AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Jeff Wu
Acting 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 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; CMS-4208-P

Dear Acting Administrator Wu:

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) 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, issued on December 10, 2024.

The AMA commends CMS for proposing many policy changes aimed at improving the quality and accessibility of health care for Medicare beneficiaries. These proposals reflect CMS' commitment to addressing systemic barriers and promoting transparency. The following highlights our key recommendations in response to the proposed rule.

- The AMA strongly supports CMS' proposal to reinterpret statutory language to include U.S. Food and Drug Administration (FDA)-approved anti-obesity medications (AOMs) under Medicare Part D. Recognizing obesity as a chronic disease requiring comprehensive management, the AMA applauds the expansion of coverage for these medications, particularly glucagon-like peptide-1 (GLP-1) receptor agonists. These therapies represent significant advancements in obesity treatment but remain inaccessible to many due to prohibitive costs and lack of coverage.
- The AMA strongly advocates for removing utilization management (UM) barriers, such as prior authorization and quantity limits, for medications treating opioid use disorder (OUD), including buprenorphine and methadone. These restrictions delay access to lifesaving treatments and exacerbate the drug overdose epidemic, particularly amidst the widespread availability of illicit fentanyl.
- The AMA supports CMS' efforts to enhance transparency in the utilization of internal coverage criteria, particularly for prior authorization and other UM processes. The AMA underscores the importance of aligning MA coverage decisions with evidence-based clinical criteria and ensuring patients and physicians have access to these criteria.

- The AMA applauds CMS' proposals to strengthen UM analyses. Recognizing that MA enrollees from specific populations may be differently impacted by prior authorization delays, the AMA supports the collection of granular data on utilization practices to identify and address health disparities.
- The AMA supports CMS' proposal to require agents and brokers to educate beneficiaries about Medigap guaranteed issue (GI) rights when enrolling in MA. Clear communication about coverage limitations and the 12-month trial period is critical for informed decision-making.
- The AMA commends CMS for examining the impact of vertical integration on Medical Loss Ratio (MLR) calculations and overall transparency in MA and Part D plans. Vertical integration can obscure spending on patient care, raising concerns about accountability.
- The AMA opposes CMS' proposed opioid prescribing quality measures that rely on outdated thresholds from the 2016 Centers for Disease Control and Prevention (CDC) guidelines. Such measures undermine evidence-based pain management and stigmatize the use of opioids for legitimate medical conditions.
- The AMA supports physician-led management of obesity, emphasizing that AOMs should be part of a broader care plan that includes behavioral counseling and lifestyle interventions. The AMA also urges CMS to reconsider reliance on body mass index (BMI) as the sole criterion for obesity, advocating for a more objective approach that considers diverse patient factors.
- The AMA recommends codifying network adequacy standards for substance use disorder (SUD)-related services and supports CMS' proposal to evaluate network adequacy at the plan level. Ensuring robust networks for behavioral health and SUD treatment is vital for access to care.
- The AMA supports CMS' proposal to strengthen oversight of Medicare marketing and communications to combat misleading practices. The AMA agrees with eliminating the "content standard" from the marketing definition to ensure comprehensive regulation of communications materials.

Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies

Part D Coverage of Anti-Obesity Medications (AOMs) and Application to the Medicaid Program

The AMA appreciates CMS' attention to the issue of access to AOMs. Access to these important medications has become a significant issue with the market entry of GLP-1 agonists with FDA-approved indications for treatment of obesity, which represents a major advance in the treatment of clinical obesity. However, patients have long faced barriers to access to AOMs broadly, and we are now seeing significant barriers to access to these newly available, highly efficacious therapeutic options. These barriers are primarily financial in nature and result in large part from a lack of coverage of this drug class, although the overwhelming demand for these new therapeutic options has also contributed to access concerns. For patients who do have coverage for AOMs, that coverage frequently comes with significant cost sharing due to the high list prices accompanying the medications.

In 2013, the AMA House of Delegates adopted policy that recognized obesity as a disease state with "multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."[1] In 2023, the AMA House of Delegates adopted additional policy supporting coverage of

[1] https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml.

FDA-approved AOMs.[2] The AMA has long recognized obesity as a serious public health threat with multiple risks to patients and that creates significant costs to the health care system. However, patients suffering from clinical obesity have long struggled to receive adequate treatment, resulting in obesity rates that continue to grow rather than decline. Highly efficacious new therapeutic options show tremendous potential to reverse this trend and help patients reduce health risks and live healthier lives. The extremely high costs of these drugs, coupled with a lack of coverage for a huge number of patients, have made them essentially unavailable to the patients who need them most. **For this reason, the AMA supports CMS' proposal to reinterpret current statute to include AOMs as Part D drugs for the treatment of a clinical disease state.**

While the AMA has been excited to see incredible progress in therapeutic options for the treatment of obesity, the blockbuster GLP-1 medication class is not without significant policy concerns. The extremely high list prices of these drugs have resulted in bringing many of the nation's most challenging drug policy issues to the forefront with good solutions yet to be pursued and implemented. **Should CMS finalize the proposal to cover AOMs, including GLP-1 medications, the AMA strongly urges the agency, working in collaboration with the Department of Health and Human Services (HHS) and other federal health agencies, to pursue any available avenues to seek to lower the cost of these medications.** This could include, but is not limited to, immediately seeking to include these drugs in the Medicare drug negotiation programs. The AMA was pleased to see the January 17, 2025, announcement that CMS plans to include Ozempic, Wegovy, and Rybelsus in the next round of negotiations, however, should CMS finalize coverage for AOMs as proposed, we urge the agency to move to include other available GLP-1 medications to increase price competition and hopefully lower prices of all available options. It should also include a coordinated effort by HHS to promote timely development of FDA-approved generic GLP-1 options as soon as possible upon expiration of exclusivities held by brand manufacturers.

The AMA is also aware that high-priced drugs are typically accompanied by significant patient cost-sharing. Should CMS finalize this coverage proposal, formulary placement within Part D plans could still impact patient access to these treatments, as significant cost-sharing requirements seen in certain formulary tiers can render a drug prohibitively expensive for some patients despite the existence of coverage for the drug. While we appreciate that prescription drug cost-sharing is capped for Medicare beneficiaries, high cost-sharing requirements can still threaten access for many patients. **We encourage CMS to work with Part D plans and, where applicable, state Medicaid plans, to ensure that covered AOMs, including GLP-1s, are not subject to excessive cost-sharing that renders them inaccessible for certain beneficiaries**.

Additionally, covering new AOM options at current prices and demand levels threatens to balloon health care expenditures to potentially unsustainable levels. While we should pursue all avenues to ensure availability of these therapeutics for patients, including working to lower the prices paid for these treatments, we recognize that we must also appropriately manage health care expenditures. Unfortunately, we are aware that increasing drug expenditures potentially impact all Medicare and Medicaid beneficiaries, as they are most frequently managed through across-the-board premium increases. In addition to efforts to lower the list prices for AOM options, **we strongly urge CMS to ensure that the**

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[2] https://policysearch.ama-assn.org/policyfinder/detail/anti-obesity%20?uri=%2FAMADoc%2Fdirectives.xml-0-1498.xml; https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-631.xml.

impacts of increased expenditures on AOMs do not have a negative financial impact on beneficiaries through significantly increased premiums.

Unintended Consequences of Demand for AOMs

Given the demonstrated success of many new AOMs, it is understandable that demand for these drugs has reached very high levels for clinical obesity patients seeking treatment options, but also among patients without obesity seeking weight loss options as well. The exploding demand has contributed not only to the expenditure and coverage issues outlined above, but also to a cottage compounding industry seeking business opportunities through low cost AOM offerings for patients. The AMA has long recognized the vital role that compounding pharmacies play in helping to provide specialized products not otherwise available on the market. Compounding pharmacies serve a critical need for individual patients who need special dosage, formulations, or have other individualized needs not served by available FDA-approved drugs. They also serve to meet broader specialty-specific needs, such as specialized dosing and delivery methods for ophthalmology drugs or pediatric formulations. They are not without risk, however, especially where sterile injectables are concerned, and are less regulated compared to brand manufacturers. Further, given the nature of compounded products, they are not FDA-reviewed for safety and efficacy.

