challenges posed by transitioning from propriety to standardized RTBTs. However, we agree with CMS' assessment that the ultimate impact of RTBTs is contingent on prescribers actually receiving the correct patient-specific information in a payer's RTBT response. **The only way to guarantee that physicians can access accurate, patient-specific cost and coverage information at the point of prescribing for the greatest number of patients is for CMS to move away from today's limited proprietary RTBT solutions and to adopt its proposal that RTBTs utilized by Part D plan sponsors adhere to the NCPDP standard version 13.** We agree with CMS' proposal to adopt NCPDP RTPB Version 13 effective January 1, 2027.

Beneficiary RTBT

The AMA appreciates CMS' ongoing efforts to improve price and cost transparency for all Medicare beneficiaries. As noted in the proposed rule, CMS recognizes that the NCPDP RTPB standard was not designed for beneficiary RTBTs, and the AMA supports CMS' perspective that it is not necessary or appropriate to adopt a beneficiary facing RTBT standard at this time. As CMS correctly notes, beneficiary RTBTs are made directly available to Part D plan enrollees by their Part D sponsor, and it is not necessary for these beneficiary RTBTs to interface with their physician's electronic prescribing system or EHR to deliver pricing and coverage information to the beneficiary. **The AMA agrees with this perspective, and we would like to emphasize that it is critical that any pricing and/or coverage information provided in a physician-facing RTBT matches the information displayed in the beneficiary's RTBT.** Until a beneficiary-facing standard is developed that can guarantee the information shared in both physician and beneficiary-facing RTBTs is always consistent, CMS should not require conformance with any standard for beneficiary RTBTs.

NCPDP F&B standard version 60

As CMS notes, the NCPDP F&B standard provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems on a batch basis. Applications utilizing the F&B standard provide useful patient coverage information, and, as CMS states in the proposed rule, the NCPDP F&B standard plays an important foundational and complementary role for many other standards used by electronic prescribing, electronic PA, and RTPB applications. The AMA supports CMS' proposals to adopt the NCPDP F&B standard version 60 effective January 1, 2027.

Implementation Deadlines and Transition Periods for Electronic Prescribing Standards

For both the updated versions of the NCPDP SCRIPT and F&B standards, as well as the new NCPDP RTPB standard, the AMA supports CMS' proposed implementation deadline of January 1, 2027 (with a preceding transition period for the SCRIPT and F&B standard updates).

As noted above, the AMA believes the backwards compatibility of the new versions of the SCRIPT and F&B standards should provide sufficient time for these system upgrades to be completed by the January 1, 2027, deadline. However, given the number of system upgrades CMS is proposing to require before January 1, 2027, the AMA is mildly concerned that implementing all of these system updates simultaneously may result in some physicians experiencing technical issues or missing the implementation deadline for one or more standard. Our physician members place high value on being able to reliably engage in electronic prescribing and receive accurate and timely patient cost and coverage information, and the only way to guarantee that physicians can fully utilize these NCPDP standards and maximize their utility is if all of the necessary system updates occur prior to the January 1, 2027, deadline. **We therefore strongly encourage CMS to monitor the implementation progress for all of the standards named in this rule, when finalized, to ensure that all systems have been updated properly and on time in order to maintain care continuity and prevent any unnecessary treatment delays merely due to technical challenges.**

In this rule, CMS proposes to no longer list a specific date for the start of a transition period, which has historically begun six months after the effective date of a final rule. CMS instead proposes that any transition period would begin as of the effective date of the final rule and last until the expiration of the prior standard's version, as stated in Office of the National Coordinator (ONC) or Part D regulation. The AMA generally supports this change and believes consistently starting future transition periods earlier, as the regulation proposes, has the potential to expedite the implementation process for future standard updates. However, while we recognize the potential benefits of this change, the AMA is concerned that, if implemented as proposed, this change could lead to confusion within the health information technology (health IT) vendor community regarding when they can begin their work updating their systems. For example, implementers who are not aware of this change may unintentionally delay implementing the new standard in their systems because of their prior understanding of when transition periods begin (i.e., historically six months after the effective date of the final rule). As such, we request that CMS consider implementing extra "communication guardrails" to ensure that information regarding when the transition period begins is relayed as clearly and directly as possible to the health IT vendor community.

