January 23, 2025

Dorothy Fink, Acting Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Jeff Wu, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Submitted electronically via regulations.gov

RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P)

Dear Acting Secretary Fink and Acting Administrator Wu:

On behalf of the American Academy of Family Physicians (AAFP), which represents 130,000 family physicians and medical students across the country, I write in response to the proposed rule published in the Federal Register on December 10, 2024, regarding Contract Year (CY) 2026 policy changes to the Medicare Advantage (MA) program. The AAFP commends CMS for proposals in this rule which will reduce beneficiary cost-sharing, bolster network adequacy requirements, and make the use of prior authorization processes more transparent. We recommend CMS:

- Codify the definition of Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines to ensure Part D plans provide comprehensive and timely coverage for vaccines;
- Implement requirements that limit cost-sharing for insulin;
- Expand MA and Medicaid coverage to include anti-obesity medications;
- Implement clear guidelines to ensure MA plans' ethical and transparent use of Artificial Intelligence (AI) and other related tools;
- Accelerate alignment between traditional Medicare and MA plan cost-sharing requirements for behavioral health services;
- Expand the metrics plans must publicly report to depict plans' use of prior authorization processes and the impact to beneficiaries;
- Eliminate network adequacy exception rationales that MA plans may use to bypass network adequacy criteria;
- Require plans to submit provider directory data in a standardized format so beneficiaries are better able to compare plan networks during enrollment;

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

- Prevent plans from inappropriately including overhead and administrative costs in the MLR numerator that do not meet the quality improvement activity criteria;
- Finalize proposals to improve the transparency of internal coverage criteria and increase safeguards to ensure internal coverage criteria are deployed to increase patient safety (not insurer profits).

II. Implementation of Inflation Reduction Act (IRA) Provisions for the Medicare Prescription Drug Benefit Program

A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices (ACIP) Under Medicare Part D

CMS proposes to codify the definition of "ACIP-recommended adult vaccine" to ensure Part D plans provide timely, comprehensive coverage of vaccines without exception. The proposal clarifies that all categories of ACIP recommendations must be covered; there are no exceptions for vaccines recommended with shared clinical decision-making, for example. CMS also proposes to clarify that enrollees are not subject to cost-sharing for Part D vaccines, regardless of the vaccine's formulary tier placement. Finally, beneficiaries must be fully reimbursed by the plan when they choose to receive a vaccine from an out-of-network provider.

We strongly support these proposals and urge CMS to finalize them. Beneficiaries have been subject to unexpected cost-sharing for vaccines recommended by ACIP with shared clinical decision-making, including the RSV vaccine. We support CMS clarifying that all categories of ACIP recommendation should be included. This will ensure beneficiaries are able to access to vaccines ACIP recommends based on individual risk factors such as likelihood of exposure. We applaud these proposals to clarify provisions in the IRA and eliminate unintended access gaps.

The AAFP appreciates CMS' recognition that some Part D plans have implemented policies that undermine vaccine-related provisions of the IRA. If a Part D plan formulary excludes or restricts coverage for certain brands of vaccines, beneficiaries would be subject to out-of-pocket costs when they agree to be vaccinated at a location that does not have a particular brand in stock, or they would have to search for and make another appointment at a location that offers the Part D plan's preferred brand.

It is unreasonable to expect physician practices to offer all brands and formulations of approved vaccines. Physicians must purchase vaccines upfront, and they are not paid until after a vaccine is administered. Acquiring and maintaining vaccines and related supplies is a

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

significant financial investment; it is also a risk because there is no way to be reimbursed for the cost of unused vaccines. Limiting vaccine coverage to certain brands or manufacturers would increase the overhead costs and financial risks to physician practices offering vaccines. Formulary restrictions on vaccine products would also decrease beneficiary access by limiting the number of sites where a beneficiary is able to be vaccinated without cost-sharing.

The AAFP also supports proposed codification of regulations to prevent plans from imposing cost-sharing on covered Part D- vaccines received from an out-of-network provider. CMS clarifies that Part D plans must provide full reimbursement (the full cash amount a beneficiary paid, including vaccine administration fees, dispensing fees, and sales tax) as reported in the direct member reimbursement (DMR) request. **This clarification will reduce uncertainty regarding beneficiary reimbursement when a vaccine is administered in a physician's office.**

Under this proposal, beneficiaries would still be required to pay the costs up-front and wait for reimbursement when receiving a vaccine in a physician's office. The initial out-of-pocket cost will continue to deter access for beneficiaries who prefer to be vaccinated by their physician. The AAFP recommends that patients receive all recommended immunizations from their usual source of primary care. **We continue to call for expanding Part B coverage to include all ACIP-recommended vaccines which will ensure Medicare beneficiaries are never subject to out-of-pocket costs when they receive a vaccine from their physician.** We recognize CMS lacks the statutory authority to address this issue but encourage partnership with Congress to address this remaining access gap.

B. Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D

CMS proposes to codify definitions and requirements related to the implementation of cost-sharing limitations on insulin established in the Inflation Reduction Act. The maximum cost-sharing amount for insulin products would be no more than 35 dollars, 25 percent of the maximum fair price, or 25 percent of the negotiated price—whichever is the lesser amount for a one-month supply. CMS further proposes to clarify that the term "covered insulin products" includes products with more than one type of insulin, as well as products that include both insulin and a non-insulin drug. Finally, CMS confirms that the maximum cost-sharing amounts must also apply to insulin products received from an out-of-network provider when a beneficiary submits a direct member reimbursement request (which ensures members are reimbursed for the full cash price paid).

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

The AAFP supported provisions in the IRA that lower prescription drug costs and we recommend CMS codify these coverage requirements as proposed. We recognize that health is a basic human right for every person and the right to health includes universal access to affordable health care. More than 20 percent of people over the age of 65 have diabetes.[i] Research shows that when an individual transitions to Medicare, their out-of-pocket spending on diabetes medications increases.[ii] Approximately 10 percent of Medicare beneficiaries with diabetes either skip doses or take smaller doses than prescribed, and nonadherence rates are higher for beneficiaries who are dissatisfied with out-of-pocket costs for medication or lack of medications included on the plan formulary.[iii] **We applaud CMS for codifying maximum amounts for cost-sharing and formulary inclusion requirements, which both have a meaningful impact on medication adherence and health outcomes.**

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

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

CMS proposes to update the interpretation of drugs that must be statutorily excluded from Part D and Medicaid coverage. Specifically, CMS proposes to recognize obesity as a chronic disease; as such, Part D plans would be required to cover products that are FDA-approved to treat obesity. This reinterpretation would also prevent state Medicaid programs from excluding these drugs from Medicaid coverage.

The AAFP supports the inclusion of all classes of FDA-approved anti-obesity medications in public and private payer formularies. We strongly recommend that CMS finalize this proposal and update the interpretation of section 1927(d)(2) of the Social Security Act to ensure AOMs are covered in Part D and Medicaid.

J. Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence

CMS proposes to clarify that MA organizations must provide all beneficiaries with equitable access to services, including when AI or other automated systems are used to support decision-making.

The AAFP strongly recommends CMS finalize this proposal, which will help to ensure AI tools are used appropriately in health care. We applaud recent efforts to clarify that organizations must make medical necessity determinations based on the individual in the

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

Medicare Advantage Contract Year 2024 final rule and the February 6, 2024 FAQ memo. CMS notes that AI and related tools may assist in decision-making, but organizations must ultimately use the patients' medical history or physician recommendations to make a final determination. We encourage CMS to continue to audit MA organizations for compliance with these policies and when necessary, issue enforcement actions for non-compliance. The AAFP believes that AI solutions must adhere to a set of principles in order to ensure its transparent and ethical use in health care. We support CMS' continued collaboration with ASTP/ONC to mitigate implicit bias, respect patient and physician privacy, and maximize transparency in AI tools used by MA organizations.

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

CMS proposes to expand access to behavioral health services in contract year 2026. This proposal mandates that in-network cost-sharing for certain behavioral health services in MA and Section 1876 Cost Plans cannot exceed cost-sharing amounts for the same services in Traditional Medicare. The covered services include mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient services, inpatient hospital psychiatric services (for all 'Length of Stay' scenarios), outpatient substance use disorder services, and opioid treatment program services.

The AAFP supports this proposal to align cost-sharing limits for behavioral health services in MA and Cost Plans with those in Traditional Medicare. This alignment expands access to affordable behavioral health services for MA enrollees, particularly lower-income beneficiaries who are more likely to be diagnosed with behavioral health conditions. The AAFP has long advocated for improved access to behavioral health care, and parity of health insurance coverage and payment for patients, regardless of medical or mental health diagnosis. In 2021, approximately 40 percent of all mental health-related office visits (e.g., depression, anxiety) occurred in primary care settings. Further, CMS' 2024 plan data shows around 25 percent of Medicare beneficiaries have a mental illness, with roughly half enrolled in an MA plan. Thus, as family physicians often serve as the first point of contact for patients needing mental health care, particularly for lower-income patients, the AAFP commends CMS for addressing the growing need for behavioral health services for beneficiaries. This initiative is vital for improving health outcomes and reducing overall care costs for beneficiaries.

The AAFP also agrees that existing cost-sharing structures in MA plans and Section 1876 Cost Plans impose higher financial burdens on beneficiaries seeking behavioral health services compared to those in traditional Medicare. Under existing cost-sharing structures, CMS notes that "beneficiaries in traditional Medicare pay 20 percent coinsurance (with zero cost-sharing

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

for opioid treatment program services) while MA enrollees may be charged up to 50 percent coinsurance (or actuarially equivalent copayment) for the same behavioral health services."

The AAFP urges CMS to finalize and apply proposed changes in contract year 2026 without a transition period from the existing cost-sharing standards. Swift action is warranted to address the urgent behavioral crisis in the U.S. We believe MA and Cost Plans are capable of implementing these proposed changes in time for the 2026 open enrollment period, ensuring equitable access across programs through uniform implementation of the amended cost-sharing standards.

CMS outlines two key objectives guiding this proposal: "(1) improving the affordability of behavioral health services for enrollees in a timely manner; and (2) minimizing disruption to enrollees' access to care and coverage options." While we believe this proposal will make progress towards accomplishing the first objective of affordability by amending cost-sharing limits in MA and Cost Plans, the AAFP is concerned that a start date in contract year 2027 and/or transition period for existing cost-sharing standards will disrupt enrollees' access to care.

The AAFP believes that delaying implementation to 2027 or fracturing implementation through a transition period both have the potential to prolong financial and structural barriers that currently prevent patients from accessing needed behavioral health services. Further, delayed implementation may financially discourage beneficiaries from seeking needed care which can worsen patient outcomes and lead to more intensive and costly downstream interventions.

A transition period may also introduce inconsistencies in access to behavioral health services between plans. As plans transition at varying rates, some patients will benefit from fully implemented cost-sharing reductions, while others continue to face higher cost-sharing burdens. This undermines the proposal's goal to provide timely and affordable behavioral health care, and slows progress towards achieving equal access to mental and physical health services, as intended by the Mental Health Parity and Addiction Equity Act (MHPAEA). Additionally, the transitionary approach to implementation may make it more difficult for patients and physicians to navigate cost-sharing responsibilities across plans. These inconsistencies can increase administrative burden on physicians and create health literacy barriers for patients, impeding access to care. Implementing these changes immediately in 2026 would reduce administrative burdens and improve equitable, timely access to behavioral health care for beneficiaries.

CMS' evaluation of the potential impact of the proposal, with a transition period, on MA enrollee utilization supports the AAFP's position that a transition period is unnecessary. The

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

MA encounter data analysis indicates that the proposal is unlikely to cause an "immediate drastic change in utilization of the behavioral health service categories to the extent that a transition period is warranted."

The AAFP encourages CMS to monitor behavioral health network adequacy to protect physicians as MA and Cost Plans restructure cost-sharing limits. Lower cost-sharing may increase behavioral health care utilization, prompting plans to redistribute cost-sharing to compensate. This could lead to increased clinical responsibility and patient volumes for physicians without adequate resources, exacerbating burnout and limiting access. As we previously stated in response to CMS-4205-P for contract year 2025, stronger network adequacy requirements are necessary to expand and ensure access to behavioral health care services. Thus, the AAFP encourages CMS to continue strengthening these requirements and supporting integrated behavioral health models as an avenue to do so. Integrated behavioral health models can foster better resource utilization and ensure that providers have the necessary network support to deliver comprehensive behavioral health services.

M. Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

Building upon the April 2024 MA program rule, CMS proposes to expand the metrics MA plans must report in their annual health equity analysis. CMS proposes eight metrics that describe a plan's use of prior authorization requirements, including frequency of use, common outcomes, and response times. Plans must compare these metrics for enrollees with certain social-risk factors (SRFs) and enrollees without SRFs.

The AAFP supports this enhancement of the annual health equity analysis and urges CMS to finalize these proposals. We greatly appreciate CMS considering previous comments suggesting additional requirements for plans to disaggregate these metrics by service or item, as disaggregation will help to identify specific gaps in coverage criteria or problems with the prior authorization process. Identifying disparities in prior authorization denial rates or response times for a specific service will enable MA plans to prioritize policy changes that would reduce health inequities. In future rulemaking, we encourage CMS to consider requirements that plans report these metrics in such a way that enables easy comparison from year to year. Reviewing annual changes in these metrics over time would encourage plans to assess whether their actions to address prior authorization gaps are effective.

We also recommend CMS finalize the proposal to add mental health or substance use disorder diagnoses to the list of SRFs MA plans must incorporate into their annual health equity analysis. We agree this will help identify (and address) potential gaps resulting from SRFs. We continue to support analyses of health inequities which extend beyond the SRFs in

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

the April 2024 rule but recognize implementation depends on reliable identification in available data elements.

N. Medicare Advantage Network Adequacy

CMS proposes to codify certain exceptions to network adequacy standards and eliminate the exception rationale of "provider does not contract with any organization or contracts exclusively with another organization."

We agree with CMS' assessment that eliminating this rationale will encourage MA organizations to offer contracts with providers needed to meet adequacy criteria. As noted in the proposal, CMS is unable to fully review and assess whether the plan's contract negotiations were conducted in good faith due to the confidential nature of the process. As such, it would be difficult to determine if an MA organization is using this exception to bypass network adequacy criteria. **We support eliminating the rationale of "provider does not contract with any organization or contracts exclusively with another organization" from the list of exception rationales for network adequacy.**

P. Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder

CMS proposes a new requirement for plans to submit provider directory data in a standardized format that would allow CMS to make provider networks easier to compare in the Medicare Plan Finder (MPF). CMS further proposes plans must submit updates within 30 days of a provider notifying them of a change and attest that the data submitted matches the data submitted for CMS review of network adequacy.

The AAFP supports this proposal and recommends CMS finalize these requirements. Currently, enrollees must search individual plan websites to understand whether their existing physician would be covered under a specific MA plan. We believe this will help simplify coverage comparisons and allow for more informed decision-making by enrollees.

The AAFP has previously supported the concept of a standardized national provider directory if it offers physicians a single-point data entry process, as this would reduce the burden of submitting duplicative information to multiple plans. However, successful implementation would require all plans agreeing to participate. We appreciate that this proposal would make participation mandatory for all MA plans. **We encourage CMS to require MA plans to offer providers a single-point data entry process for directory updates in future rulemaking.**

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

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

To align with commercial and Medicaid Medical Loss Ratio (MLR) reporting requirements, CMS proposes to require that plans link any clinical or quality improvement bonuses to measurable quality improvement standards otherwise these bonuses or payments may not be included in the MLR numerator. CMS also proposes additional requirements to prevent the inclusion of administrative costs in the MA MLR numerator. These new policies would prevent MA plans from improperly inflating the MLR numerator, circumventing MLR rebate requirements.

The AAFP supports these proposals. More consistent regulations across Medicare, Medicaid, and Marketplace plans will help to promote fairness for beneficiaries, and we have long supported MLR requirements that prioritize affordable access to high-quality coverage for beneficiaries over insurer profits. The AAFP's Principles for Value-Based Payment support physicians sharing financial rewards based on their performance, including quality improvements. These incentives should be linked to physician compensation and prioritized over productivity measures. We agree that incentives and bonuses should be tied to specific clinical or quality improvement standards for providers, and it is critical that metrics used should align with those used across plans and payers (such as CMS' Universal Foundation). Reporting disparate measures across plans creates a significant administrative burden for family physicians and can undermine investment in quality improvement or care delivery initiatives. Therefore, **the AAFP recommends that CMS require MA plans to align metrics used for qualifying incentives for inclusion in the MA MLR numerator.**

The AAFP also supports CMS' proposal to prevent plans from including overhead or other expenses not directly related to quality improvement activities from the MLR numerator. Plans that include these expenses in the MLR numerator inappropriately inflate the MLR and create unnecessary variation in MLR reporting which in turn may make it more difficult for beneficiaries to accurately compare plans.

Request for Information on MLR and Vertical Integration

The AAFP appreciates CMS' interest in potential policies that would help address growing concerns about vertical integration in MA. We agree that MA MLR reporting is obscured for vertically integrated payer-provider organizations. The AAFP has previously shared information about the impact of health care consolidation on family physicians, including concerns that some vertically integrated organizations fail to direct payments and incentives

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

from MA contracts to physicians, or to other investments that would support the delivery of primary care. We have also encouraged CMS to improve transparency around how payments and incentives earned from MA contracts are directed. We recommend CMS consider requirements for vertically integrated organizations to direct any bonuses or incentives earned from high-quality primary care directly to the primary care physicians and/or reinvested in the practices responsible for the successful performance.

In multiple surveys, physicians have expressed a loss of professional and clinical autonomy after they are acquired or employed by a larger organization.[iv, v] Governance structures and ownership arrangements between payers and providers in vertically integrated organizations are often unclear. Greater transparency about ownership and governance within vertically integrated MA organizations may help to identify organizations which allow affiliated providers to direct how investment or incentive payments are used. Relevant reporting requirements might include the percentage of the equity an affiliated practice retains after joining a vertically integrated organization, or an affiliated practice's involvement in selecting performance goals. CMS might also consider ways to assess whether vertically-integrated MA organizations allow physicians to direct how bonus or incentive payments are reinvested, set practice management policies, and make other decisions that impact patients.

U. Enhancing Rules on Internal Coverage Criteria

CMS proposes to implement guardrails on the use of internal coverage criteria. This includes a requirement for MA plans to use evidence to prove their internal coverage criteria will improve patient safety. CMS also proposes to prohibit the use of internal coverage criteria which only serve to reduce utilization, or which fail to consider individual medical necessity. CMS further proposes requirements which would make MA plan use of internal coverage criteria more transparent and easier to understand. **The AAFP urges CMS to finalize these proposals. We continue to support guardrails on the use of internal coverage criteria by MA plans.**

Declining prior authorization requests that comply with Medicare coverage rules can hinder or delay beneficiaries from the care they need and creates a significant administrative burden on physicians. CMS continues to clarify that these denials run counter to federal statutes that require MA plans to provide the same coverage of services as traditional Medicare. **The AAFP applauds CMS' continued efforts to clarify these policies and implement safeguards to ensure utilization management techniques including prior authorization are used appropriately.**

Limiting the use of internal coverage criteria is especially urgent as MA plans are increasing the use of prior authorization (PA). An analysis of MA claims found that 7.4 percent of all PA

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

requests were denied in 2022, up from 5.7 percent in 2019.[vi] The same analysis found that 9.9 percent of denials were appealed, and more than 80 percent of these denials were later overturned. We remain concerned that the administrative burden and resulting care delays caused by prior authorization will not be reduced without additional requirements.

The AAFP strongly supports the proposals to make information about the use of internal coverage criteria easier to find and understand. We encourage CMS to expand upon this proposal by making it easier for beneficiaries to compare health plans' use of coverage criteria when evaluating an MA plan. The AAFP agrees that the proposed requirements to submit internal coverage criteria in a standardized, machine-readable format will help researchers compare coverage. However, beneficiaries need more outcomes-oriented information to make this information meaningful—specifically, metrics that allow comparisons between plan use (and denial rates) of prior authorization requests for common services. This could include requirements for plans to submit metrics in a standardized format to enable comparisons in the Medicare Plan Finder (MPF). CMS should also consider adding metrics describing how a plan uses prior authorization (such as the percentage of services that require prior authorization or the percentage of requests denied) into MA Star ratings.

W. Formulary Inclusion and Placement of Generics and Biosimilars

CMS proposes to require plans to include generics, biosimilars, and other lower-cost drugs on a formulary tier that is lower than the branded version or other reference product. CMS would also restrict plans from applying additional utilization controls for low-cost alternatives (compared to utilization controls applied for the branded version).

The AAFP's Principles for the Development and Management of Patient-Centered Formularies states that formularies should be designed to offer patients multiple levels of drug choice (from more to less restrictive) with accompanying patient cost-sharing levels to account for variables including patient preferences (e.g., "direct marketing-induced demand). There is evidence that some formulary designs do not offer patients multiple levels of drug choice and cost-sharing. For example, a 2019 analysis found that 72 percent of formularies reviewed placed at least one branded drug in a more favorable tier than its generic form, and the price of the branded drug was nearly four times the cost of the generic.[vii] This type of formulary design results in higher cost-sharing and out-of-pocket costs even though lower-cost alternatives exist. Similarly, a 2023 GAO report noted, "rebate practices may influence formulary design in ways that could affect beneficiary access for certain Part D drugs and may not be identified by a clinical formulary review."

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

We appreciate CMS' recognition that certain formulary designs reduce access to affordable generics and unfairly limit patient choice. **The AAFP supports CMS' proposal to add an additional step to the Part D formulary review process to ensure lower cost alternatives are placed on a lower cost formulary tier than brand drugs. This requirement will help to ensure beneficiaries have access to comparable alternatives with a lower out-of-pocket cost when available.**

We also strongly recommend CMS add a step to the formulary review process to confirm that a plan's formulary does not apply more utilization controls to lower-cost alternatives than the branded version or other reference product. As we have testified before, utilization controls such as prior authorization and step therapy create significant administrative burdens for physicians while reducing patient adherence to effective medication regimens. Adding this step to the formulary review process will help beneficiaries maintain access to affordable, effective prescription drug options.

We appreciate the opportunity to provide comments on proposed changes to the MA program. The AAFP is eager to collaborate with CMS to advance access to high-quality, comprehensive primary care for all. Should you have any questions, please contact Julie Riley, Regulatory and Policy Strategist, at jriley@aafp.org.

Sincerely,

Steve Furr, M.D., FAAFP

Steven Furr, MD, FAAFP
American Academy of Physicians, Board Chair

---

[i] Laiteerapong N, Huang ES. Diabetes in older adults. In Diabetes in America. 3rd ed. Cowie CC, Casagrande SS, Menke A, et al., Eds. Bethesda, MD, National Institute of Diabetes and Digestive and Kidney Diseases (US), 2018. Accessed 13 October 2023. Available from https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/diabetes-in-america-3rd-edition

[ii] Barthold D, Li J, Basu A. Patient Out-of-Pocket Costs for Type 2 Diabetes Medications When Aging Into Medicare. JAMA Netw Open. 2024;7(7):e2420724. doi:10.1001/jamanetworkopen.2024.20724

[iii] He Q, Silverman CL, Park C, Tiu GF, Ng BP. Prescription drug coverage satisfaction, cost-reducing behavior, and medication nonadherence among Medicare beneficiaries with type 2 diabetes. J Manag Care Spec Pharm. 2021;27(6):696-705. doi:10.18553/jmcp.2021.27.6.696

[iv] A March 2024 AAFP survey found that most family physicians experience a reduction in clinical autonomy after acquisition. This finding and other details from the survey were included in the AAFP's comments regarding the

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org

impact of health care consolidation submitted May 3, 2024: https://www.aafp.org/dam/AAFP/documents/advocacy/legal/administrative/LT-HHS-FTC-DOJ-Consolidation-050324.pdf

[v] "The Impact of Practice Acquisitions and Employment on Physician Experience and Care Delivery." Survey conducted by NORC at the University of Chicago for Physicians Advocacy Institute, November 2023. https://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI-Research/NORC-Employed-PhysicianSurvey-Report-Final.pdf?ver=ylnykkKFPb3EZ6JMfQCelA%3d%3d

[vi] Kaiser Family Foundation, "Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022," August 8, 2024. Available: https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/

[vii] Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Intern Med.* 2019;179(6):832–833. doi:10.1001/jamainternmed.2018.7824

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033 www.aafp.org