The overwhelming demand for GLP-1s, driven in large part by social media, has made the drug class subject to shortages that have made the drugs hard to access for people with diabetes, those with clinical obesity, and others seeking treatment for a disease covered by approved indications. The shortages have allowed compounding pharmacies seeking to pursue business opportunities to compound "essentially copies" of these FDA-approved products, otherwise prohibited by laws intended to prevent compounding pharmacies from acting as drug manufacturers.

Compounding pharmacies working with, or potentially owned, by primarily large, national telemedicine-based companies are prescribing these medications in a fashion that results in minimum burden to company-employed prescribers but that also potentially results in a substandard level of patient evaluation and care. They are also prescribing products that carry heightened risks, including active pharmaceutical ingredients (APIs) with potentially inconsistent potency, APIs sourced from questionable origins that raise concerns about quality and purity, and APIs compounded with unnecessary additives, such as vitamin B12, that have not undergone FDA review and cannot ensure safety or efficacy.

Additionally, compounded versions of GLP-1s are delivered in multi-use vials, requiring patients to draw up doses at home, as opposed to the pre-dosed autoinjectors provided with the branded medications. While this class of drug has proven itself to be largely safe and efficacious, it is not without risks, including potentially serious gastrointestinal side effects. Allowing patients to draw up their own dose has resulted in accidental dosing errors and patient-driven dosage changes can result in an increase in these serious side effects, with many known to result in hospitalization. Furthermore, social media communities and influencers without appropriate qualifications have contributed to promotion of medication misuse and harmful eating habits, increasing risks to patients. While we recognize that payment and coverage for compounded medications within the Medicare and Medicaid programs are mostly limited, we urge CMS to exercise caution if there is consideration of expanding coverage beyond the FDA-approved products. Any coverage proposals for AOMs, including GLP-1s, should be careful to recognize potential risks of medications that are not FDA-reviewed and ensure that coverage policies seek to limit potential harms.

Physician-Led Management of Comprehensive Obesity Care for Long-Term Obesity Reduction

To ensure appropriate use of these medications and to optimize results and ensure sustained reductions in obesity, GLP-1 and other AOM products should be used only after appropriate patient evaluation by a physician and in conjunction with continued care management and, ideally, appropriate lifestyle interventions. Sustained long-term medication adherence with GLP-1s and other AOMs has proven to be an issue, as many patients will discontinue use once substantial weight loss has occurred or when financial burdens of potentially high-priced medications become significant. This makes continued physician-led monitoring and obesity care management important to the successful use of AOMs. Additionally, while AOMs can be a critical component of obesity treatment, lifestyle modifications and interventions aimed at encouraging healthy habits to promote sustained obesity reduction can play a significant role in a comprehensive obesity care plan. The AMA is pleased that CMS has long covered behavioral counseling for obesity management through a National Coverage Determination as this, coupled with use of AOMs, could serve to promote a holistic approach to obesity management that encourages long term obesity reduction and improved health status for patients.

We do note, however, that while CMS has declined to define obesity in its AOM coverage proposal here, the National Coverage Determination for behavioral counseling referenced above does define obesity as a body mass index (BMI) greater than or equal to 30kg/m^2. While the AMA recognizes that the use of BMI is of some value in some instances, we also recognize that the utility of BMI as the sole indicator of obesity has significant limitations, including giving rise to concerns by not recognizing factors that may impact weight, such as race and gender.[3] We urge CMS to ensure that approaches towards obesity are consistent across coverage policies and further urge CMS to consider alternative or expanded approaches towards determining coverage eligibility for obesity management options that consider factors beyond BMI.

Impact on Merit-based Incentive Payment System (MIPS) Cost Measures

The AMA also strongly urges CMS to exclude AOMs and all other Parts B and D drugs from the Merit-based Incentive Payment System (MIPS) cost measures to ensure physicians are not inappropriately penalized for the prices of medications that are entirely beyond their control. Currently, physicians are held accountable for list prices set by the manufacturers and paid by the Part D plans, a negotiation in which the physician has no role or input, in the Asthma/COPD, Diabetes, Heart Failure, Sepsis, Chronic Kidney Disease, End Stage Renal Disease, Rheumatoid Arthritis, Prostate Cancer, and Kidney Transplant Management episode-based cost measures. These measures—and other applicable cost measures—account for 30 percent of physicians' and other MIPS eligible clinicians' final MIPS scores, which can then decrease their Medicare payment by up to nine percent. Innovative changes in payment policies for drugs designed to increase patient access and improve affordability, as well as expansions of coverage, should not inadvertently and unjustly penalize certain physicians due to their specialty or patient mix.

The AMA continues to oppose the inclusion of Medicare Parts B and D drugs in MIPS episode-based cost measures because it holds physicians accountable for spending that is far outside their control or influence. Physicians do not determine coverage, formularies, out-of-pocket costs, or list prices for drugs. Worse, they often do not have access to this information at the point of care. Additionally, prescription drugs may be subject to plans' step therapy and prior authorization or UM requirements, which further

[3] https://policysearch.ama-assn.org/policyfinder/detail/BMI?uri=%2FAMADoc%2FHOD.xml-H-440.797.xml.

limits physicians' ability to prescribe medications for their patients. We strongly urge CMS to take this opportunity to reexamine the appropriateness of including Parts B and D drugs in MIPS cost measures.

In summary, the AMA supports CMS' proposal to reinterpret the current statute in a manner that will provide coverage of AOMs aimed at treating clinical obesity. We are pleased to see CMS join physicians in recognizing obesity as a disease that requires treatment as such. While AOMs represent a critically important therapeutic option for the treatment of obesity, the AMA recognizes that they raise a number of policy questions that can continue to impact patient access and patient safety. We encourage CMS to consider options and collaborations with other federal departments and agencies to address these concerns, such as high list prices, so that we can ensure access, patient safety, and ultimately recognize the benefits of these important treatments.

Ensuring Access to Medicare Advantage Services—Guardrails for Artificial Intelligence

The AMA appreciates the opportunity to comment on CMS' proposed guardrails for artificial intelligence (AI) in MA plans. The AMA is committed to ensuring that AI technologies are integrated into health care in ways that prioritize patient safety, uphold protections for all individuals, and respect the patient-physician relationship.

The AMA has developed principles and policy to guide the ethical and responsible use of AI. These principles are particularly relevant to CMS' proposal, and we commend CMS for taking steps to address the growing role of AI in MA plans.

General Support and Recommendations

We support CMS' focus on ensuring that AI tools do not worsen health for all individuals or restrict access to care. The proposed revisions to §422.112(a)(8), which emphasize fair access to care regardless of the use of AI or automated systems, are crucial. **We strongly encourage CMS to maintain broad guardrails for MA plans, especially as some MA plans may misrepresent or obscure their use of AI by using alternative terminology, leading to a lack of transparency.**

MA plans sometimes refer to proprietary tools by their brand names without explicitly identifying them as AI. They may also use terms like "machine-assisted" or "physician decision support" to describe AI-based tools. These terms suggest the tools only play a supportive role. However, such language often obscures the true extent of AI's influence, making it unclear how decisions are made. This lack of transparency can be seen as an attempt to circumvent federal and state regulations by concealing the MA plan's reliance on AI systems.

Alignment with AMA Policy on AI and Automated Decision-Making

While the AMA supports CMS' proposals, there are opportunities to further strengthen its policy to ensure that AI tools align with the highest standards of care. In 2024, the AMA adopted comprehensive AI policy, reflecting the medical community's expectations that AI tools and technologies should be developed, deployed, and used in ways that prioritize ethical, responsible, and transparent practices. These policies highlight the critical need for AI systems to uphold the principles of fairness and accessibility, while maintaining accountability to patients and providers.

To enhance its proposals, CMS should carefully consider and integrate several of the AMA's policies, especially those focused on Payor Use of Augmented Intelligence and Automated Decision-Making Systems.

Transparency and Disclosure

CMS should require MA organizations to disclose the use of AI in decision-making, including:

- The purpose and role of AI in care delivery or coverage determinations.
- Information about training data, including its diversity and potential biases.
- Evidence supporting the system's validity, accuracy, and impact on clinical outcomes.

Patients and physicians should receive clear explanations about AI-driven determinations and have access to human oversight for challenging decisions. In addition, CMS should build on its proposals to require more granular reporting of prior authorization by adding provisions related to the use of AI in prior authorization and other UM processes. Such disclosures should include the specific AI tool used; the number of specific items/services approved or denied by AI; and the number of AI-driven denials that were later overturned on appeal. These data will assist CMS in determining if plans' use of AI in UM programs leads to increased and/or inappropriate denials, as well as if the AI tool introduces biases in decision-making.

Bias Mitigation

AI systems in MA plans must be rigorously tested for biases that may result in disparate impacts on unique populations. This includes:

- Regular audits to evaluate outcomes across demographic groups.
- Transparency in data sources to ensure representation of diverse populations.
- Implementation of mechanisms to adjust algorithms that perpetuate unintended outcomes.

Human Oversight and Clinical Judgment

The AMA emphasizes the critical role of physicians in interpreting AI recommendations. Clinical decision-making should not be overridden solely by algorithmic outputs.

CMS should mandate:

- Human review of automated decisions that impact coverage, especially those involving denial or limitation of care.
- Opportunities for treating physicians to discuss AI-driven determinations with MA plan representatives prior to final decisions.

Accountability and Risk Management

CMS must require MA organizations to be transparent about liability for errors arising from AI use. Developers and implementers of AI systems should be held accountable for inaccuracies or harm caused by their tools.

Data Privacy and Security

AI systems must adhere to stringent privacy standards. CMS should ensure:

- Patient data is protected, with mechanisms to prevent unauthorized access or re-identification of de-identified data.
- Comprehensive safeguards against AI model manipulation or cybersecurity threats.

Ongoing Monitoring and Improvement

CMS should establish a robust framework for monitoring AI systems in MA plans, including:

- Regular performance evaluations to identify and address issues such as "model drift."
- Public reporting of metrics related to AI-driven decisions, including approval, denial, and appeal rates.

Specific Recommendations for Regulatory Language

We propose the following additions to §422.112(a)(8):

- "An MA organization utilizing AI in care delivery or decision-making must document and disclose the role of AI systems to patients and providers. This includes a summary of data inputs, validation processes, and assessments to ensure transparency and address unintended outcomes."
- "An AI recommendation that limits or denies care must be reviewed by a licensed physician with relevant expertise before a final determination is issued."
- "An MA organization must conduct periodic audits to evaluate AI system performance and methods to mitigate unintended outcomes and report findings to CMS."

Definitions

Inclusive definitions are important to ensure the responsible implementation of AI in health care, and we commend CMS for providing regulatory clarity. Below are specific comments and recommendations on CMS' proposed definitions.

Definition of "Human Oversight"

The proposal mentions oversight but does not define the role of human involvement in AI decision-making. CMS should define human oversight to ensure accountability:

"Human oversight refers to the continuous involvement of qualified health professionals in reviewing, interpreting, and acting on AI outputs, particularly when decisions involve patient care or coverage determinations."

This definition should mandate that automated decisions impacting care are subject to human review before implementation, especially in cases of denial or limitation of benefits.

Definition of "Transparency"

The proposal underscores the importance of transparency but does not define what constitutes adequate disclosure. Transparency should be defined as follows:

"Transparency involves the disclosure of an AI tool's purpose, design, data sources, validation metrics, and limitations, provided in a manner that is understandable to patients and providers to foster informed decision-making."

Transparency must extend to both the training and operational phases of AI systems to build trust and accountability.

Definition of "Accountability"

While the proposal requires compliance, it lacks a definition of accountability mechanisms for AI-related decisions. The following definition should be included:

"Accountability refers to the assignment of responsibility for the outcomes and impacts of AI tools and systems, including adherence to regulatory requirements, ethical standards, and mechanisms for remediation in cases of harm or error."

CMS should mandate that developers, implementers, and MA plans share accountability for AI-related errors or unintended outcomes.

The AMA applauds CMS' proactive efforts to ensure AI improves care and protects patients. These proposed guardrails align with the AMA's policies for augmented intelligence, and we urge CMS to adopt additional measures to ensure that AI systems in MA plans meet the highest standards of safety, transparency, and accountability.

Ensuring Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits

CMS proposes to require that MA plans charge no more cost-sharing for in-network behavioral health and SUD services than patients are accountable for in traditional Medicare. This would have the effect of limiting cost-sharing for mental health specialty services, psychiatric services, intensive outpatient services, partial hospitalization services, and outpatient SUD services to 20 percent. Opioid treatment program (OTP) services would have no cost-sharing. The AMA strongly supports this proposal and urges that it be implemented as soon as possible.

Tables 8 and 10 in the proposed rule show how impactful this policy could be if finalized. Currently more than one in five MA enrollees face higher cost-sharing for mental health specialty services and psychiatric services than if they were enrolled in traditional Medicare. The percentages increase to more than 40 percent for outpatient SUD services and more than 60 percent for OTP services. While weighted average cost-sharing for outpatient SUD services is currently $60.38, this proposal would cut it by half to $30.

Even with these new limits, cost-sharing may serve as a barrier to care for some of these services. The AMA recommends that CMS provide guidance to MA plans that they should further reduce cost-sharing for this important care. For example, whereas OTP services have zero cost-sharing, outpatient SUD services have 20 percent cost-sharing. This should be reduced to zero.

It would also be helpful for CMS to provide more information about MA plans' current cost-sharing policies. While Tables 8 and 10 show the percentage of MA enrollees who would have lower cost-sharing, especially for SUD-related services, they do not display the effects on patients with plans that may already require lower cost-sharing than traditional Medicare. There is some concern that these enrollees could face higher cost-sharing than they currently do if their plans increase cost-sharing to 20 percent. We recommend that CMS provide this analysis and take it into account as the agency develops its final policy and implementation plans.

Annual Analysis of Utilization Management Policies and Procedures

The AMA strongly supports CMS' proposal to require more granular data reporting in MA plans' annual UM analyses and urges CMS to further strengthen this effort by increasing the breadth and depth of information that plans must report.

While physicians express frustration over the administrative burdens imposed by health plans' UM programs, their most significant concerns center on the negative impact of these requirements on their patients' health. In the 2023 AMA Prior Authorization Physician Survey, an overwhelming majority (94 percent) of physicians reported that prior authorization delays access to necessary care.[4] Meanwhile, patients may clinically deteriorate while they are forced to wait, with 93 percent of physicians reporting that prior authorization can negatively impact clinical outcomes. Most alarmingly, nearly one-quarter (24 percent) of physicians say that prior authorization has led to a serious adverse event (hospitalization, disability, or even death) for a patient in their care.

The AMA applauds CMS for recognizing that prior authorization can disproportionately impact specific patient populations and proposing revisions to the annual analysis of UM that would require reporting of granular metrics by each item or service, rather than aggregated for all items and services. The AMA echoes others' concerns that the current requirement for aggregated prior authorization data does not provide for the level of analysis needed to determine the potentially disproportionate impact on certain patient groups. Requiring MA plans to report more granular data to their UM Committee and on their websites will improve transparency, as well as better identify disparities and promote MA plan accountability. **For these reasons, the AMA urges CMS to finalize this provision requiring reporting of granular data (i.e., at the item/service level) regarding prior authorization approval and denial rates, overturns on appeal, and average processing times.**

In addition to posting this information at the service/item level, CMS could consider requiring plans to report this information using Current Procedural Terminology® (CPT®) code categories, which are further grouped into subcategories and anatomical areas, such as:[5]

- Anesthesia: Codes 00000–09999
- Radiology services: Codes 70000–79999
- Pathology and laboratory services: Codes 80000–89999

[4] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[5] American Medical Association. CPT® Overview and Code Approval. Available at: https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval.

Use of these categories could provide general insight into the impact of UM on particular service types for different populations. In addition, the CPT categorizations are well established and used across the health care industry.

In addition to requiring increased data granularity in the annual UM analysis, the AMA recommends that CMS make the following additional enhancements:

1. **Require plans to include additional populations in the analysis.** Currently, CMS only requires plans to report UM metrics on one population with a Special Risk Factor (SRF)—dual eligible patients or those with a disability. **We urge CMS to require plans to report on other patient groups that could be particularly vulnerable to the negative impacts of prior authorization and other forms of UM. We strongly support CMS' proposal to add patients with a mental health or SUD diagnosis to the list of SRFs that plans must review; moreover, we believe that reporting on this patient population should be required of all plans—not merely an option.** In addition, we urge CMS to require MA plans to include additional patient groups in their analyses, as detailed in our comments on the CY 2025 MA rule.[6]

2. **Require plans to submit their UM analyses to CMS for centralized public posting to increase transparency and accountability.** While having the UM analysis posted on the plan's publicly available website in a prominent manner, as is currently required, is helpful, we are concerned that both physicians and patients will struggle to locate UM program metrics. The AMA therefore recommends that these data also be published on a centralized, public website—such as a CMS webpage—to ensure easy access to the information, as well as facilitate comparison between plans. CMS should establish standardized formats and terminology for the plan analysis executive summary. Plans should also be required to report on the methodology used to report the metrics in the summary to minimize misleading information. In addition, submission of UM analyses to CMS for centralized posting will also support review and enforcement activities, which will increase plan accountability.

3. **Require plans to provide additional data regarding denials and use of AI in UM analyses.** While there is significant value in establishing the baseline UM metrics currently required by CMS, we believe the utility of these data could be enhanced by requiring plans to publish **rationale for coverage denials**. There is mounting evidence[7,8] of MA plans denying treatments for reasons not based on evidence-based medicine. A Kaiser Family Foundation (KFF) analysis[9]

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[6] https://searchlf.ama-assn.org/letter/documentDownload?uri= percent2Funstructured percent2Fbinary percent2Fletter percent2FLETTERS percent2Flfct.zip percent2F2024-1-4-Letter-to-Brooks-LaSure-re-CY-2025-MA-Comment-Letter.pdf.

[7] US Department of Health and Human Services Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. April 2022. Available at: https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete percent20Report.pdf.

[8] US Senate Permanent Subcommittee on Investigations. Refusal of Recovery: How Medicare Advantage Insurers Have Denied Patients Access to Post-Acute Care. October 17, 2024. Available at: https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf.

[9] Biniek J, Sroczynski, Neuman T. Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022. KFF. August 8, 2024. Available at: https://www.kff.org/medicare/press-release/medicare-advantage-plans-denied-a-larger-share-of-prior-authorization-requests-in-2022-than-in-prior-years/.

found that MA plans denied 3.4 million prior authorization requests in whole or in part in 2022, representing about 7.4 percent of the 46 million requests submitted that year. While only about 10 percent of these denials were appealed, the vast majority (83.2 percent) of appealed denials were fully or partially overturned, raising serious concerns about the clinical appropriateness of many initial denials. **Capturing rationales for denials will help bolster CMS' transparency goals, as well as ensure that MA plans are using appropriate coverage criteria. In addition, and as noted in the AI section of these comments, we also urge CMS to require plans to publish data regarding use of AI—particularly denial rates—in plans' UM analyses.** Inclusion of this information will help surface any potential biases in AI technologies and identify concerns about AI tools negatively impacting specific patient populations.

Medicare Advantage Network Adequacy

The AMA recommends that CMS develop specific network adequacy standards for physicians and other health professionals who provide SUD-related services. We supported the previous creation of the outpatient behavioral health requirement to help improve network adequacy for patients with mental health conditions and/or SUDs, but because this blends mental health and SUDs it is difficult to know if patients have appropriate access to SUD treatment in their MA plans. CMS should take the current requirement a step further and ensure that plans provide in-network access to physicians and other health professionals, as well as OTPs, who specifically treat SUDs.

The AMA supports the CMS proposal to review network adequacy at the MA plan level instead of its current practice of reviewing network adequacy at the contract level. As enrollees access care through a specific benefit package offered by an MA plan and not at a contract level, this change makes a lot of sense, and we recommend that it be finalized.

The AMA also supports CMS' proposals to codify the following policies: treating county equivalent localities the same as counties for purposes of network adequacy; eliminating the ability for plans to request a network adequacy exception if a "provider does not contract with any organization or contracts exclusively with another organization;" and removing the "other" category for network adequacy exceptions. CMS notes that subregulatory guidance has already established these policies, so they should impose no additional costs or burdens on MA plans.

Promoting Informed Choice—Expand Agent and Broker Requirements regarding Medicare Savings Programs, Extra Help, and Medigap

The AMA supports CMS' proposal that allows beneficiaries to receive accurate and comprehensive information about their Medicare options, particularly as it relates to Medigap federal GI rights. These changes represent an important step toward improving transparency, supporting informed decision-making, and protecting beneficiaries from the potential financial and health implications of insufficient coverage. The AMA strongly supports the proposed requirement that agents and brokers discuss with beneficiaries the impact of enrolling in an MA plan on their Medigap options. Specifically, the AMA agrees with CMS that agents and brokers must explain: 1) that beneficiaries have a 12-month trial right period during which they can disenroll from an MA plan, return to traditional Medicare, and purchase a Medigap policy with GI rights; and 2) outside this trial period, beneficiaries are no longer guaranteed the right to purchase a Medigap policy under federal law, and their health conditions may affect their eligibility and premiums.

The AMA has long advocated for expanded Medigap protections to protect access to coverage for all Medicare beneficiaries. This proposal aligns with our commitment to protecting patients and addressing the gaps in existing Medigap protections. By requiring agents and brokers to provide clear and accurate information, this proposal helps prevent unexpected barriers to coverage that can lead to financial hardship or disrupt continuity of care. The AMA also recognizes the important role of continuity of care in achieving positive health outcomes. Beneficiaries who switch between MA plans and traditional Medicare, particularly those facing adverse health events, may experience disruptions in care. Transparent discussions about Medigap GI rights can help beneficiaries make informed decisions, reduce unnecessary plan switching, and preserve continuity of care, which is associated with lower morbidity and mortality rates. While we support CMS' proposal, the AMA recommends several enhancements to further strengthen these requirements and improve outcomes for beneficiaries:

1. Agents and brokers should be required to inform beneficiaries about state-specific Medigap GI rights and explain how Medigap premiums may increase based on age or health conditions after the trial period. This will provide beneficiaries with a comprehensive understanding of their coverage options and financial implications.
2. CMS should consider extending GI protections beyond the 12-month trial period to align Medigap protections with those under the Affordable Care Act (ACA), where modified community ratings are permanent and universal. Extending these protections would allow beneficiaries to retain access to affordable supplemental coverage, regardless of when they choose to return to traditional Medicare.
3. CMS should encourage MA organizations and brokers to provide these required disclosures through multiple formats, including written materials, online tools, and interactive portals. This approach allows beneficiaries of all literacy levels and access capabilities to fully understand their rights and options.
4. Beneficiaries with disabilities often face unique challenges in accessing Medigap policies. We recommend that CMS require specific guidance tailored to these populations so they are fully informed and adequately protected.

The AMA will continue its efforts to educate physicians and the general public on the implications of participating in programs offered under MA and educate physicians and the public about the lack of Medigap policies with MA plans and how this may affect enrollees. We also firmly believe that Medicare beneficiaries should be aware that while traditional Medicare requires minimal prior authorization for services, MA plans frequently impose UM requirements on a variety of items and services, which can result in care delays and barriers to accessing medically necessary care. While we agree that these plans may deliver valued benefits and trusted coverage for millions of Medicare beneficiaries, tighter scrutiny and an oversight plan that monitors the activities of its agents and brokers should be instituted to ensure an optimal level of compliance to protect MA enrollees. CMS has broad authority to regulate the marketing and enrollment activities of MA and Part D plans, and we would encourage the agency to leverage that towards combating the fraudulent practices that are likely undermining the trust in the Medicare program as a result.

Format Medicare Advantage Organizations' Provider Directories for Medicare Plan Finder

The AMA supports CMS' proposal to require that MA plan provider directory data be submitted in a format that would allow this information to be added to the Medicare Plan Finder (MPF). Currently, the MPF does not contain provider directory information and requires users to exit the MPF to find the detailed network information they need to make informed plan selections. For example, during an open enrollment period, if a beneficiary wants to determine if their current physician(s) is in-network for the

MA plans they are considering, they must leave the MPF and look on each plan's website for this information. Providing directory information directly in the MPF will create a more user-friendly experience for beneficiaries and help to avoid situations where a patient chooses a plan based on information available in the MPF (e.g., cost sharing) only to find out that their physician is not in-network or the network physicians are not accessible or do not have the cultural or linguistic capabilities the patient needs. We urge CMS to finalize this proposal.

Promoting Informed Choice—Enhancing Review of Marketing & Communications

Given the negative trends highlighted in this proposed rule, it is evident that the current CMS definitions have allowed loopholes for marketing by MA organizations, Part D sponsors, and their downstream entities. **The AMA agrees with CMS' proposal to eliminate the "content standard" within the marketing definition and expand the scope of marketing materials subject to the MA and Part D marketing and communications regulations.**

Strengthening Oversight

CMS has identified an important gap in current law where there are mandates for the submission and review of marketing materials and applications. However, the law does not clearly define what materials fall under the term marketing. This has allowed certain communications to bypass protections that shield beneficiaries from misleading practices. By removing the content standard of the definition, CMS will regain the ability to monitor and oversee all communications materials and activities that meet the existing intent standard more effectively, ensuring that communications that previously fell outside the narrow scope comply with regulatory standards. This change would result in more advertisements being subject to necessary review, thereby strengthening protection for the Medicare population.

AMA policy highlights the importance of enforcing MA regulations to hold CMS accountable for transparency and adherence to minimum standards that protect physicians and their patients. Given the mounting scrutiny from Congress resulting in multiple probes[10] of the industry including hearings[11] and extensive reports,[12] the AMA supports proposals that broaden the scope of regulated materials, closing loopholes that exempt certain communications from oversight.

Evolving Marketing Tactics

The AMA commends CMS for recognizing the need to adapt regulations to the evolving marketing landscape. For example, a KFF analysis of TV advertisements during the 2023 Medicare open enrollment period revealed that TV ads for MA plans constituted over 85 percent of all Medicare-related airings.[13] Many of these ads featured government-issued Medicare card imagery or directed viewers to non-official hotlines and created a misleading sense of urgency for beneficiaries to act immediately (e.g., ads used language that suggested people with Medicare are "missing out" on significant benefits if they are not

[10] Senate Finance Committee, "Wyden Questions Medicare Marketers' Business Tactics," (Jan 2024).
[11] Senate Finance Committee hearing entitled "Medicare Advantage Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences" (Oct. 2023).
[12] Senate Finance Committee report entitled "Deceptive Marketing Practices Flourish in Medicare Advantage" (Nov. 2022).
[13] Baum, and Erika Franklin Fowler, "How Health Insurers and Brokers Are Marketing Medicare," KFF, (Sept. 2023).

enrolled in a MA plan). Under the current standard, the lack of detail in the communication's statement would avoid triggering regulatory requirements, allowing it to bypass inquiry.

With the proliferation of digital advertising and other innovative marketing strategies, it is imperative to broaden the scope of materials subject to CMS review. The AMA concurs with CMS' assertion that more vigorous oversight of materials influencing beneficiary decision-making is essential. Such measures would enable CMS to act swiftly on non-compliant ads, mitigate misinformation, and better trace the origins of problematic communications.

The AMA is committed to continuing to educate physicians and the public on the implications of participating in MA programs. This includes addressing the lack of secondary coverage, such as Medigap policies, within MA plans and highlighting how UM requirements can delay care and create barriers to medically necessary treatment. While MA plans may deliver valued benefits and trusted coverage for millions of Medicare beneficiaries, tighter scrutiny and an oversight plan that monitors the activities of its agents and brokers should be instituted to ensure optimal compliance to protect MA enrollees.

The AMA strongly encourages CMS to leverage its regulatory authority to address fraudulent and misleading marketing practices that likely undermine public trust in the program. By finalizing this proposal, CMS can safeguard Medicare beneficiaries better against predatory tactics and promote informed decision-making.

Enhancing Rules on Internal Coverage Criteria

The AMA strongly supports CMS' proposals to clarify and further strengthen requirements regarding MA plans' use of internal coverage criteria, including those used in prior authorization and other UM programs, to make medical necessity determinations. The AMA applauds CMS for continuing to address ongoing problems surrounding MA plans' use of internal coverage criteria that interferes with beneficiaries' ability to access medically necessary care—especially treatment that would have been covered by traditional Medicare. Multiple studies have raised serious questions regarding the clinical validity of such internal plan criteria. For example, in the 2023 AMA Prior Authorization Physician Survey, more than one in three (35 percent) physicians reported that clinical criteria used by health plans to make medical necessity determinations are rarely or never evidence based.[14] Moreover, a 2022 Office of Inspector General (OIG) report found that 13 percent of prior authorization requests denied by MA plans met Medicare coverage rules, and 18 percent of payment request denials met Medicare and MA billing rules.[15] The OIG report cited numerous cases of MA plans applying dubious clinical criteria, such as a 76-year-old with multiple orthopedic conditions and at-risk for falls being denied a walker because the patient had received a cane within the past five years. In another troubling case, a 67-year-old was denied admission to an inpatient rehabilitation facility for not meeting the MA plan's coverage rules, despite the patient's recent ischemic stroke, difficulty swallowing, and significant risk for aspiration and pneumonia. These findings call into serious question the validity of the clinical criteria being used by MA plans in coverage decisions and suggest a consistent failure to base criteria on nationally recognized

[14] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[15] US Department of Health and Human Services Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. April 2022. Available at: https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete percent20Report.pdf.

standards of care as determined by the appropriate national medical specialty society. More recently, media investigations[16] and a Senate Subcommittee on Investigations report[17] discovered alarming patterns of inappropriate denials of post-acute and rehabilitative care by MA plans and raised specific concerns about the clinical algorithms used in medical necessity decisions.

In addition, the lack of transparency in plans' UM programs and clinical criteria makes it extremely difficult to assess their mechanics and validity. Indeed, a majority of physicians surveyed by the AMA report that it is difficult to determine if a particular medical service or prescription drug even requires prior authorization;[18] it is far more difficult for physicians to actually access the underlying clinical criteria used by a plan to make coverage decisions. Denial letters often provide scant rationale for coverage decisions, with plans merely stating that a request "did not meet coverage criteria." Health plans frequently claim that their internal clinical criteria are "proprietary;" unfortunately, the resulting black box leaves physicians in the dark when trying to understand and overcome denials—and patients suffering while they wait for medically necessary treatment.

CMS' proposed clarifications and additional requirements surrounding internal coverage criteria take meaningful steps to address these concerns. We support CMS' detailed and comprehensive scope for defining internal coverage criteria; in particular, we agree with the critical importance of including any outside (i.e., non-CMS) sources used in MA plans' AI tools or algorithms within the scope of what constitutes internal coverage criteria. We also support CMS' refinement of regulatory language to ensure correct interpretation of policies regarding use of internal coverage criteria and believe these changes will protect patient access to vital care. We concur with CMS' proposal to require MA plans to demonstrate that any imposition of additional coverage criteria for an item or service would **explicitly support patient safety.** MA plans should be able to provide clear, specific clinical justification for how an additional criterion would protect patient safety; for example, requiring lab values to confirm a patient's kidney function could be a valid criterion if a particular therapy is not safe for patients with renal dysfunction. **Importantly, MA plans should be able to cite the specific safety issue or adverse event of concern in proposing additional clinical criteria; vague references to patient safety should <u>not</u> be sufficient to employ additional coverage restrictions.**

We fully support adoption of the two proposed prohibitions against use of internal coverage criteria, as they firmly align with long-standing AMA advocacy and policy. We strongly agree that MA plans should be prohibited from using coverage criteria without any clinical benefit. As stated in Principle #1 of our Prior Authorization and Utilization Management Reform Principles, "Any UM program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone."[19] Furthermore, we concur that MA plans should be prohibited from using an internal coverage criterion to automatically deny benefits without reviewing patient-specific data to make an individual

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[16] Herman B, Ross C. UnitedHealth used secret rules to restrict rehab care for seriously ill Medicare Advantage patients. STAT News. December 28, 2023. Available at: https://www.statnews.com/2023/12/28/medicare-advantage-united-health-navihealth-rehab-care-restrictions/.

[17] US Senate Permanent Subcommittee on Investigations. Refusal of Recovery: How Medicare Advantage Insurers Have Denied Patients Access to Post-Acute Care. October 17, 2024. Available at: https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf.

[18] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[19] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

medical necessity determination. Our Principles advocate for such flexibility to account for the unique clinical needs of each patient. **We urge CMS to finalize these prohibitions regarding inappropriate use of internal coverage criteria as written.**

We commend CMS for taking important steps to increase the transparency and accessibility of MA plans' internal coverage criteria. We fully support all of CMS' proposals to increase the detail and improve the structure of plans' website postings, to include requiring plans to indicate which specific items and services use internal coverage criteria and the evidence on which the criteria are based. We also appreciate CMS' clarification that MA plans must make clinical criteria easily available on their websites, without requiring a login/password or fee payment. **We urge CMS to additionally clarify that if MA plans are using criteria developed by an outside vendor and linking to that vendor's website, the vendor similarly cannot require a login/password or impose fees to access the clinical criteria.** Finally, we strongly support CMS' additional suggestions to increase the transparency and accessibility of MA plans' internal coverage criteria. Physicians and their patients struggle to navigate plan websites to locate and interpret information; as such, developing a standard template for posting internal coverage criteria would be highly beneficial. In addition, requiring MA plans to report all information related to internal coverage criteria to CMS would support further oversight and enforcement of these important new program requirements.

The AMA appreciates CMS' ongoing efforts to improve the clinical validity and transparency of internal coverage criteria employed in the MA program and believes that these changes can improve beneficiary access to care. However, we must note that similar protections are not in place regarding the coverage criteria used for prescription drugs in the Part D program. **We therefore urge CMS to undertake further regulatory action that will bring sound clinical validity and transparency to the coverage criteria used in making medical necessity determinations for <u>prescription medications</u>, as many beneficiaries rely on these treatments to improve and maintain their health and well-being.**

<u>Prohibition on Reopening of Medical Necessity Decisions Except for Good Cause</u>

We strongly support CMS' proposal to strengthen existing regulations that prohibit MA plans from retroactively reviewing and denying coverage of outpatient or inpatient items or services for which favorable medical necessity decisions have already been issued via prior authorization, pre-service determination, or concurrent review for any reason other than good cause (e.g., fraud). The AMA regularly hears complaints from our members about health plans retroactively denying payment for services that have already undergone medical necessity review and approval; this unfair and unjustified practice places physicians and patients under extreme financial and emotional duress. We also agree that MA plans should not be able to later deny coverage based on a lack of medical necessity for previously approved treatment based on new clinical information that became available after the initial determination. The availability of new clinical data in such cases does not constitute good cause to reopen the decision, as both the physician's clinical recommendation and the plan's initial approval were appropriately based on the information present at the time. **Both physicians and patients should be able to rely upon an MA plan's coverage determination via prior authorization, pre-service determination, or concurrent review of inpatient or outpatient treatment without fear of the plan's later reopening and reconsidering its decision.**

Proposed Regulatory Changes to Medicare Advantage and Part D Medical Loss Ratio (MLR) Standards

Request for Information on MLR and Vertical Integration

The AMA shares the concerns raised by policymakers, the Medicare Payment Advisory Commission, and researchers that MA and Part D organizations are becoming increasingly vertically integrated, with this integration obscuring the amounts these companies are spending on actual patient care versus earned profits. These concerns are compounded by recent investigations, such as that published by *STAT News*, which found that the insurer UnitedHealthcare (UHC) pays Optum-branded physician groups—which are owned by UHC's parent company UnitedHealth Group—more than other physicians.[20] This investigation discovered that for some types of care, UHC pays Optum practices approximately two times the average market price. Other recent reporting by the *Wall Street Journal* suggests that UnitedHealth Group encourages its Optum-owned physician practices to assign additional (and sometimes inappropriate) diagnosis codes to UHC-covered MA patients to increase risk scores, which in turn boosts the amount CMS pays UHC to manage the care of these patients.[21] The complicated relationships and financial accounting between parties in these "closed loop" systems (i.e., where the MA plan "payer" and the physician practice "payee" are owned by the same parent company) may obfuscate actual MA-related profits and MLR calculations.

For these reasons, the AMA commends CMS for soliciting additional information and input on how MLR calculations should be adjusted to account for vertical integration in MA and Part D plans. The AMA urges CMS to evaluate and accept recommendations that will improve the transparency of MLR calculations, promote accountability in the MA and Part D programs, and ensure that these benefits are administered in a manner that improves the safety, effectiveness, quality, and efficiency of health care services. Based on the recent investigations noted above, one of many possible areas of new data collection and analysis could be requiring MA plans to provide information regarding payment rates for plan-owned or -employed physicians and other providers compared with physicians not under the financial umbrella of the MA plan's parent company. These data could elucidate how vertical integration may be impacting MLR calculations and obscuring the exact dollars plans spend on patient care. We applaud CMS for undertaking this important area of inquiry that will improve the transparency and accuracy of MLR reporting, increase accountability among MA and Part D plans, and ensure appropriate use of premium dollars for quality, efficient, health care delivery.

Proposal To Add Provider Payment Arrangement Reporting in the Medicare MLR Reporting Regulations

The AMA supports CMS' proposals to collect additional details regarding alternative payment models (APMs) for MA plans to provide additional transparency into expenditures and their relationship to MLR standards.

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[20] Herman B, Ross C, Lawrence L, Bannow T. UnitedHealth pays its own physician groups considerably more than others, driving up consumer costs and its profits. STAT News. November 25, 2024. Available at: https://www.statnews.com/2024/11/25/unitedhealth-higher-payments-optum-providers-converts-expenses-to-profits/.

[21] Weaver C, Mathews A, McGinty T. UnitedHealth's Army of Doctors Helped It Collect Billions More From Medicare. Wall Street Journal. December 29, 2024. Available at: https://www.wsj.com/health/healthcare/unitedhealth-medicare-payments-doctors-c2a343db.

Specifically, CMS plans to specify that MLR reports include aggregate expenditures by provider payment arrangement type in MA and to make accompanying changes to the MLR Reporting Tool to add separate fields to capture various categories of expenditures for provider payment arrangements, including specifying between fee-for-service, APMs, and population-based payments. The AMA supports this proposal and CMS' efforts to ensure that APM payments are being accurately accounted for in MLR calculations and MA beneficiaries are getting an appropriate level of benefits. The AMA also agrees that additional data collection regarding APMs is important as APMs become increasingly prevalent in MA markets and therefore make up a greater share of MA physician reimbursement. We also support CMS' proposal to solicit feedback on the specific data categories and elements through notice of public comment and rulemaking and encourage CMS to consider how variable performance-based elements built into MA physician reimbursement contracts can impact total expenditures on physician services and therefore impact MLR calculations.

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

In the 2026 MA proposed rule, CMS proposes to add or update the following measures to the program, and we offer the following measure specific comments:

Initiation and Engagement of Substance Use Disorder Treatment (IET) (Part C)

The AMA asks that CMS consider the potential for unintended consequences that may result from the use of this measure. We believe that there is a real risk that this measure will not truly represent the quality of care provided or available to the patient. Overall, a health plan's ability to provide treatment options to patients may be very dependent on the availability of services within a community or region and the measure does not currently account for those instances. We acknowledge the potential positive for counting each episode of "treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth visit, or medication treatment." However, "medication treatment within 14 days" is unacceptable as medications for opioid use disorder often are necessary at the point of care and not two weeks later. In addition, it is not clear what type of treatment is being suggested in the different initiation situations envisioned by CMS. The AMA strongly urges tying a qualifying episode of treatment to one that is evidence-based. We urge consideration of recommendations put forward by Substance Abuse and Mental Health Services Administration as well as the American Society of Addiction Medicine and American Academy of Addiction Psychiatry for optimal courses of treatment for initiation. It also is unclear, because the measure relies on administrative claims, whether it captures patient choice such as refusal of treatment; patient barriers such as pharmacies' denial of access to medication; or even health plan barriers such as prior authorization and step therapy. Each of these will affect initiation as well as engagement. In addition, we were unable to identify any analyses or other information demonstrating that the developer has evaluated the degree to which these scenarios (e.g., availability of services in an area) impact the validity of the performance scores. As a result, because the score does not appear to take into account the specific types of care or availability of care, we do not support inclusion of this measure in the Part C & D Star Ratings program.

Initial Opioid Prescribing for Long Duration (IOP-LD) (Part D)

The AMA strongly opposes this measure. As proposed, it will hurt Medicare enrollees who benefit from opioid therapy, further stigmatize a legitimate medical option, and inappropriately target physicians who prescribe opioids to patients with pain. We strongly oppose prescribing thresholds based on arbitrary, low-quality evidence that have demonstrated negative effects on patients. We are extremely surprised that

this measure seeks to justify use of a three-day or seven-day opioid prescription as the norm when the use of such thresholds was unequivocally repudiated by the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain.[22] We believe that this measure requires significant rework with input from the pain medicine specialists as well as patient advocates who were involved in the revisions to the 2022 CDC guideline.

As background, it is critical to highlight that the 2022 CDC guideline removed from its recommendations the same numeric prescribing thresholds that this proposed measure seeks to use to evaluate physicians' prescribing. The Pharmacy Quality Alliance (PQA) restates the three-day and seven-day thresholds from the 2016 guideline but fails to mention that those numeric thresholds were removed from the 2022 guideline.

The 2022 CDC guideline emphasizes multiple times:

"This clinical practice guideline provides voluntary clinical practice recommendations for clinicians that should not be used as inflexible standards of care. The recommendations are not intended to be implemented as absolute limits for policy or practice across populations by organizations, health care systems, or government entities."

The AMA appreciates that the proposed measure states that it would not apply to patients with cancer, in hospice, with sickle cell disease or who receive palliative care. Nearly all inappropriate prescribing restriction laws and policies, however, use similar language, but all generally fail to ensure protection for members of these vulnerable populations. Since the publication of the original 2016 CDC guideline, the AMA has heard from numerous physicians and patients who treat patients with these diseases or in these situations where pain care was denied. The proposed measure might say "individual," but the very fact of specific numeric thresholds will cause patients who benefit from dosages or quantities greater than three to seven days to be denied medication beyond those thresholds. In addition, the AMA strongly disputes the PQA's claim that the 2022 CDC guideline supports the proposed measure because the CDC rejected the use of hard thresholds in the 2022 guideline. In addition, the measure admits that it is based on "low" or "very low" evidence. Subjecting Medicare enrollees and physicians to such a scheme is counterproductive to patient safety and high-quality care. The AMA opposes this measure because patient harm has been an undeniable result of the failed 2016 CDC guideline—including to patients with cancer, and who receive hospice and palliative care.

In the revised 2022 CDC guideline, the authors emphasize the misapplication of the 2016 one-size-fits-all approach. The 2022 guideline removed the numeric thresholds because they also proved impossible to implement with any sensitivity to vulnerable populations, including those with cancer, sickle cell disease, or in hospice or palliative care. CDC cited misapplications including "rapid opioid tapers and abrupt discontinuation without collaboration with patients, rigid application of opioid dosage thresholds, application of the guideline's recommendations for opioid use for pain to medications for opioid use disorder treatment (previously referred to as medication assisted treatment), duration limits by insurers and pharmacies, and patient dismissal and abandonment." It is not surprising that when a state law, pharmacy chain or health insurer policy uses a specific numeric limit, patients are denied anything above that limit—regardless of whether the opioid analgesic is for acute, sub-acute or chronic pain. Measures, systems, algorithms and other policies or procedures have never demonstrated any sensitivities toward

[22] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.

individualized pain care. CDC finally understood this and revised the 2016 guideline accordingly. It follows that the AMA strongly opposes using discredited hard, numeric thresholds as a quality measure because—not only are they not recommended by CDC—but they have a long history of causing patient harm.

The AMA similarly appreciates that the PQA claims that it "routinely monitors its measures and associated feedback regarding potential unintended consequences." If that is the case, the AMA questions why the PQA is choosing to not follow the CDC's 2022 admonitions against the use of hard thresholds. The AMA also questions why the PQA did not allow its panel of caregivers and patients to vote on the measure. In revising the 2016 CDC opioid prescribing guideline, the CDC held multiple listening sessions and convened a workgroup[23] consisting of more than 20 patient advocates and pain medicine physicians and other health care professionals to help ensure CDC did not repeat the mistakes and harms associated with the 2016 guideline. The CDC also held multiple, public listening sessions to understand the depths of harm caused by the 2016 guideline. This broad public and scientific input made clear to CDC that removing the arbitrary numeric thresholds of the 2016 guideline was essential to try and prevent further harm. If PQA rejects the input of patients and physicians who helped demonstrate to CDC why removing arbitrary thresholds was important, the PQA will essentially be sanctioning patient harm for Medicare enrollees.

Furthermore, we question CMS' continued insistence to move forward and propose the measure given during the 2024 Medicaid Child and Adult Core Set Annual Review workgroup meeting, the workgroup recommended to remove the measure from the program starting in 2026. During the meeting CDC highlighted their lack of support for the measure and the numerous problems and patient harm it is causing. The IOP-LD measure was also reviewed during the 2023-2024 Measure Under Consideration (MUC) Process and the Pre-Rulemaking Measure Review (PRMR) Clinician Workgroup under CMS contract could not reach consensus which further highlights the challenges with the measure. Workgroup members specifically questioned the evidence base for the measure and the lack of alignment with clinical guidelines.

The AMA believes that it is absolutely critical to help improve patients' access to high quality care for pain-related conditions while also minimizing opioid overuse. Regrettably, this measure is not aligned with the evidence and has significant unintended negative consequences to patients. As a result, the AMA does not support the inclusion of this measure in the Part C & D Star Ratings program.

Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C)

The AMA appreciates CMS actively monitoring the effectiveness of the Plan Makes Timely Decisions About Appeals measure. The measure evaluates the percentage of appeals timely processed by the plan out of all the plan's appeals decided by the Independent Review Entity. As a result, CMS proposes, beginning with the 2026 measurement year, substantive updates to the measure, which the AMA supports. We frequently hear from physicians regarding the lack of timeliness by health plans in responding to and reviewing appeal decisions and are encouraged that the proposed changes will improve these response times. A 2018 OIG report showing that MA plans overturn 75 percent of their own denials

[23] 2019 Opioid Workgroup. Centers for Disease Control and Prevention. Available at https://www.cdc.gov/injury/bsc/opioid-workgroup-2019.html.

underscores the importance of timely appeal processing in protecting patient access to medically necessary care.[24]

Universal Foundation: Streamlining the measurement set for the Part C and D Star Ratings program.

As part of CMS' efforts to align quality measurement across CMS programs and propose the use of measures from the Universal Foundation measure set in the Star Ratings system in the future, CMS submitted the Social Need Screening and Intervention Part C measures to the 2024 Measure Under Consideration (MUC) list. During the 2024 MUC commenting process, the AMA submitted comments and reiterate our concerns to CMS with the readiness of the measure and lack of alignment with the other social need screening/health equity and intervention measures that were placed on the 2024 MUC list for use in the CMS provider quality programs, including MIPS. While the Part C *Social Need Screening and Intervention* measure provides a more complete picture of whether it is feasible to collect the data when compared to the similar social needs/health equity measures proposed and finalized for MIPS, we remain concerned with the lack of reliability testing, no correlations with relevant quality measures, and limited gap data. Most importantly, quality measures should facilitate and optimize quality improvement at the point of care. A measure that is overly complex and not adequately tested cannot achieve this goal and requires significant refinement and evaluation before it should be considered for any CMS program.

We are also concerned that MA plans will place the burden on the physician to screen and address any issues related to patients' social needs, as opposed to the health plan screening and providing the necessary support services. For example, the second evaluation report of the CMMI Accountable Health Communities model found that there were several factors that contribute to whether a community service provider may offer services to individuals, including limited availability of affordable housing and transportation services and whether some patients were able to meet the eligibility requirements for a service. These gaps are not within the clinician's control and contribute to our concerns.

The AMA also requests that CMS align the quality measures addressing inappropriate use of antipsychotics in individuals with a diagnosis of dementia in the Medicare Part C & D programs and the Nursing Home Quality Initiative (NHQI). We recognize that the appropriate use of antipsychotics is a patient safety concern and are strongly committed to ensuring that individuals are not prescribed antipsychotic medications when it is not medically necessary. However, we also believe that CMS must ensure that quality measures are aligned across programs to provide consistent signals of what is considered high quality care and ensure that each measure should be evidence-based and minimize unintended consequences to patient care.

Both measures seek to determine how many individuals with dementia receive antipsychotic medications, but the Medicare Part C & D measure stewarded by the PQA excludes those individuals who have a psychiatric disorder or related condition such as bipolar disorder or schizophrenia. The NHQI measures stewarded by CMS apply to short-stay and long-stay nursing home residents and excludes individuals with diagnoses such as schizophrenia or Huntington's disease. This request is also supported by the 2023 review of the NHQI measures by a technical expert panel where they recommended that the measure should exclude additional severe mental illnesses (e.g., bipolar disorder)[25]. While the intent of both measures is clearly aligned, the specifications including denominator exclusions and which antipsychotic

[24] US Department of Health and Human Services Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. September 2018. Available at: https://oig.hhs.gov/documents/evaluation/3140/OEI-09-16-00410-Complete percent20Report.pdf.
[25] https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf.

medications are included in each measure (which are not easily accessible to review and compare) must also be consistent.

In addition, we ask that both measure stewards consider whether individuals who receive hospice care should be excluded from the measures since some antipsychotic medications are considered clinically appropriate end-of-life care. For example, an analysis of the Minimum Data Set and hospice claims from 2011 – 2017 identified that the CMS' efforts to reduce inappropriate prescribing negatively impacted individuals receiving hospice care in long-term care settings for whom receipt of these medications could be considered clinically appropriate.[26] While there are several settings in which hospice care is provided (e.g., home, facilities), much of the care occurs within a nursing facility or assisted living facility with an average length of stay of 109 days and 165 days, respectively.[27] We believe that hospice care should be evaluated as a potential denominator exclusion across the measures.

The AMA remains committed to ensuring that individuals receive the highest quality and clinically appropriate care. We believe that a thorough comparison of the measure specifications should be completed and aligned and are willing to assist CMS in these efforts.

Improving Experiences for Dually Eligible Enrollees

The AMA supports CMS' proposals to improve experiences for dually eligible enrollees, which aim to eliminate redundancies to reduce burden and confusion amongst enrollees while promoting more efficient processes.

Specifically, the AMA supports CMS' proposal to integrate member identification cards for MA plans and Medicaid managed care plans effective January 1, 2027. We agree this will reduce confusion and burden for enrollees as well as clinical and billing staff. We support the delayed implementation to allow time for MA and managed care organizations to prepare and ensure they are in compliance with all Medicare and Medicaid requirements. The AMA likewise supports CMS' proposal to integrate Health Risk Assessments (HRAs) to simultaneously satisfy Medicare and Medicaid requirements for enrollees of separate Dual Special Needs Plans (D-SNPs) and Medicaid managed care plans. We agree that aligning HRAs will reduce the burden on enrollees and promote coordinated data sharing across plans. Based on feedback in response to this rule, we believe allowing more flexible timing requirements could help facilitate alignment of HRAs while reducing compliance burden.

While we understand CMS' desire to start by applying these new policies to Applicable Integrated Plans to reduce operational complexity and implementation burden in the first stage, we encourage the agency to work toward expanding this policy to all Highly Integrated Dual Eligible SNPs and eventually all D-SNPs in the future by building a data sharing mechanism across Medicaid managed care, MA, and Medicaid fee-for-service organizations to facilitate timely sharing of relevant data across plans.

The AMA supports CMS' proposals to codify timeliness standards and outreach standards and strengthen HRA and individualized care plan (ICP) requirements, including that ICPs must be: 1) whole person-centered based on the enrollee's individualized preferences; 2) developed through an interdisciplinary care team with the active participation of the enrollee (or a representative); 3) identify enrollee-specified

[26] Gerlach LB, Fashaw S, Strominger J, et al. Trends in antipsychotic prescribing among long-term care residents receiving hospice care. J Am Geriatr Soc. 2021;69(8):2152-2162. doi:10.1111/jgs.17172.
[27] https://www.nhpco.org/wp-content/uploads/NHPCO-Facts-Figures-2024.pdf.

goals and objectives, including measurable outcomes as well as specific services and benefits; and 4) updated as warranted by changes in the health status or care transitions of enrollees. We agree these changes will help ensure HRAs and ICPs are more patient centered.

We likewise support efforts to post template State Medicaid agency contracts with D-SNPs in an effort to promote transparency and facilitate comparisons to identify best practices and opportunities for improvement.

Formulary Inclusion and Placement of Generics and Biosimilars

Our physician members' experience reflects and amplifies CMS' concern that Part D plans' formulary design and UM programs may favor brand or reference products over less expensive generic or biosimilar drugs. Indeed, in the AMA's most recent survey, over half (55 percent) of physicians who complete prior authorizations for prescription drugs report that this process is at least sometimes required for generic medications.[28] While the AMA's survey results do not specifically address whether pharmacy benefit managers (PBM) are placing prior authorization on generic drugs to drive utilization of brand medications, the data do suggest that prior authorization may be creating a barrier to patients accessing cost-effective generic medications. Such counterintuitive UM practices and formulary designs financially harm patients and the Part D program, as PBMs are driving utilization to more costly medications—presumably motivated by rebate arrangements with pharmaceutical manufacturers. In addition, UM and unfavorable formulary placement for generic and biosimilar medications also result in administrative burdens and rework for physicians, who rightfully expect that these less expensive drugs will be favored by PBMs and easily accessible when prescribed to their patients—only to later receive pharmacy callbacks when a generic medication requires prior authorization or is placed on a higher formulary tier. Physicians are understandably frustrated that arbitrary formulary placements based on business arrangements versus sound economics block treatment access and burden their practices. **The AMA therefore supports CMS' plans to instate an additional step in the Part D formulary review process to ensure that plans (1) offer broad access to generics, biosimilars, and other lower cost drugs and (2) incorporate fewer utilization controls on generic drugs and low-cost alternatives than on brand drugs and reference products.**

Need to Eliminate Barriers to Effective Treatment with Buprenorphine

MA, MA-Part D, and standalone Part D plans should be prohibited from imposing prior authorization, step therapy or fail first requirements on medications for opioid use disorder (OUD). The nationwide drug overdose epidemic is extremely 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 OUD. 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

[28] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

instead turn in the opposite direction to satisfy their craving and ward off withdrawal and never get the chance to recover.

These plans also should be required to include all forms of buprenorphine in formularies and network pharmacies, and they should be prohibited from imposing quantity limits on buprenorphine doses. A clinical considerations paper published by the American Society of Addiction Medicine discussed key factors in treatment protocols for patients with OUD, emphasizing that treatment must be individualized to the patient and one-dose-fits-all approaches are not effective in addressing this epidemic. It discussed patient needs for different formulations and doses of buprenorphine. Doses should not be limited to 16-24 mg daily as this may not be sufficient for patients to achieve or sustain 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 and Part D plans should not be allowed to cavalierly play with people's lives when they substitute their judgment for that of physicians.

More recently, in a December 27, 2024 notice in the Federal Register, the FDA clarified that current buprenorphine labeling does not require a maximum dose restriction. Although the FDA label for many buprenorphine products to treat OUD suggests that doses above 24mg daily have not been shown to be effective, these labels do not reflect current patient experience with use of illicitly manufactured fentanyl or that physicians report benefits of doses above 24mg for some OUD patients. The FDA encourages submission of supplemental new drug applications to modify labeling for buprenorphine-containing transmucosal products for the treatment of OUD.

The AMA has received multiple reports from physicians that MA and Part D plans have been using the current FDA labeling as a justification for restrictions such as prior authorization, quantity limits, or denials of doses of 24mg or higher. These restrictions often prevent patients from accessing buprenorphine at a dose that can effectively manage their OUD, which can have tragic results. Several states also have statutory buprenorphine dose restrictions based on the outdated FDA labeling.

Finally, a 2024 report from the NIH National Institute on Drug Abuse provides further support for abandoning outdated and misinformed buprenorphine dose restrictions, noting that patients with OUD who receive a higher daily buprenorphine dose may have a lower risk of subsequent emergency department visits or use of inpatient services related to behavioral health. It is therefore in both plans' and patients' interests to discontinue quantity limits on buprenorphine as it could lower other medical costs while improving patients' health outcomes. **The AMA strongly urges CMS to take note of these findings and the growing body of evidence that further affirms buprenorphine as a safe, effective, and lifesaving tool in the fight against the illicit fentanyl overdose epidemic.** It is also critically important that CMS prohibit quantity limits and all other drug UM techniques that restrict patients' access to the formulations and doses of buprenorphine that are needed to effectively treat their OUD.

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.

Sincerely,

James L. Madara, MD