ONC-HIPAA-CMS Standards Cross Reference

The AMA supports CMS' proposal to cross-reference the Part D e-prescribing requirements with the standards adopted by ONC and the standards adopted by HHS for electronic transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We appreciate CMS' recognition of the challenges posed by the traditional approach of independently adopting e-prescribing standards in the Part D regulations or undertaking rulemaking to make conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions. The AMA supports CMS' proposed approach to adopting new standards, and we agree that the proposed framework will support greater alignment between ONC and CMS, improve the ability to synchronize timelines, reduce confusion, and minimize regulatory burdens.

We appreciate the continued recognition of the value of the NCPDP standards, and we encourage HHS to explore the opportunity to broaden the applicability of NCPDP standards to payers beyond Part D plans.

Requiring drug plans beyond the Part D program to support NCPDP SCRIPT ePA transactions, as well as the new NCPDP RTPB standard, will significantly increase the reach of these technologies and bring the associated benefits of reduced administrative burdens and increased transparency to a larger number of patients in a physician's panel.

Eligibility Requirements under HIPAA

The AMA supports CMS' proposal to revise the Part D requirements to indicate that eligibility transactions must comply with 45 CFR 162.1202.

The AMA appreciates CMS' recognition of the challenges posed by incongruencies between the HIPAA and Part D regulations with regards to the eligibility transaction requirements. We agree that ensuring that any updates to the HIPAA standards for eligibility transactions are reflected in the Part D regulation will be beneficial for future rulemaking related to eligibility transactions. The AMA concurs with CMS that there does not appear to be any immediate concerns about the impact of this proposed change, and the AMA agrees that establishing a cross-reference would help avoid any potential future conflicts as well as mitigate potential compliance challenges for the health care industry and enforcement challenges for HHS.

Health Equity in Utilization Management

Annual Health Equity Analysis of Utilization Management Policies and Procedures

We applaud CMS for continuing to explore concrete ways to embed health equity in its work. We agree with CMS, and other interested parties, who conclude that utilization management (UM) practices in MA, especially the use of prior authorization (PA), create barriers for patients in accessing medically necessary care.

In the 2022 AMA Prior Authorization Physician Survey, the overwhelming majority of physicians reported that PA leads to care delays, treatment abandonment, and negative clinical outcomes (94 percent 80 percent, and 89 percent, respectively).[4] With this in mind, we applaud CMS for acknowledging that the use of PA may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, due to several factors that align with our 2022 survey findings, including: the administrative burden associated with processing PA requests, a reduction in medication adherence, and overall worse medical outcomes due to delayed or denied care.[5] As such, the AMA strongly supports PA reform to reduce patient harm and physician practice burdens.

Moreover, the interaction between MA plans and PA creates geographic and racial inequities throughout the health care system. Nearly 44 percent of Hispanic Medicare beneficiaries and over 31 percent of African American Medicare beneficiaries are enrolled in MA plans. Moreover, data show an increasing trend in minority enrollment.[6] However, members of these racial and ethnic groups tend to be in plans with lower quality ratings.[7] Nevertheless, a study found that when Black enrollees had access to the

[4] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[5] 88 FR 78540 (Nov. 15, 2023).
[6] https://bettermedicarealliance.org/wp-content/uploads/2020/10/Comparing-the-Demographics-of-Enrollees-in-Medicare-Advantage-and-Fee-for-Service-Medicare-202010141.pdf.
[7] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13977.

highest-rated plans they chose five-star plans more often than White enrollees by 3.2 percentage points.[8] This demonstrates that a lack of enrollment of Black Americans in high quality plans is not by choice, but rather is due to a lack of access. This structural barrier prohibiting access to high quality MA plans for non-White Americans is due, in part, to the way that the MA program is administered, since MA tends to pay more to plans with healthier enrollees and underpay for more medically complex enrollees—who often tend to be from racial and ethnic minoritized populations.[9] Furthermore, having additional individuals who have more medical complications impacts MA performance scores, and thus, payment bonuses for insurers, which leads to restricted access to better MA plans in locations where residents might need more care. For this reason, PA denials by MA plans have a bigger impact on historically minoritized Medicare patient populations. MA PA requirements also disproportionately harm those with disabilities or chronic illness, as they create barriers to treatment for sicker patients needing medical devices, Part B drugs, or inpatient rehabilitation services—further undermining efforts to advance health equity in MA. This inequal access to high quality MA plans demonstrates the lack of equity that is inherent within the current health care insurance system and needs to be remedied.

