AMERICA'S PHYSICIAN GROUPS

January 27, 2025

Jeff Wu
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted via https://www.regulations.gov/commenton/CMS-2024-0345-0006

Re: Medicare Program; 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; Health Information Technology Standards and Implementation Specifications (CMS–4208–P)

Dear Acting Administrator Wu:

America's Physician Groups (APG) appreciates the opportunity to respond to the proposed rule from the Centers for Medicare & Medicaid Services (CMS) on 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; Health Information Technology Standards and Implementation Specifications. APG welcomes your agency's openness to stakeholder input and ongoing commitment to improving health care for all Americans.

Below, APG will first provide (I) a brief description of our organization, followed by (II) a summary of CMS's proposals, (III) a summary of APG's recommendations, (IV) our fuller comments and recommendations, and then (IV) our conclusion. Together these comments and recommendations reflect the voice of APG's membership and the commitment to working with the agency to ensure that all Medicare beneficiaries have consistently accessible, high-quality, equitable, person-centered health care. This commitment pertains to all Medicare beneficiaries, regardless of whether they receive their benefits through the traditional, fee-for-service program or through a Medicare Advantage plan.

I. About America's Physician Groups

APG is a national association representing more than 360 physician groups that are committed to the transition to value, and that engage in the full spectrum of alternative payment models and Medicare Advantage (MA). APG members collectively employ or contract with approximately 195,000 physicians (as well as many nurse practitioners, physician assistants, and other clinicians), and care for approximately 90 million patients, including roughly 30 percent of all Medicare beneficiaries who are enrolled in MA.

APG's motto, "Taking Responsibility for America's Health," underscores our physician groups' preference for being in risk-based, accountable, and responsible relationships with all payers, including MA health plans, rather than being paid by plans on a fee-for-service basis. Delegation of risk from payers to providers creates the optimal incentives for our groups to provide integrated, coordinated care; make investments in innovations in care delivery; advance health equity; and manage our populations of patients in more constructive ways than if our members were merely compensated for the units of service that they provide.

II. CMS's Proposed Rule

CMS's proposed rule aims to lower the barriers between Medicare enrollees and the care that best meets their health care needs. A key goal is adding more transparency on the plan management side with an explicit focus on patient impact. The proposed rule promotes informed beneficiary choice by increasing agent and broker disclosure requirements and requiring greater information collection concerning prior authorization and utilization management policies and its impact on health equity. CMS is continuing to move toward Universal Foundation measures to align quality measures across all programs including MA, traditional fee-for-service Medicare, and ACOs.

The proposed rule also aims to improve access to obesity treatment by reinterpreting current statute to allow for the coverage of anti-obesity medications.

III. Summary of APG's Recommendations

A. Recommendations Related to Coverage of Anti-Obesity Medications

- **APG recommends that CMS finalize the policy to cover anti-obesity medications for the treatment of obesity in Medicare Part D and Medicaid programs.**
- **APG recommends that CMS review the design and application of Part D sponsors' anti-obesity medication prior authorization policies to ensure that these do not interfere with appropriate prescribing.**
- **APG recommends that CMS evaluate the impact of anti-obesity medication coverage on Part D costs and make refinements – or suggest refinements for Congress to include in legislation – to Part D policies as needed.**

B. Recommendations Related to Promoting Informed Choice by Expanding Agent/Broker Requirements

- **APG recommends that CMS finalize the policies to promote informed Medicare beneficiary choice by expanding requirements for brokers and agents to provide information on the availability of support for low-income enrollees, existing resources for state programs that can help with healthcare costs, and Medigap federal guaranteed issue rights. In addition, APG recommends that CMS develop and provide standardized information in the form of brochures or pamphlets on these topics to agents and brokers that they can relay to beneficiaries.**

C. Recommendations Related to Prior Authorization and Health Equity

- **CMS should not require any new prior authorization data reports until the agency evaluates the reports that were finalized in 2024 and share these results transparently with all stakeholders, including an assessment of whether the reports should be modified or discontinued.**

D. Recommendations Related to Utilization Management and Health Equity

- **APG recommends that CMS cease the introduction of new process measures and instead focus on the development of a limited number of quality measures that assessment health outcomes that are meaningful to patients in terms of morbidity and mortality.**

IV. APG's Detailed Comments and Recommendations

CMS includes multiple proposals to improve the functioning of the MA and Part D programs in the proposed rule. APG provides feedback on key proposals that are particularly pertinent to our members, including those related to:

- Coverage of anti-obesity medications
- Promoting informed choice by expanding agent/broker requirements
- Prior authorization and health equity
- Quality rating changes

A. Coverage of Anti-Obesity Medications

Existing law bars Medicare and Medicaid from covering drugs that are "agents when used for anorexia, weight loss, or weight gain." CMS proposes reinterpreting statute to require Medicare Part D and Medicaid to cover anti-obesity medications (AOMs) that are intended to treat obesity. The new interpretation is based on the prevailing medical consensus that defines obesity as a disease.[1] CMS would permit Part D sponsors to define obesity for the purposes of their prior authorization (PA) criteria if the Part D sponsor's PA criteria are not more restrictive than the FDA labeling for the particular AOM. CMS notes that this approach is consistent with that regarding other disease states for which the agency does not specify diagnostic criteria, but reviews Part D plan-submitted PA criteria for clinical appropriateness.

CMS notes that, if finalized, the proposed reinterpretation of restrictions on AOMs would mean

[1] https://media.npr.org/documents/2013/jun/ama-resolution-obesity.pdf

that AOMs, when used for weight loss or chronic weight management for the treatment of obesity, could not be excluded from Medicaid drug coverage. States would continue to have the discretion to use preferred drug lists and PA to establish certain limitations on the coverage of these drugs if such practices are consistent with the requirements of federal statute to ensure appropriate use.

Concurrently, the Department of Health and Human Services has proposed that AOMs Ozempic, Rybelsus, and Wegovy be included in the next round of Medicare Part D price negotiations. If this policy proceeds as planned, the negotiated prices will become effective in 2027.[2]

As physicians who take responsibility for the cost and quality of care for the patients that they serve, APG members recognize the importance of effectively managing chronic conditions, which leads to better health outcomes overall and improved quality of life. Given this recognition, APG welcomes CMS's proposal to cover AOMs, which have proven to be an important treatment for some patients.

Adding AOMs to the treatment options available to Medicare and Medicaid patients along with modifications to lifestyle, diet, and exercise, along with surgical interventions, would ensure that physicians have the appropriate tools at their disposal to allow them to prescribe the intervention best suited to each person. APG believes that the choices of treatment options should be person-centered, clinically informed decisions between physicians and their patients. As such, APG encourages CMS to review the design and application of Part D sponsors AOM PA policies to ensure that these do not interfere with appropriate prescribing.

- **APG recommends that CMS finalize the policy to cover anti-obesity medications for the treatment of obesity in Medicare Part D and Medicaid programs.**
- **APG recommends that CMS review the design and application of Part D sponsors' anti-obesity medication prior authorization policies to ensure that these do not interfere with appropriate prescribing.**

APG acknowledges that coverage of AOMs would impose new costs on the Medicare Part D and Medicaid programs and enrollees, regardless of whether prices for the drugs are negotiated, and cautions CMS that if the agency finalizes the proposed policy to cover AOMs, the methods for appropriately addressing AOM costs must reflect stakeholder input and be implemented before coverage begins. These methods should be shared transparently and in a timely manner to ensure that stakeholders have time to provide informed feedback. If AOM coverage is finalized, CMS should evaluate the impact of the expanded coverage on Part D costs and make refinements – or suggest refinements for Congress to include in legislation – to Part D policies as needed.

- **APG recommends that CMS evaluate the impact of anti-obesity medication coverage on Part D costs and make refinements – or suggest refinements for Congress to include in legislation – to Part D policies as needed.**

B. Promoting Informed Choice by Expanding Agent/Broker Requirements

Current statute requires MA organizations and Part D sponsors to provide certain information to MA and Part D enrollees concerning benefits, coverage, plan rules, and other information that could inform potential enrollment changes. A list of topics agents and brokers of first tier, downstream, and related entities are required to cover when marketing to potential enrollees was established as part of the April 2023 final rule. In addition, MA organizations and Part D sponsors must adhere to fair marketing

[2] https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower

standards as outlined by CMS.

CMS proposes that agents and brokers be required to discuss the availability of support for low-income enrollees, including Part D Low-income subsidy, including any assistance in premium, deductible, and prescription drug costs. CMS also requires agents and brokers to review existing resources for state programs that can help with healthcare costs, including Medicare Savings Programs (MSP) before enrolling beneficiaries in an MA, MA-PD, or Part D plan.

Finally, CMS notes that the agency received feedback from various stakeholders about the lack of clarity beneficiaries received related to the impact that MA plan enrollment has on selecting a Medigap plan in the future. To address this issue, CMS proposes that agents and brokers convey information regarding Medigap federal guaranteed issue rights to beneficiaries who are enrolling into an MA plan when first eligible for Medicare, and to those who are dropping Medigap to enroll in an MA plan for the first time. Specifically, agents and brokers must explain that (1) beneficiaries who enroll in an MA plan generally have a 12-month period under federal law in which they can disenroll from the MA plan and switch back to Traditional Medicare and purchase a Medigap plan with Medigap federal guaranteed issue rights and (2) enrollees are not guaranteed the right under federal law to purchase Medigap plans if they switch back to Traditional Medicare from MA outside of the 12-monrh "trial right" period.

APG supports CMS's proposals to promote informed beneficiary choice by expanding requirements for brokers and agents. To further ensure that Medicare beneficiaries receive clear information to inform their choices about enrolling in an MA, MA-PD, or Part D plan, APG suggests that CMS develop and provide standardized information in the form of brochures or pamphlets to agents and brokers that they can relay to beneficiaries on the availability of support for low-income enrollees, existing resources for state programs that can help with health care costs, and Medigap federal guaranteed issue rights.

- **APG recommends that CMS finalize the policies to promote informed Medicare beneficiary choice by expanding requirements for brokers and agents to provide information on the availability of support for low-income enrollees, existing resources for state programs that can help with healthcare costs, and Medigap federal guaranteed issue rights. In addition, APG recommends that CMS develop and provide standardized information in the form of brochures or pamphlets on these topics to agents and brokers that they can relay to beneficiaries.**

C. Prior Authorization and Health Equity

CMS has received feedback from stakeholders on barriers to care that can arise as an effect of utilization management practices, including the use of prior authorization (PA) by MA organizations. Rules published in April 2024 require MA plan sponsors' utilization management committees to include at least one member with expertise in health equity. The rule also required MA organizations to conduct an annual health equity analysis on the use of PA, which must examine the impact of PA at the plan level, on enrollees with one or more of the specified social risk factors. The analysis must be made available in a prominent manner on the MA plan sponsor's publicly available website.

CMS proposes standardized data that will be required for the health equity report. For each separately covered item or service, MA plans must report the following: (1) the percentage of standard prior authorization requests that were approved; (2) the percentage of standard prior authorization requests that were denied; (3) the percentage of standard prior authorization requests that were

approved after appeal; (4) the percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved; 5) the percentage of expedited prior authorization requests that were approved; (6) the percentage of expedited prior authorization requests that were denied; 7) the average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations; and (8) the average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations.

CMS also seeks stakeholder input on a request for information on the methods used to group data in the study and on the possibility of adding "a mental health or substance use disorder diagnosis" to the list of social risk factors that MA plans must use to conduct the annual health equity analysis.

APG appreciates CMS's concern about the potential unintended consequences that PA and other utilization management policies can have on patients. However, it is premature to require MA plans to track and report the effects of PA for each covered item or service when MA plans have not yet been required to submit the PA reports at the aggregate service level that were finalized less than 12 months ago.

CMS should evaluate the findings of these aggregate service level reports before instituting more burdensome reporting requirements to determine if there are any issues that would warrant requiring more detailed reporting. In fact, the evaluation of the required reports should be shared transparently with all stakeholders and include an assessment if the reports should be modified or discontinued.

- **CMS should not require any new prior authorization data reports until the agency evaluates the reports that were finalized in 2024 and share these results transparently with all stakeholders, including an assessment of whether the reports should be modified or discontinued.**

D. Quality Rating Changes

CMS is continuing to move toward Universal Foundation measures to align quality measures across all programs including MA, traditional fee-for-service Medicare, and ACOs.

CMS is proposing to add the Initiation and Engagement of Substance Use Disorder Treatment (IET) quality measure starting with the 2028 Star Ratings. IET is a composite measure that averages two separate rates: Initiation of Substance Use Disorder Treatment and Engagement of Substance Use Disorder Treatment. Contracts must have scores on both rates to receive a score for IET. The initiation and engagement rates will be averaged into one measure to lessen the complexity of Star Ratings via minimizing the number of new rating measures.

CMS is also creating an Initial opioid prescribing for long duration (IOP-LD) quality measure that will also start with the 2028 Star Ratings. IOP-LD will be an addition tool for Part D sponsors to monitor initial opioid prescription exposure to reduce the risk for long-term opioid use and opioid use disorder. The measure will use the manual specifications and value sets from the Pharmacy Quality Alliance (PQA).

Starting with the 2029 Star Ratings, CMS plans to update the agency's existing quality measure for breast cancer screening. The measure is being updated due to April 2024 guidance from the U.S. Preventive Services Task Force (USPSTF). CMS is proposing to expand the age range for the breast cancer screening measure by adding the age range of 40-49 so that the new measure range will encompass ages 40-74. CMS notes that expanding the age range will increase the size of the population required for

screening. The updated age range will start in measurement year 2027. The updated measure will be on the display page for the 2027 and 2028 Star Ratings and will be included in the 2029 Star Ratings if finalized through rulemaking.

CMS is proposing updates to the Plan Makes Timely Decisions about Appeals measure. CMS notes that the update is intended to align with the movement towards electronic submissions. The proposal will eliminate the grace period that Independent Review Entities (IRE) allows for appeal files that are submitted electronically. CMS is also clarifying that the electronic system receipt date will be considered as the date that the IRE received the appeal, regardless of whether the receipt occurred during the IRE's business hours. The legacy appeal measure will remain in the Star Ratings until the updated measures have been on the display page for at least two years, and updated measure will be integrated starting with the 2029 Star Ratings.

APG generally supports CMS's overall strategy of establishing a core set of quality measures in the Universal Foundation to align quality measures across Medicare programs. However, APG cautions CMS that, in addition to seeking alignment, it should continue efforts to focus on a core set of measures that that reflect meaningful outcomes for patients and reduce undue administrative burdens on clinicians. APG members have concerns about the proliferation of clinical quality measurement that rely on process measures rather than outcome measures, and notes that CMS appears to be retreating from the previous goal of streamlining quality measurement. As it stands, adoption of new measures, even those that offer an improvement relative to current options, increase reporting demands that are already significant. If CMS opts to continue to refine the Universal Foundation measure set, the agency must ensure there is not significant growth in the number of measures that MA plans, providers, and ACOs must report.

- **APG recommends that CMS cease the introduction of new process measures and instead focus on the development of a limited number of quality measures that assessment health outcomes that are meaningful to patients in terms of morbidity and mortality.**

V. Conclusion

APG appreciates and welcomes CMS's proposed policies in this proposed rule and supports the agency's ongoing efforts to ensure that the MA and Part D programs continue to evolve to better serve the needs of Medicare beneficiaries. APG encourages CMS to consider the modifications to the proposed policies described in this letter to further refine the proposed policies and help to avoid unintended consequences.

Sincerely,

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