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Administration Marketa Wills, M.D., M.B.A. January 27, 2025

Office of the Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services P.O. Box 8016 Baltimore, MD 21244-8016

Re: Comments on Medicare Program; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and the Programs of All-Inclusive Care for the Elderly (CMS-4208-P)

Dear Administrator,

The American Psychiatric Association (APA), the national medical specialty society representing over 38,900 psychiatric physicians and their patients, appreciates the opportunity to comment on the proposed Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program (CMS-4208-P). The proposed improvements to the Medicare Advantage program and Medicare Part D prescription drug program will benefit many of Medicare's most vulnerable beneficiaries.

Over 25% of the over 66 million Medicare beneficiaries report having a mental health disorder. Of the over 12 million beneficiaries eligible for both Medicare and Medicaid, half have a mental health condition, and many are individuals with lower incomes and/or individuals suffering from multiple health conditions. Additionally, rates of suicide continue to increase with older Americans at greatest risk.

Funding for services to treat mental health disorders has historically lagged funding for physical health care with approximately 5-6% of total US health care expenditures allocated to mental health services in-spite of the prevalence of disorders⁵ and research showing that increased investment in mental health services results in decreased costs related to emergency department visits, inpatient hospitalizations, and long-term cost savings associated with improved physical health. Underfunding the system has led to increased costs for beneficiaries (i.e., variable cost sharing/copays, out-of-network care), coverage limitations (i.e., no or limited coverage for substance use disorders), as well as low reimbursement rates for

¹ The term mental health disorders, includes substance use disorders

² U.S. Government Accountability Office, (Sept. 2024) Behavioral Health: Information on Cost-Sharing in Medicare and Medicare Advantage, https://www.gao.gov/assets/gao-24-106794.pdf

³ Kaiser Family Foundation, (2023, January) "A Profile of Medicare-Medicaid Enrollees (Dual Eligibles)," https://www.kff.org/medicare/issue-brief/a-profile-of-medicare-medicaid-enrollees-dual-eligibles/

⁴ National Institute of Mental Health (NIMH), (2023), Retrieved from www.nimh.nih.gov

⁵ National Institute of Mental Health (NIMH), (2023), Retrieved from www.nimh.nih.gov

clinicians, including psychiatrists who are paid 24% less than physician colleagues. Low reimbursement rates along with a growing demand for services have become a disincentive to participate in insurance networks and Medicare.

A 2023 Kaiser Family Foundation study⁷ found that while Medicare Advantage (MA) plans cover the same services as Traditional Medicare, the cost sharing policies, use of prior authorization techniques, limited clinician networks, and lack of out-of-network coverage create barriers for patients with mental health disorders to access necessary care to the point that the MA plan offering is of no benefit. These limitations continue despite MA plans receiving higher payments through risk adjustment to cover the higher-than-expected cost of providing care to beneficiaries with higher risk adjustment factor scores. Several of the policies within this proposed rule will begin to address these barriers.

Promoting Informed Choice—Format Provider Directories for Medicare Plan Finder

We applaud CMS's proposal to require MA organizations to submit provider directory data to the Medicare Plan Finder and annually attest to its accuracy. It is essential that MA organizations be held accountable for the accuracy of the information contained in the provider directory. We are optimistic that this proposal will improve directory accuracy and ultimately allow beneficiaries to evaluate Medicare options and decide if a particular network meets their needs before making a purchasing decision. Further, we are hopeful this proposal could eliminate ghost networks.

However, this proposal is only part of the solution to the access problem. MA organizations are increasingly using prior authorization to limit care. According to a Kaiser Family Foundation study, in 2022, virtually all Medicare Advantage enrollees (98%) were in plans that required prior authorization for some mental health and substance use disorder services. More than 9 in 10 Medicare Advantage enrollees were in plans that required prior authorization for inpatient stays in a psychiatric hospital (93%) and partial hospitalization (91%). Slightly more than 8 in 10 Medicare Advantage enrollees were in plans that required prior authorization for opioid treatment program services (85%), therapy sessions with other mental health providers besides psychiatrists (sometimes referred to as mental health specialty services; 84%, therapy sessions with a psychiatrist (84%), and outpatient substance abuse disorder services (83%). According to a 2023 Kaiser Family Foundation study, "of the 46.2 million prior authorization determinations in 2022, more than 90% (42.7 million) were fully favorable, meaning the requested item or service was approved in full. 8 The remaining 3.4 million (7.4%) were denied in full or in part. In comparison, between 2019 and 2021, less than 6% of prior authorization requests were denied." Additionally, in 2022, only 9% of denied prior authorizations were appealed. This data suggests that prior authorizations are used to impede access to necessary care given the high rates of successful authorizations.

As a result, even if a beneficiary finds an appointment with a psychiatrist listed in the directory, MA may deny their care resulting in delayed or no access for these patients. Further, an increasing number of our member psychiatrists are reporting that they are leaving MA networks because of the increasing numbers

⁶ Kaiser Family Foundation, (2023, April28) "Mental Health and Substance Use Disorder Coverage in Medicare Advantage Plans". Mental Health and Substance Use Disorder Coverage in Medicare Advantage Plans | KFF

⁷ Kaiser Family Foundation, (2023, April 28) Mental Health and Substance Use Disorder Coverage in Medicare Advantage Plans, Mental Health and Substance Use Disorder Coverage in Medicare Advantage Plans | KFF

⁸ Kaiser Family Foundation. (2024, August 8), Medicare Advantage in 2024: Premiums, Out-of-Pocket Limits, Supplemental Benefits, and Prior Authorization | KFF

of prior authorizations and slow reimbursement of claims. However, our members are also reporting that when they have applied to join networks, they have not been able to get on a network panel. Costs and administrative burdens to both psychiatrists and MA plans would be cut by eliminating or restricting the use of prior authorization requests to manage care.

Promoting Informed Choice—Enhancing Review of Marketing and Communications

We applaud CMS for its efforts to ensure Medicare Advantage marketing to beneficiaries is not misleading, inaccurate, or confusing by proposing to expand the definition of marketing materials to include anything with an intent to draw a beneficiary's attention to a plan or plans and, as such, requiring these materials to be submitted to CMS for review. This proposal may help address some of the predatory marketing practices causing harm to beneficiaries. However, APA remains concerned these proposals do not go far enough given the widespread misleading practices in the MA industry and the lack of meaningful enforcement.

APA members have been increasingly concerned about the marketing practices of MA plans. Individuals enroll with limited knowledge or understanding of the constraints of the coverage. MA plans tout their benefits, like low copays or premiums and the inclusion of dental and vision care, yet fail to mention limitations or gaps in coverage (i.e., limited networks, limited formularies, absence of access to case management for seriously mentally ill patients) or clearly explain the challenges that could arise if the patient wants to revert to the Traditional Medicare plan, especially if they've never been enrolled in Traditional Medicare. APA members have also expressed concerns about the "seamless conversion" process available to some MA plans, explaining that individuals may be unwittingly enrolled in an MA plan after failing to specifically opt out.

The flood of marketing materials eligible individuals receive from various MA plans increases the likelihood that key information is being missed. MA is seen as a poor option for individuals with a MH/SUD that requires ongoing care. Limitations as to health insurance literacy coupled with functional limitations/impairments due to physical and mental health disorders make the process to choose the best coverage challenging. Consideration should be given to providing additional support to those with chronic conditions or those dually eligible for Medicare and Medicaid. Attention needs to be given to ensure that the coverage information is written concisely at a fourth-grade level with comparisons across plans of key information clearly outlined and available in multiple languages. Guidance from an impartial, knowledgeable individual, who can ideally converse in the individual's native language could help guide individuals to choose a plan that best meets their needs.

Improving Access—Enhancing Rules on Internal Coverage Criteria

APA supports CMS's proposals to define "internal coverage criteria," require that such criteria only be used to supplement or interpret the plain language of Traditional Medicare criteria, establish policy guardrails, and require MA plans to publicly post their internal coverage criteria on their web sites. We are particularly grateful to CMS for including in the definition of coverage criteria those criteria developed by third parties and often described as proprietary, and for clarifying that such criteria include both those that are adopted by the MA plan as well as those that are relied upon for medical necessity determinations. We also strongly support CMS's proposed policy guardrails that would prohibit the use of any criterion that does not have any clinical benefit, and therefore, exists solely to reduce utilization of the item or service, and that would prohibit the use of any criterion used to automatically deny coverage of basic benefits without the MA organization making an individualized medical necessity determination.

We further commend CMS for ensuring these internal coverage criteria are displayed in a prominent manner on the MA plan's web site and easily available to the public without barriers.

While we hope that the new policy guardrails will eliminate many of the pervasive coverage criteria that harm beneficiaries more than help them, APA is concerned with CMS's proposal to eliminate the requirement that plans demonstrate that the clinical benefit of internal criteria are highly likely to outweigh any clinical harms. We appreciate CMS's concern that MA plans have not been able to demonstrate such benefit through evidence, but we do not believe that this failure reflects the unenforceability of the provision, but rather that MA plans are routinely using internal coverage criteria that do not meet this requirement. One common criterion is the use of dosage limits on buprenorphine to treat opioid use disorder. In a recent notice, the Food and Drug Administration (FDA) identified how managed care plans have misinterpreted buprenorphine labeling to require a dosage cap of 16mg/day, when higher dosages may be clinically beneficial to some patients, especially in light of the fentanyl crisis. Even without the FDA notice, there was no evidence to suggest that these dosage caps have clinical benefits that outweigh clinical harms, or that these dosage caps support patient safety. Accordingly, we continue to believe that it is appropriate that MA and Part D plans be required to demonstrate that any internal coverage criteria have clinical benefits that are highly likely to outweigh any clinical harms to prevent plans from imposing criteria that are not based in evidence.

Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

APA supports CMS's cost-sharing proposal which seeks to align MA in-network cost-sharing with Traditional Medicare for intensive outpatient (IOP) services, MH specialty services, opioid treatment program (OTP) services, outpatient SUD services, partial hospitalization (PHP), psychiatric services, and inpatient hospital psychiatric services. APA supports parity of coverage for treatment of all mental health disorders including substance use disorders. MA plans have an opportunity to allocate the funds they are paid through risk adjustment to address the complex needs of mental health patients by incentivizing patients to engage in care through low or no-cost cost sharing, and right-sizing payments to psychiatrists that better reflect the cost of providing care and in line with payments to their physical medicine colleagues. Aligning financial incentives for beneficiaries and psychiatrists could improve patient outcomes through better patient engagement and increase in network participation in Medicare Advantage. Increasing network participation increases access to care for patients and reduces the need for beneficiaries to pay for out-of-network care.

We urge CMS to extend these cost-sharing adjustments to mental health services provided in primary care, and specifically, to encourage MA plans to reduce the costs associated with behavioral health integrations services such as the Collaborative Care Model. Fifty to 70% of individuals seek mental health care in primary care settings. Though the Collaborative Care model has been shown to improve patient outcomes faster through team-based care, the cost sharing amounts have become a barrier to treatment

Care for Substance Related Disorders, (2016), https://www.psychiatry.org/getattachment/94678c6f-2095-4c92-b88d-8d6aa3578bcb/Postion-2016-Equitable-Access.pdf

⁹ Food and Drug Administration, (Dec. 27, 2024) "Modifications to Labeling of Buprenorphine-Containing Transmucosal Products for the Treatment of Opioid Dependence," 89 Fed. Reg. 105613, https://www.govinfo.gov/content/pkg/FR-2024-12-27/pdf/2024-30776.pdf

¹⁰ APA Position Statement on Equitable Access to Quality Medical

¹¹ Bowman Family Foundation, (May 2024), Mounting Evidence That Use of the Collaborative Care Model Reduces Total Healthcare Costs, https://www.filesbff.org/CoCM_Total_Healthcare_Costs_Issue_Brief.pdf

for some who would benefit. Incentivizing this evidence-based model of care through low to no-cost share amounts would encourage engagement by those patients who would most benefit from this treatment model.

We encourage CMS to monitor the impact of the proposed changes to cost sharing to ensure it does not adversely impact care for individuals with mental health and substance use disorders. Ensuring ongoing access to the full continuum of care is important in maintaining the health of individuals, particularly those with chronic conditions. Monitoring data to assess any increase or decrease in the number of individuals treated, and the frequency and type of visits would be one way to assess whether the goal of increasing access is achieved.

Ensuring Equitable Access to Medicare Advantage Services – Guardrails for Artificial Intelligence (AI)

We appreciate that this proposed rule builds on previous regulations to enforce critical safeguards on insurers' use of artificial intelligence. We support the requirement for plans to ensure AI algorithmic transparency as well as to monitor and address potential biases. APA agrees that plans should err on the side of human oversight, ensuring clinicians retain control over medical decisions affecting patient care. We also agree with CMS's proposal that AI and automated systems must be used in a way that ensures equitable access to Medicare Advantage services. The use of AI must comply with existing Medicare regulations that prohibit discrimination and promote equal access to MA services. MA plans must disclose their use of AI tools, ensuring that beneficiaries and providers are informed about how AI impacts coverage and care decisions.

Formulary Inclusion and Placement of Generics and Biosimilars

APA supports CMS's ongoing actions to monitor and ensure that beneficiaries have broad access to generics, biosimilars and other lower cost drugs through Part D formularies. We agree that reviewing the plan's formulary and utilization management process is important in determining if Part D sponsors are complying. A number of APA members report they are receiving prior authorization requests for generic medications, including new and existing prescriptions. We encourage CMS to take steps to ensure patients have access to a broad array of medications including generics, biosimilars and other lower cost drugs.

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss these comments in more detail, please contact Becky Yowell (qualityandpayment@psychiatry.org), Sr. Director, Reimbursement Policy and Quality.

Sincerely,

Marketa Wills, MD, MBA, FAPA

CEO and Medical Director

American Psychiatric Association