Requirement to include at least one member of the UM Committee with expertise in health equity

CMS is proposing to change the composition and responsibilities of the UM Committee by requiring that a member of the UM Committee have expertise in health equity. The AMA applauds CMS for recognizing the importance of having a UM Committee that is composed of individuals who understand, and therefore, can make informed decisions concerning UM. Inequity in health care is a deep, systemic structural challenge that will not be properly addressed without sustained effort, robust support, and strong, dedicated leadership.

However, because the size requirement of a UM Committee is not defined/outlined in § 422.137(c), the impact of having potentially only one member of the Committee with health equity expertise may not have the long-term, robust impact of truly advancing health equity in this space. **As a result, the AMA recommends that CMS require the UM Committees to include at least two individuals with expertise in health equity including at least one individual with a master's degree or PhD in public health. The AMA further recommends that these two members of the committee be physicians, who are independent, not employed by the MA organization or plan, and free of conflict relative to the MA organization and MA plan.** Having two physicians, free of conflict relative to MA plans/organizations, and specifically not employed by an MA plan or organization, will be a key means to ensuring the advancement of health equity and will help to promote collaboration, accountability, and impactful outcomes. Moreover, including two physicians, instead of "at least one," will support the larger goal of improving the overall structure and culture of how health insurance plans and their ecosystems deliver service to all Americans, especially those from marginalized and minoritized communities, rural communities, and medically complex patients, such as those individuals with chronic diseases (e.g., asthma, chronic obstructive pulmonary disease [COPD], obesity, cardiovascular disease, and diabetes).

Requirement that the UM Committee must conduct an annual health equity analysis of the use of PA

CMS is also proposing that the UM Committee conduct an annual health equity analysis of the use of PA by examining the impact of PA on enrollees with one or more of the following social risk factors (SRFs): receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or having a disability as determined using the variable original reason for entitlement code for Medicare.

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[8] *Id.*
[9] https://ldi.upenn.edu/our-work/research-updates/why-are-there-disparities-in-enrollment-in-medicare-advantage/.

The AMA applauds CMS for proposing that the UM Committee must conduct an annual health equity analysis of the use of PA at the plan level, on enrollees with the two noted SRFs. There is ample research which indicates that those SRFs would be a good first step.[10] However, the AMA believes that these two SRFs are too limited and that additional SRFs should be included in the UM Committee's annual health equity analysis in order to achieve a true understanding of the disparities that exist.

For example, a 2019, Association of Black Cardiologists (ABC) research paper titled, "Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients" noted that:

> [u]nderserved and minority patients face unique challenges to cardiovascular care and treatment that impact their health outcomes. The ability to access new treatments is often hampered by utilization management processes… In particular, the need for [PA] … for specific drugs focused on cardiovascular care has been a barrier to treatment and a burdensome process for physicians and other providers.[11]

The ABC study goes on to suggest that "lower resource levels at cardiology practices with a majority of patients from underserved and minority populations may pose a unique barrier to responding to PA needs for these patients, further fostering existing treatment disparities."[12] Practice resource levels are a critical consideration in evaluating PA's impact, as 35 percent of physicians reporting having staff who work exclusively on PA.[13] Therefore, race and ethnicity play an important role in the chances of experiencing PA and its negative effects, which is further demonstrated by a study that showed that being of Asian descent and utilizing MA for gynecologic oncology care resulted in a higher chance of experiencing PA.[14] According to this study experiencing PA resulted in an average two week delay in care, which when treating cancer could have serious health consequences for patients. As such, racial and ethnic background should be considered as an SRF.

Moreover, studies have shown that Qualified Health Plans (QHPs) in the South are approximately 16 times more likely to require PA for PrEP as compared to QHPs in the Northeast.[15] This regional discrimination is particularly concerning since the southern region of the US is the region with the most new HIV diagnoses each year.[16] This study demonstrates a need for an SRF that considerers the LGBTQ+ community and the geographic location of the patient.

Furthermore, a study has shown that adults who "received health care in an emergency room in the past year were about twice as likely to have experienced [PA] problems, compared to those who did not use the ER (25 percent vs. 13 percent)."[17] As such, emergency care should also be included as an SRF. The same study also found that people who sought treatment for a mental health condition in the past year were more likely to experience PA problems than those who did not (26 percent vs. 13 percent); a similar

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[10] https://www.kff.org/health-reform/issue-brief/consumer-problems-with-prior-authorization-evidence-from-kff-survey/.
[11] https://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.
[12] *Id.*
[13] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/#:~:text=Prior%20authorization%20varied%20by%20patient,%E2%80%9326.0)%20of%20white%20patients.
[15] https://pubmed.ncbi.nlm.nih.gov/32492164/.
[16] *Id*.
[17] https://www.kff.org/health-reform/issue-brief/consumer-problems-with-prior-authorization-evidence-from-kff-survey/.

difference in the rate of PA-related problems was seen for patients who sought treatment for diabetes in the past year compared with those who did not (23 percent vs. 14 percent). These data suggest that diabetes and mental health conditions (e.g., depression and anxiety) should be included as SRFs in the health equity analysis of PA's impact.

We also note that there have been growing concerns related to inappropriate coverage denials of post-acute care by MA plans. A 2022 Office of the Inspector General report found that stays in post-acute facilities were one of the prominent service types for MA coverage denials that **met Medicare coverage rules**.[18] More recently, investigative journalists have uncovered problematic practices regarding plans' inappropriate use of algorithms to prematurely discharge MA patients from post-acute care facilities.[19] We therefore urge CMS to include patients seeking post-acute care in the UM health equity analysis.

Therefore, the AMA strongly recommends that CMS should initially include additional populations in the health equity analysis. Specifically, the AMA believes that the following groups should be included (this list is not exhaustive):

- **Members of racial and ethnic communities that have been historically minoritized;**
- **Members of the LGTBQ+ community;**
- **Members of rural communities/geographic location of the patient;**
- **Members of economically marginalized communities;**
- **Individuals who have visited the ER in the past year;**
- **Individuals who were hospitalized and sought post-acute care;**
- **English language learners (formerly limited English proficiency);**
- **Members with mental health conditions, including depression, anxiety, and SUD;**
- **Individuals with chronic diseases such as asthma,[20] COPD, cancer,[21,22] obesity, cardiovascular disease, diabetes[23], pregnancy;[24] and**
- **Individuals with a combination of chronic conditions/diseases (e.g., physical and behavioral health, including substance use disorder).**

In addition, these reports should indicate the number of plan beneficiaries for which a particular SRF cannot be determined. The AMA strongly advocates that reporting of sensitive data, such as race, ethnicity, LGTBQ+ status, and preferred language, should be *strictly voluntary* for patients. As such, health plans may not have data for all patients on some of these SRFs. These reports should thus indicate the number of people the plan omitted from the analysis due to lack of data (e.g., the number of people who did wish not to respond to a specific SRF-related question) to allow for an assessment of the completeness of the data and inform any decision-making based on the analysis.

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[18] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.
[19] https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/.
[20] https://pubmed.ncbi.nlm.nih.gov/33404389/.
[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/#:~:text=Prior%20authorization%20varied%20by%20patient,%E2%80%9326.0)%20of%20white%20patients.
[22] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2810824#:~:text=Importance%20Prior%20authorization%20(PA)%20requires,urgent%20treatment%20or%20symptom%20management.
[23] https://www.kff.org/health-reform/issue-brief/consumer-problems-with-prior-authorization-evidence-from-kff-survey/.
[24] https://pubmed.ncbi.nlm.nih.gov/31962106/.

Requirement that the health equity analysis be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website

The AMA supports CMS' requirement for the health equity analysis to be posted on the MA plan's publicly available website in a prominent manner and clearly identified in the footer of the website. However, **the AMA suggests CMS require an executive summary be provided and posted prominently on the website to promote understanding of the UM Committee's findings by individuals with an elementary school level of health literacy.** In line with this, the terms used in the summary should be clearly defined and unambiguous. **The AMA further recommends that CMS provide the executive summary and health equity analysis in a format that is understandable for English language learners**. **The AMA also recommends that a visual diagram be included on the website to ensure those members of the public who absorb information through visual means are able to digest the information. Moreover, the AMA strongly encourages CMS to ensure that any materials publicly released meet or exceed the requirements of section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended in 1998.**

In addition, we urge CMS to create a formal oversight and audit process to ensure that these health equity provisions, when finalized, protect vulnerable populations from care disparities. As previously requested in our February 2023 comments, we urge CMS to require submission of UM Committee activities, analyses, and reports to the Agency.[25] **As such, MA plans should be required to submit their annual health equity analysis to CMS so that these data can be appropriately leveraged to review/audit plans, appropriately enforce UM program requirements, and identify potential policy gaps to address in future rulemaking.** These data could also be used to determine if additional granularity should be required in future health equity analyses, such as requiring reporting of additional SRFs or UM data by specific service types (vs. the aggregate reporting required in this first regulatory iteration). Finally, we urge CMS to create a centralized website to house the health equity analyses for all MA plans so that beneficiaries and health care professionals can easily locate these data and compare plan performance.

Biosimilar Requirements

The AMA has concerns about CMS' proposal to permit biosimilar biological products other than interchangeable biological products to be substituted for their reference products as maintenance changes that require 30 days advance notice. The AMA recognizes that, under regulation, CMS is required to pursue "a cost-effective drug utilization management program" and that CMS believes the biosimilar market could offer opportunities for additional cost savings; however, despite the potential for financial savings, the AMA is generally concerned about patient safety, physician autonomy, and the impact of CMS' proposed changes on **patients currently stabilized on reference products**.

As CMS states in the proposed rule, maintenance changes are generally expected to pose a minimal risk of disrupting drug therapy or are warranted to address safety concerns or administrative needs. CMS notes that the vast majority of negative formulary changes are "maintenance changes that CMS routinely approves, and the vast majority of maintenance changes are substitutions." The AMA understands that the majority of these changes are routinely approved; however, we caution CMS from over generalizing all

[25] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfr.zip%2F2023-2-13-Letter-to-Brooks-LaSure-re-CY-2024-Medicare-Advantage-v3.pdf.

"generic-to-brand" substitutions as being equivalent, which may not necessarily be the case for a biosimilar substitution for a reference biologic on the Part D sponsor's formulary.

The AMA believes that, without concurrent regulatory modifications regarding the definition of "biosimilars" and "interchangeable biosimilars," it is premature to include substitution of biosimilar biological products as a maintenance formulary change in the Part D program. The current regulatory structure for biological products establishes a far more stringent testing and approval pathway for interchangeable products (i.e., demonstrating a biosimilar is an interchangeable biosimilar requires additional evidence of efficacy). AMA policy (H-125.976) strongly supports the FDA's pathway for demonstrating biosimilar interchangeability, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug. AMA policy also supports enhancements to the biosimilar interchangeability pathway in order to allow development and designation of more interchangeable biosimilars, enabling access to more less expensive biologics that provide, safe, and accessible treatment options for patients.[26]

The AMA does not necessarily dispute CMS' statements regarding the similar safety and efficacy profiles between biosimilar biological products and interchangeable biosimilars; however, without FDA regulatory changes that address biological product classification and the ability of pharmacists to change products without a new prescription from a physician, it is premature to allow Part D plans to treat substitution of a biological biosimilar product for a reference product as a maintenance formulary change. For this reason, the AMA opposes CMS' proposal to permit biosimilar biological products other than interchangeable biological products to be substituted for their reference products as maintenance changes.

However, if CMS elects to move forward with this proposal, we urge that Part D enrollees currently taking the reference product be exempt from the formulary change for the remainder of the contract year. As noted in the rule, state pharmacy laws require pharmacists to consult with the prescribing physician prior to substituting a biosimilar biological product for a reference product. CMS also stated in the rule that "established drug therapies should not be changed for non-clinical reasons to avoid risk to patient safety and that prescribers need to be consulted before changing medications," and the AMA strongly agrees with this statement. The physician consultation required to comply with state pharmacy laws and protect patient safety means that CMS' proposed change could result in care delays and disruptions in ongoing therapy. This is particularly concerning given the current challenges surrounding formulary transparency and communication of changes to patients, physicians, and pharmacists. An unsuspecting patient may only learn of a Part D plan's maintenance change when attempting to refill their reference product prescription and could face significant therapy delays until a new prescription is issued and filled. Care disruptions can be particularly dangerous for this vulnerable patient population, many of whom live with debilitating autoimmune diseases or cancer. **The AMA supports CMS' goals of increasing uptake of potentially less expensive biosimilar medications, but this should not come at the cost of care disruptions for patients currently stabilized on a reference biological product.**

The AMA appreciates CMS' recognition of the importance of education to advance the uptake and acceptance of biological products and encourages CMS to continue to develop its educational resources regarding biosimilars so that patients and health care professionals are better informed regarding the risks

[26] Biosimilar Interchangeability Pathway H-125.976. https://policysearch.ama-assn.org/policyfinder/detail/H-125.976?uri=%2FAMADoc%2FHOD.xml-H-125.976.xml.

and benefits posed by biosimilars. The AMA shares the Administration's goals of ensuring that patients have access to affordable, safe, and life-changing medications.

Enhanced Right to Appeal

The AMA supports CMS' proposal to require a QIO, rather than the MA plan, to review untimely fast-track appeals of a MA plan's decision to terminate services for non-hospital providers services and eliminate the provision requiring forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility.

CMS proposes aligning MA beneficiaries' appeal rights with those of traditional Medicare when terminating coverage for HHA, SNF, and CORF care. AMA supports these changes aiming for parity in appeal processes between the two Medicare programs. Both traditional Medicare and MA offer expedited appeals for service termination disagreements, but the handling of untimely appeals differs.

In accordance with AMA policy,[27] these proposals would bring alignment between MA plan regulations and Traditional Medicare and expand the rights of MA plan beneficiaries to access the fast-track appeals process. There is notorious abuse in the current MA structure,[28] especially as it relates to those that involve the termination of skilled nursing facilities, comprehensive outpatient rehabilitation facilities, and home health agencies. **The AMA commends CMS for seeking uniform appeal rights between MA and traditional Medicare, addressing access disparities, especially in post-acute care.**[29]

Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

Data Integrity (§§422.164(g) and 423.184(g))

The AMA has repeatedly highlighted to CMS the need for the Star Ratings program to focus more on compliance, communication, and access, as opposed to the current emphasis that relies on physician action. Therefore, **we support CMS' proposal for purposes of determining if a contract is subject to a potential reduction for the Part C and D appeals measures' star ratings, the data that must be produced by the plan to validate the accuracy of the appeals measures**. We also support CMS' proposal that the two-part C appeals measure star ratings be reduced to one star if the agency does not have accurate, complete, and unbiased data to validate the completeness of the measures. We believe the changes to the measure will hold plans more accountable and transparent and result in better quality of care.

Social Need Screening and Intervention Measure

The AMA appreciates CMS' recognition of the importance of this issue, and we agree that health plans can play a critical role in addressing the social needs of patients. The AMA supports the initial set of factors for screenings and interventions (food, housing, and transportation), as they clearly impact an

[27] https://policysearch.ama-assn.org/policyfinder/detail/medicare%20fee%20for%20service%20medicare%20advantage?uri=%2FAMADoc%2Fdirectives.xml-D-285.959.xml.
[28] https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021.
[29] Humana accused of using AI to deny care to seniors (axios.com).

individual's health outcomes and ensure the necessary resources and tools are available to assess and address a patient's social needs. However, as indicated in the measure specifications, of the three social risk domains only food insecurity has been finalized while housing instability and transportation remain in a draft phase. The sharing of these data points across providers and settings is integral to ensuring that physicians, practices, health plans, and other stakeholders are coordinating efforts, and we believe that data standards that enable interoperability are imperative to the success of these measurement efforts to ensure that they remain in sync with these activities. **Therefore, we urge CMS to consider further staging on the implementation of all three factors as it is important that the data collected and reported be standardized and align with the work of the Health Level 7 Gravity Project**. Furthermore, we agree that it may be useful to stage implementation of this measure to initially focus on screening until such time that there are adequate sample sizes to allow health plans to report on the interventions provided to patients.

In addition, further detail on what would satisfy the intervention requirement would be useful as these activities or referrals should be widely available within a region or community and demonstrated to be effective in meeting the individual's needs. **We also encourage CMS to provide additional guidance on how this measure should be implemented and reported over time, particularly on whether screening on all the factors must be completed annually and whether the referrals or activities from previous measurement periods would still satisfy the intervention component for the current reporting year.** We believe that applying the measure to an intervention is appropriate and encourage CMS to monitor the timeframe with evaluation and adjustment, if warranted to better take into consideration the processing time required to close the loop on a social care referral.

Lastly, **there is a need for the measure specifications to clearly state the level of accountability and applicability. This measure is for a health plan, and it is incorrect at this time to apply it to physician-level measurement in the absence of any resources or tools that would be widely and readily available to physicians.** In addition, this measure must also be tested at the physician-level before being applied.

Payment for Routine Costs Associated with Clinical Trials

The Medicare program has been covering the routine costs that patients face when they enroll in clinical trials since the year 2000, costs that are the responsibility of MA plans as well as regular Medicare. As CMS did not know how to adjust its MA capitation payments to account for these costs, it established an "initial" policy that these bills would be paid by the fee-for-service Medicare contractors instead of by the MA plans. More than two decades later, this "initial" policy is still in place. **The AMA urges CMS to develop a new, coordinated payment policy for the costs associated with participation in clinical trials to ensure that physicians and others who deliver these services are paid directly and that the requirement that patients seek reimbursement for billed services is eliminated.**

Clinical trial sponsors are responsible for paying the costs of the agent under investigation, but there are many other patient care costs for those who enroll in qualified clinical trials. These include conventional care that would be provided absent a clinical trial; services for the provision of the investigational item, such as administration of an investigational chemotherapeutic agent; monitoring of the effects of the item or service and prevention of complications; and diagnosis and treatment of complications that may arise. These associated costs can be very expensive. Because they are currently handled as if the patient is in Original Medicare instead of MA, the patient's share of the costs can also be very expensive. Patients enrolled in MA do not have access to Medicare supplemental or Medigap insurance like those in Original

Medicare, so they have had to pay the full cost sharing amounts themselves and then attempt to get reimbursed by their MA plan. **These extra expenses are a significant burden to patients who may already be dealing with advanced disease, and they also present a significant barrier to enrollment by MA patients in clinical trials. There is no justification for patients with MA to basically loan their plans the money for their coinsurance and then have to wait to be reimbursed. CMS should quickly develop and deploy a better approach.**

Another routine cost associated with clinical trials that needs to be addressed is the cost of consulting with a physician about potential enrollment in a clinical trial. **The AMA recommends that CMS require MA plans to allow and pay for out-of-network referral of patients with MA for the purpose of consultation for enrollment in a clinical trial, and that these consultations be considered administratively as participation in a clinical trial.** Combined with the above recommendation on eliminating the high upfront costs that MA patients enrolled in clinical trials must pay, ensuring coverage for the consultations that help patients learn about and enroll in clinical trials could significantly advance clinical research and future patient care.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

CMS proposes changes that would help ensure that SSBCI items and services offered are appropriate and improve or maintain the health or overall function of chronically ill enrollees. First, Medicare Advantage Organizations (MAOs) must demonstrate evidentiary support that an item or service offered as SSBCI would maintain or improve the health or function of a chronically ill enrollee specifically at the time of submission. MA plans must also develop written policies based on objective criteria and follow through on these policies, and subject to being reviewed annually by CMS to ensure compliance, as well as document denials of SSBCI eligibility.

CMS also proposes strengthened disclaimer requirements to be used in all marketing of plans so that beneficiaries are aware that SSBCI are available to enrollees who meet specific eligibility criteria, including listing specific medical conditions and requiring plans to clearly state that having a particular condition does not automatically guarantee an individual SSBCI. MA plans would also be required to notify enrollees mid-year of any unused supplemental benefits that are available to them.

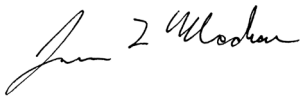
The AMA generally supports these changes, which promote transparency for beneficiaries around what SSBCIs they may be eligible for, as well as protections to help ensure that MA dollars are being spent for the benefit of MA beneficiaries. We believe these changes will also help promote uptake of SSBCI, which as the rule points out has been low to date. The AMA recognizes that chronically ill patients often face unique obstacles that supplemental benefits can hope to overcome to improve their overall health and function, so we support the proposed changes that are designed to help improve the transparency, uptake, and protection of SSBCI.

More specifically, the AMA believes that ensuring supplemental benefits are based on evidentiary data is a reasonable standard that would help to ensure the benefits remain sufficiently flexible to meet the needs of a diverse range of different types of beneficiaries while ensuring the clinical integrity of the benefits and that they stand to reasonably improve beneficiaries' health or function. In addition to being subject to annual reviews by CMS, CMS should expand on these proposals by requiring plans to update their evidence base with ongoing data about the utility of these benefits beyond the number of approvals or denials, with specific criteria proposed in future rulemaking subject to comment by interested parties. Collecting and publishing such data will both ensure that these benefits are successfully maintaining or

improving the health and functionality of beneficiaries and will also help to indicate which interventions are most successful, so they can be more widely adopted by more MA plans and benefit more beneficiaries.

We thank you for the opportunity to provide input on this Proposed Rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD