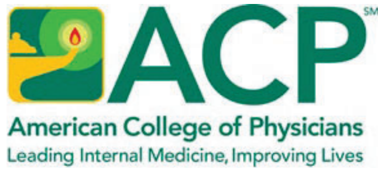

January 27, 2025

Acting Administrator Jeff Wu
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Washington, DC 20001

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 (RIN 0938–AV40)

Dear Acting Administrator Wu,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS's) notice of proposed rulemaking regarding changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program (Part D), Medicare Cost Plan Program, Programs of All-Inclusive Care for the Elderly (PACE) for Contract Year (CY) 2026. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP is confident that implementing key proposals within the proposed rule would strengthen CMS policies, improve access to affordable care for patients, advance health equity efforts, and support physicians in delivering quality, innovative care while protecting the integrity of the Medicare trust funds. ACP appreciates the opportunity to provide feedback and looks forward to working with CMS to implement policies that support and improve the practice of internal medicine and health outcomes across the country.

Vaccine Cost-Sharing Changes
CMS is codifying the requirements outlined in the Inflation Reduction Act (IRA) by proposing $0 cost-sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) under Part D for 2026 and each subsequent plan year. When the IRA was first introduced in Congress, ACP supported key provisions, including making vaccines free in Medicare for seniors. For all ACIP-recommended adult vaccines, the deductible will not apply, and there will be no coinsurance or any other form of cost-sharing. These cost-sharing limits have been in place since 2023 through program instruction authority, and ACP supports CMS codifying this provision of the IRA. The College remains supportive of affordable access to necessary, preventive vaccines, as recommended by standards established by ACIP.

Insulin Cost Sharing Changes
ACP is pleased by CMS's proposal to codify cost-sharing guidelines for insulin medications and supports any efforts to lower out-of-pocket costs for patients to obtain life-saving medications. For people living with type 1 diabetes, insulin must be taken for life, and in the past 15 years, the price of insulin has

nearly tripled – making it difficult for people with diabetes to manage their care. High costs of medicine can lead people to ration their medicine, as was evident with over one million people who rationed their insulin in 2021 due to financial concerns. Rationing insulin also puts patients' health at risk and leads to preventable complications from lack of diabetic control, which increases costs.

Medicare Prescription Plan Payment Program

ACP commends CMS's proposal to develop the Medicare Prescription Plan Payment program as this will help beneficiaries better manage the high costs of prescription medicine. Medication mis-adherence due to cost increases the risk of patients experiencing detrimental outcomes and increases the likelihood of subsequent health care spending as patients continue to present with the same ailments that need to be treated by the health care system. Affordable health care should be accessible to all and as physicians leverage critical tools such as prescription drugs, it is important to implement policies to allow patients to share in the benefit that innovative therapeutic tools have to offer.

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

ACP has designed a broad range of initiatives to reduce the impact of obesity on U.S. populations. Under current policy, anti-obesity medications are only coverable in Part D if the drug is being used to treat another condition that is a medically accepted indication other than weight loss or weight management. However, changes in the prevailing medical consensus towards recognizing obesity as a disease and the increasing prevalence of obesity in the U.S. population necessitate re-evaluation and consideration of this policy.

The College is committed to addressing chronic health conditions and the stigma, culture, and socioeconomic factors that influence these conditions. ACP supports evidence-based strategies that physicians can employ to identify, prevent, and treat obesity, including best practices to diagnose and counsel patients, to assess and address the burden of weight-related disease, address secondary causes of weight gain, and help patients set individualized and realistic weight loss goals and an effective treatment plan. The College supports this proposal from CMS to cover anti-obesity medications under Part D and Medicaid and believes this will expand coverage of these groundbreaking medications. As these medications become more widely available, the College urges CMS to keep in mind cost considerations and the financial strain on the healthcare system. We support policies that advance effective treatments, including coverage for lifestyle modification and adjunctive therapies such as medications that treat obesity. As future therapies under FDA investigation are likely to expand the available repertoire of medications, it is critical that they are extensively evaluated for safety and efficacy and that regulators consider the cost, improvement in weight-related conditions, and effect on other comorbid conditions.

Promoting Informed Choice — Format "Provider" Directories for Medicare Plan Finder

ACP supports CMS's proposal to add "provider" directories to the Medicare Plan Finder, as this will allow beneficiaries to compare different Medicare Advantage plans and their benefits meaningfully. Furthermore, health plans are responsible for clearly communicating to consumers whether a physician or other clinician is in-network, and communication should be achieved in a reasonable and timely manner.

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

Agents and brokers play a key role in helping beneficiaries enroll in Medicare and guiding them on whether traditional Medicare or Medicare Advantage is the best option. Nearly one-third of

beneficiaries over 65 rely on an agent or broker to help make decisions. Additionally, agents and brokers often have financial incentives and receive a higher commission for enrolling beneficiaries in Medicare Advantage plans than in Medigap supplemental plans.

ACP supports CMS's decision to expand the topics agents and brokers must address with enrollees. Some of these topics include the availability of the Part D Low-Income Subsidy (LIS) and communicating Medigap Federal guaranteed issue (GI) rights to beneficiaries who are enrolling into an MA plan when first eligible for Medicare. Additionally, there will be a requirement that agents and brokers must pause before finalizing the enrollment and ask the beneficiary if they have any remaining questions. This could help address any outstanding confusion on enrollment dates, plan networks, and benefits. Choosing a Medicare plan is complex, and beneficiaries trust agents and brokers to identify an option that best fits their health care needs. The College supports adding these requirements for agents and brokers and hopes this will better empower enrollees to make informed decisions about their health care.

Promoting Informed Choice — Enhancing Review of Marketing & Communications
The College agrees with CMS that the marketing and communications landscape around MA and Part D is constantly changing, and it is important to modify and refine regulations and requirements as necessary to reflect those changes. ACP has supported CMS's proposals to increase transparency for MA plans and their marketing policies. Unfortunately, there are still efforts from MA plans and third-party marketing organizations (TPMOs) to promote misinformation through both television and mail advertisements, confusing beneficiaries. The College agrees with CMS's assessment that it is time for an updated definition of marketing that will allow more rigorous oversight and review. Beneficiary complaints remain rising, expressing dissatisfaction and misleading information about enrollment and plan benefits. It will be more constructive to beneficiaries if CMS can take a more proactive approach to dealing with misleading advertisements instead of addressing these materials after complaints have already been received.

CMS proposes broadening the definition of marketing for MA and Part D communications materials by eliminating the current content standard and replacing it with an intent standard to determine whether materials are marketing and communications activities. This would expand the scope of materials prospectively submitted to CMS for approval, which would increase insight and prevent misleading materials from ever being published. The College supports this and believes it will empower CMS to better ensure that MA organizations, Part D sponsors, and TPMOs are not promoting misleading or inaccurate information to enrollees. It is essential that CMS and other federal agencies charged with implementation are sufficiently resourced. This proposal, if finalized, will enhance transparency in marketing materials and protect beneficiaries. ACP supports this broadened definition of marketing and believes it will enable enrollees to make more informed and educated decisions about their health care.

Promoting Transparency for Pharmacies and Protecting Beneficiaries from Disruptions
The College supports CMS's proposal to modify the timeline of network transparency and notification for Part D sponsors and pharmacies. By October 1 of the year prior to the plan year, Part D sponsors will be required to inform pharmacies which plans the pharmacies will be in-network for that plan year. The list of in-network plans will also be available upon request for pharmacies after October 1. This enables pharmacies to accurately inform customers about what plans they will be a participant in. Given that pharmacy contracting practices from Part D sponsors, or pharmacy benefit managers (PBMs) acting on their behalf have come under increased scrutiny, this proposal is a crucial step in mitigating lopsided contracting practices. This will especially benefit smaller, independent pharmacies who often have less negotiating power.

CMS has received complaints from beneficiaries who find out at the beginning of the plan year that their preferred pharmacy is no longer in-network. By establishing this October 1 deadline, pharmacies will now have additional time to inform beneficiaries of any network changes. This also aligns with the Annual Enrollment Period (AEP) that begins on October 15. The College supports proposals to increase transparency and enable Medicare beneficiaries to make informed choices about their care.

Administration of Supplemental Benefits Coverage through Debit Cards
ACP supports recent efforts from CMS to increase transparency of supplemental benefits by acquiring information on usage, patterns, and costs to ensure that these benefits are improving health outcomes. The College is concerned that there is enrollee confusion on debit cards provided by MA plans, with beneficiaries not receiving guidance on what plan-covered supplemental benefits can be purchased. This proposal to further clarify the parameters on usage of plan debit cards will help minimize confusion for beneficiaries, establish guardrails, and provide instructions for usage and customer service support. MA plans must also disclose any supplemental benefits, the premium, and any applicable conditions and limitations, which must include eligible over the counter (OTC) items and which benefits may be accessed using the debit card. The College is also concerned about potentially misleading marketing tactics around debit cards and supports CMS' proposal of new parameters on marketing of supplemental benefits which would prohibit MA organizations form marketing the dollar amount of a supplemental benefit or the method by which the benefit is administered, such as via debit card. This will help promote informed choice among MA beneficiaries and minimize misleading MA supplemental benefit advertisements.

Improving Access — Enhancing Internal Coverage Criteria
The ACP is pleased by CMS's proposal to clarify the definition of "internal coverage criteria" as it relates to utilization management by MA plans and further supports efforts to enhance transparency in the coverage determination process to improve satisfaction among those requesting necessary coverage for beneficiary treatments.

Ensuring Equitable Access to Behavioral Health Benefits through Section 1876 Cost Plan and MA Cost Sharing Limits
One of ACP's 2025 priorities is Ensuring Access to Care, with a specific focus on addressing the behavioral health crisis in the United States. The College is aware that there are significant barriers to patients accessing affordable behavioral health services and continues to work towards improved access to mental health services and substance use disorder treatment. ACP commends CMS for proposing behavioral health cost-sharing standards for MA and Cost Plans to improve affordability and access for enrollees. It is alarming that between 23-25 percent of all MA plans charge in-network cost-sharing amounts that are greater than cost sharing in traditional Medicare for mental health specialty services, psychiatric services, and partial hospitalization, and that figure increases to 42-71 percent when comparing outpatient substance use disorder services and opioid treatment program services. The College supports the requirement that in-network cost sharing for behavioral health services be no greater than that for traditional Medicare. This will improve affordability for a wide scope of behavioral health services, and impact millions of beneficiaries as Medicare Advantage enrollment continues to increase.

Enhancing the Health Equity Analysis
ACP appreciates the proposed changes to § 422.137(d) that require Medicare Advantage (MA) organizations to conduct an annual health equity analysis of prior authorization use. By mandating that

this analysis be disaggregated by each covered item and service, we believe this will enhance transparency and accountability, ensuring that disparities in healthcare access and outcomes are identified and addressed.

Furthermore, ACP supports the requirement for MA organizations to make the results of these analyses publicly available on their websites. This step is crucial for fostering an informed patient population and enabling stakeholders to monitor and advocate for improvements. The estimated annual burden of 6,136 hours and cost of $769,945 for web developers and programmers to compile and post the data is a necessary investment to achieve these goals.

ACP remains supportive of Utilization Management Committees ("Committee") in MA organizations and appreciates the steps that CMS has taken over the past few years to ensure that these committees are addressing health equity. Specifically, ACP appreciates CMS's step toward enhancing transparency and accountability by creating the requirement to have at least one member of the committee to have expertise in health equity. However, the College remains concerned about the make-up of these committees, and that there are not adequate degrees of separation between the committee members and the MA plan. In our previous comments, ACP believes that requiring only one practicing physician who is independent and free of conflict relative to the MA plan or organization is far too few. The College again recommends CMS revising the composition of utilization management committees to protect the process's integrity and implement necessary safeguards.

Ensuring Equitable Access to Medicare Advantage Services — Guardrails for Artificial Intelligence
ACP strongly supports CMS's proposal to require MA organizations to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. This proposal is intended to clarify that MA organizations must provide all enrollees, without exception, equitable access to services, including when MA organizations use AI or other automated systems to aid their decision-making, and not discriminate based on any factor that is related to the enrollee's health status. As expressed in the College's position paper, *Artificial Intelligence in the Provision of Health Care*, ACP recommends that clinical safety and effectiveness, as well as health equity, must be a top priority for developers, implementers, researchers, and regulators of AI-enabled medical technology. Furthermore, ACP believes that the development, testing, and use of AI in health care must be aligned with principles of medical ethics, serving to enhance various aspects of patient care and decision making as well as health care equity and justice. The College believes that AI technology, when appropriately used, should enhance patient care and decision making based on patient values, interests, and preferences. ACP believes that CMS's proposed policy is likely to improve patient care and decision making based on patient values and interests.

ACP also believes that the use of AI and other emerging technologies in health care should reduce rather than exacerbate disparities in health and health care. As a matter of both fairness and safety, data used to train AI models should be carefully selected and assessed for suitability for the intended populations, locations, and uses of the resulting AI model. Additionally, ACP calls for AI model development data to include data from diverse populations for which resulting models may be used. The College also believes that research evaluating the effect of AI technology on the practice of medicine, patient access to care, and the quality and effectiveness of patient care, including assessments of whether AI use in medicine contributes to or drives biased or discriminatory health practices or inequitable health outcomes, is necessary. ACP believes CMS's proposals are likely to lessen the inequitable effects of automated tools currently used by MA organizations.

Given that CMS's proposals are likely to improve equitable access to care, helping to ensure that marginalized and underserved populations are not denied services or harmed by the use of these new technologies, the College strongly supports these proposals.

Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors
The College agrees with CMS that there are serious concerns about the safety and transparency of contractors and practitioners that have access to an enrollee's home and the exclusion of these entities from an MA organization's "provider" directory. ACP supports the proposal from CMS to strengthen individual protections and transparency through requiring direct furnishing entities to be clearly identified in the "provider" directory. These entities who provide in-home and at-home services will have to be clearly identified and listed, which will ensure beneficiaries are aware of who is entering their homes and have access to personally identifiable information (PII) and protected health information (PHI). Additionally, community-based organizations (CBOs) will require an additional notation in the "provider" directory, which will promote community engagement from local organizations, who are well-positioned to serve their specific populations. The College is supportive of these changes, which will all contribute to increased transparency and safety for MA beneficiaries.

Conclusion
Thank you for this opportunity to comment on CMS's notice of proposed rulemaking regarding changes to the Medicare Advantage Program, Medicare Part D, and other federal programs for CY26 and beyond. ACP is confident these recommended changes would improve the strength of these proposals and help promote access to affordable care for Medicare patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. The College appreciates the opportunity to offer our feedback and looks forward to continuing to work with the agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Ph.D., Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

Leslie Algase, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians