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January 27, 2025

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Dorothy Fink, MD
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4208-P–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

Submitted electronically via https://www.regulations.gov.

Dear Acting Administrator Wu and Acting Secretary Fink,

Thank you for your commitment to strengthening the Medicare Advantage (MA) program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, and for providing the opportunity to respond to the proposed rule. This response is submitted on behalf of the Center for American Progress (CAP). CAP is an independent, nonpartisan policy institute based in Washington, D.C. dedicated to improving the lives of all Americans through bold, progressive ideas, strong leadership, and concerted action. CAP's interconnected teams of policy experts and advocates have spearheaded and published research on Medicare and MA reform, prescription drug affordability, out-of-pocket health care costs, and access to health care for older Americans. We welcome the opportunity to provide input on further improving the MA and Medicare Part D programs.

In this letter, we highlight the many areas of the proposed rule that will protect Medicare beneficiaries. We also outline several areas of concern regarding enforcement, attestation of network directory accuracy, terminating pharmacy contracts without cause by Part D sponsors, the effects of market consolidation on the calculation of medical loss ratios (MLRs), and agent and broker communications and financial incentives.

Advancing health equity is central to CAP's mission. Similarly, in the CMS Framework for Health Equity 2022–2032, CMS recognized that to attain the highest level of health for all people, CMS "must give our focused and ongoing attention to address avoidable inequalities and eliminate

health and health care disparities." We agree and underscore that to safeguard and improve health care access for historically underserved racial and ethnic groups and low-income populations and enrollees with significant health care needs, all CMS proposed rules should be viewed through this equity lens.[1] By that logic, MA organizations, first tier, downstream, or related entities (FDRs), and all other Medicare-affiliated payers must be responsible for eliminating avoidable differences in quality of care and health outcomes and ensuring the provision of care and support that all Medicare beneficiaries need to thrive.

While we applaud CMS's recent efforts to protect Medicare beneficiaries, those protections are meaningful only to the extent that they are enforced.[2] To that end, we implore CMS to improve enforcement actions by making penalties to MAOs serious enough to deter misconduct or poor performance, up to and including canceling plans' contracts for non-compliance with rules. Furthermore, when plans and their FDRs fail to comply with rules, enrollees should also be protected and offered special enrollment periods (SEPs) that empower them with the ability to make new coverage choices.

Cost-sharing

By protecting Medicare Part D beneficiaries from excessive cost-sharing for recommended vaccines and insulin products, the Inflation Reduction Act of 2022 (IRA) protects low-income beneficiaries and racial and ethnic minorities from health inequities while benefiting all Medicare Part D enrollees. We applaud CMS for codifying rules stating that there shall be no cost-sharing for recommended adult vaccines, that the Medicare Part D deductible shall not apply to covered insulin products, and that Medicare Part D cost-sharing amounts for a one-month supply of each covered insulin product must not exceed the statutorily defined "applicable copayment amount" for all enrollees. Should those rules come under threat in the future, CAP estimates that over ten million Medicare beneficiaries could lose over $1 billion in savings in addition to direct threats to their health and well-being.[3]

Coverage for anti-obesity medications

We are supportive of the decision by CMS to allow Part D coverage of anti-obesity medications (AOMs) when used to treat obesity for individuals with obesity who do not have another medical condition.

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[1] Centers for Medicare & Medicaid Services, "CMS Framework for Health Equity 2022–2032," (Washington: 2024) available at https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.

[2] Centers for Medicare & Medicaid Services, "2024 Medicare Advantage and Part D Final Rule (CMS-4201-F)," (Washington: 2023) available at https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f.

[3] Projected $1.161 billion in savings based on $400 million in savings for beneficiaries from vaccines with no cost-sharing in 2023 and $734 (Part D) + $27 (Part B) in savings for beneficiaries from $35 cap on insulin based on the amount beneficiaries would have saved had insulin cap been in effect in 2020; CAP analysis based on data from Assistant Secretary for Planning and Evaluation, "Inflation Reduction Act Research Series: Medicare Part D Enrollee Vaccine Use After Elimination of Cost Sharing for Recommended Vaccines in 2023," U.S. Department of Health and Human Services, May 3, 2024, available at https://aspe.hhs.gov/sites/default/files/documents/3854c8f172045f5e5a4e000d1928124d/part-d-covered-vaccines-no-cost-sharing.pdf; Assistant Secretary for Planning and Evaluation, "Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics," US. Department of Health and Human Services, January 24, 2023, available at https://aspe.hhs.gov/sites/default/files/documents/ae8306ca30f1d639076cf7633fc2d8fd/aspe-insulin-affordibility-datapoint.pdf.

CMS has recognized the prevailing medical consensus that obesity is a disease and is known to increase the risk for many additional health problems.[4] A 2021 study published in the *Journal of Managed Care & Specialty Pharmacy* found the annual medical care expenditures of adults with obesity to be double that of people with normal weight.[5] According to a 2021 study cited by the CDC, adult obesity in the United States was associated with $172.74 billion of annual excess medical costs in 2019 dollars.[6]

GLP-1 receptor agonists (GLP-1s), which are known to promote weight loss,[7] as well as improve other conditions including hyperglycemia, insulin sensitivity, sleep apnea, and blood pressure, have been shown to lower health care costs among chronically obese patients,[8] and can be especially effective when paired with nutritional[9] behavior changes. As obesity disproportionately affects racial and ethnic minorities, broader coverage of AOMs will positively affect health disparities.[10]

While AOMs are far more expensive in the United States than in comparable countries, there is evidence that prices will decrease, which would help blunt the financial cost of expanding coverage for the drugs.[11] Generic equivalents of GLP-1s were approved by the FDA in 2024 and will be entering the market soon,[12] and on January 17, 2025, HHS announced that

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[4] Centers for Medicare & Medicaid Services, "Biden-Harris Administration Announces Medicare Advantage and Medicare Part D Prescription Drug Proposals that Aim to Improve Care and Access for Enrollees," available at https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-medicare-advantage-and-medicare-part-d-prescription-drug, (Washington: 2024); National Institute of Diabetes and Digestive and Kidney Diseases, "Health Risks of Overweight & Obesity," available at https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks; Centers for Medicare & Medicaid Services, "Intensive Behavioral Therapy for Obesity," (Washington), available at https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=253#, (last accessed January 2025); Yan Xie, Taeyoung Choi, and Ziyad Al-Aly, "Mapping the effectiveness and risks of GLP-1 receptor agonists," *Nature Medicine* (2025), available at https://www.nature.com/articles/s41591-024-03412-w?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream.

[5] John Cawley, Adam Biener, Chad Meyerhoefer, and others, "Direct medical costs of obesity in the United States and the most populous states," *Journal of Managed Care & Specialty Pharmacy*, 27 (3) (2021): 354-366, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10394178/pdf/jmcp.2021.20410.pdf.

[6] Zachary J. Ward, Sara N. Bleich, Michael W. Long, and others, "Association of body mass index with health care expenditures in the United States by age and sex," *Public Library of Science ONE* 16 (3) (2021), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247307; Centers for Disease Control, "Consequences of Obesity," (Washington: 2022), available at https://www.cdc.gov/obesity/basics/consequences.html.

[7] Mihaela-Simona Popoviciu, Lorena Păduraru, Galal Yahya, and others, "Emerging Role of GLP-1 Agonists in Obesity: A Comprehensive Review of Randomised Controlled Trials," *International Journal of Molecular Sciences,* 24 (10449) (2023), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10341852/pdf/ijms-24-10449.pdf.

[8] Doug Van Wie, Noor Abdel-Samed, Kristin Kelly, and others, "Putting Medical Costs on a Diet: Why Payers Have the Cost of GLP-1s All Wrong," *Executive Insights*, 26 (46) (2024), available at https://www.lek.com/insights/hea/us/ei/putting-medical-costs-diet-why-payers-have-cost-glp-1s-all-wrong.

[9] David D Kim, Jennifer H Hwang, and A Mark Fendrick, "Balancing innovation and affordability in anti-obesity medications: the role of an alternative weight-maintenance program," *Health Affairs Scholar* 2 (6) (2024), available at https://academic.oup.com/healthaffairsscholar/article/2/6/qxae055/7661043?login=false.

[10] James B Kirby, Lan Liang, Hsin-Jen Chen, and others, "Race, Place, and Obesity: The Complex Relationships Among Community Racial/Ethnic Composition, Individual Race/Ethnicity, and Obesity in the United States," *National Library of Medicine,* 102 (8) (2012): 1572-1578, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC3464818/.

[11] Assistant Secretary for Planning and Evaluation, "Medicare Coverage of Anti-Obesity Medications," (Washington: 2024), available at https://aspe.hhs.gov/sites/default/files/documents/127bd5b3347b34be31ac5c6b5ed30e6a/medicare-coverage-anti-obesity-meds.pdf.

[12] U.S. Food and Drug Administration, "FDA Approves First Generic of Once-Daily GLP-1 Injection to Lower Blood Sugar in Patients with Type 2 Diabetes," Press release, December 23, 2024, available at https://www.fda.gov/news-

Ozempic, Rybelsus, and Wegovy would be included in the next set of 15 Part D negotiated drugs, which should drop prices to the Medicare program even further.[13]

Over time, AOMs could also decrease costs to the Medicare program by helping to reduce costs related to comorbidities, and they will undoubtedly improve quality of life resulting from reduced disability and pain for some Medicare enrollees with obesity. The USC Schaeffer Center estimates that coverage for AOMs could generate approximately $175 billion to $245 billion in cost offsets in the first 10 years if private insurance followed Medicare's lead in covering obesity treatments; the cumulative social benefit to society could reach $100 billion per year if all eligible Americans were treated.[14]

Promoting informed choice—including provider directories in Medicare Plan Finder

Beneficiaries cannot make informed decisions about their health coverage without accessible and accurate network directories. Therefore, we applaud CMS's efforts to improve enrollees' experiences through reasonable network directory requirements.

We agree with the proposal to expand on the existing requirements applicable to MA organizations regarding their provider directories to include a new provision requiring MA organizations to submit or otherwise make available to CMS/HHS their plan provider directory data in a format, manner, and timeframe that CMS/HHS determines in order for the MA organization's provider directory data to be integrated online by CMS/HHS for display on Medicare Plan Finder; to include a requirement that MA organizations update provider directory data within thirty days of receiving information from providers of a change; and to require MA organizations to attest that the information being submitted to CMS/HHS under this new requirement is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements.

As provider directories change frequently, we understand that real-time attestation with each update may not be feasible. However, given the importance to beneficiaries of network directory accuracy, yearly attestation is insufficient. We reiterate the recommendation from our May 2024 comment letter in response to CMS's Request for Information on MA Data that attestation of

events/press-announcements/fda-approves-first-generic-once-daily-glp-1-injection-lower-blood-sugar-patients-type-2-diabetes.

[13] U.S. Department of Health and Human Services, "HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors," Press release, January 17, 2025, available at https://www.hhs.gov/about/news/2025/01/17/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower-prescription-drug-costs-seniors.html; John Wilkerson, "Generic GLP-1 drugs could help Medicare drive a harder bargain for Ozempic and Wegovy," STAT, January 7, 2025, available at https://www.statnews.com/2025/01/07/generic-glp-1-drugs-help-medicare-price-negotiation-semaglutide-ozempic-wegovy/.

[14] Alison Sexton Ward, Bryan Tysinger, Phuong Giang Nguyen, and others, "Benefits of Medicare Coverage for Weight Loss Drugs," University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics, April 18, 2023, available at https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/.

directory accuracy should be required every 90 days,[15] as it is for qualified health plans.[16] We also strongly recommend that reporting on compliance with attestation rules be made public, so that prospective enrollees can see clearly each MA plan's level of compliance with network accuracy reporting requirements. Furthermore, CMS should consider that compliance with attestation be part of the agency's MA star rating methodology.

Given how critical a physician's network participation can be to an enrollee's choice of MA plans, we recommend that very strong enforcement mechanisms be in place, up to and including canceling plans' contracts for non-compliance with network directory reporting requirements. Importantly, enforcement should include not only penalties for MA plans but also opportunities for enrollees. SEPs with Medigap guaranteed issue rights for enrollees should be triggered if an MA plan attests to directory accuracy and the directory is then found to have been inaccurate at the time.

Promoting transparency for pharmacies and protecting beneficiaries from disruptions

Independent pharmacies cannot effectively run their businesses when left in the dark about network inclusion. We agree with CMS's position that it is important to give independent pharmacies the information they need to appropriately care for their customers. We therefore support the outlined proposals requiring MA provider directory data to be submitted for use to populate the Medicare Plan Finder, requiring Part D sponsors or FDRs to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year, and requiring MA organizations to attest that this information is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements.

Network pharmacies' reciprocal rights to terminate contracts without cause

We share CMS's belief that pharmacies, particularly small, unaffiliated pharmacies, lack the ability to negotiate reciprocal termination terms on their own.[17] Therefore, we agree with the proposal to require Part D sponsors to allow pharmacies to terminate their network contracts without cause after the same notice period that the sponsor is allowed to terminate network pharmacy contracts without cause.

[15] Center for American Progress, "Re: CMS-4207-NC–Medicare Program; Request for Information on Medicare Advantage Data," May 29, 2024, available at https://www.americanprogress.org/wp-content/uploads/sites/2/2024/07/CAP-Re-CMS-4207-NC-Medicare-Program-RFI-on-Medicare-Advantage-Data.pdf; The Federal Register, "Medicare Program; Request for Information on Medicare Advantage Data," (Washington: 2024), available at https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

[16] Centers for Medicare & Medicaid Services, "No Surprises Act Overview of Key Consumer Protections," (Washington: 2023), available at https://www.cms.gov/files/document/nsa-keyprotections.pdf.

[17] Gwen Dilworth, "'Desperate times': Independent pharmacies fear closure, due in part to pharmacy benefit managers," News From The States, October 8, 2024, available at https://www.newsfromthestates.com/article/desperate-times-independent-pharmacies-fear-closure-due-part-pharmacy-benefit-managers; US Federal Trade Commission, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies," (Washington: 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

The fact that Part D sponsors can terminate pharmacy contracts without cause,[18] however, is unfair as it denies pharmacies the expected benefit of a contract.[19] Further, the six largest pharmacy benefit managers (PBMs), which make up 96 percent of the PBM market,[20] are vertically integrated with mail order and specialty pharmacies, placing them in direct competition with independent pharmacies.[21] There is evidence from investigative reports that these PBMs may have taken steps to deprive independent pharmacies of revenue to force them to close.[22] Already, approximately 10 percent of rural,[23] independent retail pharmacies closed in the decade from 2013 to 2022. To protect independent pharmacies, we suggest that sponsors should be allowed to cancel contracts with pharmacies only for material breaches of contract terms.[24]

Administration of supplemental benefits coverage through debit cards

Medicare beneficiaries are inundated with marketing and advertising from MA plans–including MA plans that advertise the promise of benefits or allowances in the form of debit or "flex cards" to attract enrollees. Yet these flex cards that enrollees can use to access supplemental benefits can likely induce enrollees to select health plans without evaluating whether the plan meets their specific health needs, whether the plan offers the most extensive coverage for the least cost to them, or if their preferred provider is in network with the MA plan.[25]

To ensure enrollees fully understand what benefits are available to them and how to access them, we support CMS's proposals to require plans to include information about which items can be purchased with debit cards and to require stronger disclosures and guardrails for supplemental benefits that are administered using debit cards. As these benefits come with limitations on their use and CMS has clarified that "plan debit cards are not cash benefits and cannot be considered as such,"[26] they should not be allowed to be marketed in ways that imply that they are cash benefits, for example, by calling them monthly "allowances." To limit this and other misinformation, we recommend that the final rule limit television, billboard, and radio

[18] Jeffrey S. Baird, "What to Know About Working with PBMs," Pharmacy Times, February 20, 2018, available at https://www.pharmacytimes.com/view/what-to-know-about-working-with-pbms.
[19] Jonathan L. Swichar and Bradley A. Wasser, "Pharmacy Fights Back Against PBM Termination Notice," America's Pharmacist, November 2017, available at https://www.duanemorris.com/articles/pharmacy_fights_back_against_pbm_termination_notice_1117.html
[20] Nicole Rapfogel, "5 Things To Know About Pharmacy Benefit Managers," Center for American Progress, March 13, 2024, available at https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/.
[21] U.S. Federal Trade Commission, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies," (Washington: 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[22] Reed Abelson and Rebecca Robbins, "The Powerful Companies Driving Local Drugstores Out of Business," The New York Times, October 19, 2024, available at https://www.nytimes.com/2024/10/19/business/drugstores-closing-pbm-pharmacy.html.
[23] U.S. Federal Trade Commission, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies," (Washington: 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[24] Jonathan L. Swichar and Bradley A. Wasser, "Pharmacy Fights Back Against PBM Termination Notice," America's Pharmacist, November 2017, available at https://www.duanemorris.com/articles/pharmacy_fights_back_against_pbm_termination_notice_1117.htm.
[25] David Lipschutz, "Center Testimony for Senate Hearing on MA Marketing," Center for Medicare Advocacy, November 1, 2023, available at https://medicareadvocacy.org/center-testimony-for-senate-hearing-on-ma-marketing/.
[26] Chiquita Brooks-LaSure, "Thank you for your letter to President Biden regarding Medicare Advantage (MA) supplemental benefits and their potential impact on enrollees' eligibility for federal assistance," Centers for Medicare & Medicaid Services, January 8, 2025, available at https://medicareadvocacy.org/wp-content/uploads/2025/01/Doggett-Final-Signed.pdf.

marketing that mentions debit card amounts while allowing plans to include debit card dollar amounts in written plan materials, accompanied by clear and explicit language explaining the limited use of debit cards.

These benefits are also advertised without explanations of how receiving these benefits may be counted as income, jeopardizing enrollees' eligibility for government assistance programs, such as Medicaid, Supplemental Security Income (SSI), the Program of All-Inclusive Care for the Elderly (PACE), and federal rental assistance.[27] We suggest that CMS should require MA plan materials for products that include flex cards to include language explaining that supplemental benefits may be counted as income, highlighting how those cards may affect their eligibility for financial assistance programs, and, specifically for recipients of benefits from the U.S. Department of Housing and Urban Development (HUD), that using debit cards to pay for rent and utilities may affect their eligibility for HUD assistance.[28]

As many questions involving debit cards arise at the point of sale, including which items can be purchased and which stores accept debit cards,[29] we support the proposed requirement that MA plans offer a customer service support line for members using debit cards. We ask CMS to implement this requirement in a manner that is most helpful to Medicare enrollees. CMS should consider requiring customer service to be available in multiple modalities (phone, text, email) available to the store clerk processing the transaction as well as the enrollee. This assistance should be made available in multiple languages and with language interpretation (including American Sign Language). CMS should require MA plans to train the staff for these customer service lines on the potential loss of public benefits addressed above and to disclose that to members who inquire about using their flex cards in ways that could jeopardize those benefits.

The method that plans use to deliver benefits should not impede an MA enrollee's access to the full array of supplemental benefits for which they are eligible. Therefore, we support CMS proposals to require MA plans to provide enrollees with instructions on the use of debit cards and alternative means of accessing their benefits in the event they cannot use the debit card.

Enhancing rules on internal coverage criteria

As CMS has previously clarified, the statutes and regulations that set the scope of coverage in the traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans. CMS has codified the specific requirements that determine when MA organizations may use internal coverage criteria, what the criteria must be based on, rules for making the internal coverage criteria publicly accessible, and enrollee protections related to the use of prior authorization.

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[27] Leading Age, "Medicare Advantage Supplemental Benefits: Impact on Eligibility for Government Programs," September 2024, available at https://leadingage.org/wp-content/uploads/2024/09/Flex-Card-Issue-Brief-FINAL090424.pdf; Kata Kertesz, "Warning: MA Plan Flex Cards May Impact Housing Benefits of Low-Income Beneficiaries," Center for Medicare Advocacy, October 3, 2024, available at https://medicareadvocacy.org/ma-plan-flex-cards-may-impact-benefits/.

[28] U.S. Department of Housing and Urban Development, "Frequently Asked Questions (FAQ): HUD-assisted Housing and Medicare Advantage Supplemental Benefits," January 2025, available at https://www.huduser.gov/portal/portal/sites/default/files/pdf/FAQ-Medicare-Advantage-Supplemental-Benefits.pdf.

[29] Scott Maucione, "Safeway stores unable to accept Medicare Advantage card," WYPR, January 5, 2025, available at https://www.wypr.org/wypr-news/2025-01-05/safeway-stores-unable-to-accept-medicare-advantage-card ; Chard Snyder, "What are some reasons that the benefits card might not work at the point of sale?", available at https://www.chard-snyder.com/support-center/faqs/what-are-some-reasons-that-the-benefit-card-might-not-work-at-the-point-of (last accessed January 2025).

We applaud CMS for defining the phrase “internal coverage criteria,” and clarifying the appropriate use of referenced Local Coverage Determinations. We agree with the decision to refine the regulatory text to more plainly state CMS’s established intent about interpreting existing policies; the proposal to add more structure and detail to the public accessibility requirements; and the requirement to make required internal coverage criteria information more understandable, readable, and easier to locate.

We agree that a coverage criterion must be prohibited when it exists to reduce utilization of the item or service and does not have any clinical benefit and that an internal coverage criterion is prohibited when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination as required.

We also agree that regulatory text needs to be refined to more clearly state CMS’s interpretation of existing policies and to achieve the goal of protecting patients without decreasing access to medically necessary care.

It is imperative that when consumers are making a choice among MA plans, they have all necessary information to inform that choice—including how plans make coverage determinations. Therefore, we agree with the proposal that by January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. Further, we suggest that any internal coverage criteria used by the MA organization should be required to be publicly displayed on MA organization websites, not only “provide[d] in a publicly available way.”

As both the internal coverage criteria and the items and services to which they apply are critical to ensuring appropriate access to Part A and Part B benefits in the MA program and there is value in comparing use of internal coverage criteria across all MA organizations, we believe CMS should require annual reporting to CMS of the information in plain and accessible language so that it may be publicized by the agency.

Clarifying MA organization determinations to enhance enrollee protections in inpatient settings

Multiple occurrences of reopening authorizations or payment determinations (otherwise known as ‘organization determinations’) after issuing approvals have been reported in the press, including surgeons being pulled out of surgeries to attest to the appropriateness of a service.[30] These organization determinations are unacceptably disruptive for patients and providers. Barring extraordinary exceptional circumstances, MA plans should not be allowed to take back authorizations after the fact.

Rates of prior authorization denials in MA have increased in recent years. In 2022, insurers fully or partially denied 7.4 percent of prior authorization requests, compared to 5.8 percent in

[30] Suzanne Blake, “Doctor Says UnitedHealthcare Stopped Cancer Surgery to Ask If Necessary,” Newsweek, January 8, 2025, available at https://www.newsweek.com/doctor-says-unitedhealthcare-stopped-cancer-surgery-ask-if-necessary-2012069; Laura Dyrda, “What happened when an insurer rescinded surgery approval after the case started,” Becker’s ASC Review, August 27, 2021, available at https://www.beckersasc.com/asc-coding-billing-and-collections/what-happened-when-an-insurer-rescinded-surgery-approval-after-the-case-started.html; Lauren Weber, “Patients Stuck With Bills After Insurers Don’t Pay As Promised,” KFF Health News, February 7, 2020, available at https://kffhealthnews.org/news/prior-authorization-revoked-patients-stuck-with-bills-after-insurers-dont-pay-as-promised/.

2021.[31] Notably, over 80 percent of denials that were appealed were overturned. We applaud CMS for the clarifications and proposals that protect beneficiaries from the abuse of excessive prior authorization and inappropriate claims denials by MA organizations. Protecting beneficiaries in this way is the direction in which CMS rules should be heading.

In addition to concerns over prior authorization, CMS estimates that only 10 percent of 60,000 inpatient approvals that are downgraded to observation status are being handled in line with existing rules. Enrollees must be protected from these unfair practices of MA organizations. We agree with the proposal to strengthen requirements related to notifying providers and physicians and with the proposed clarification requiring MA organizations to provide proper notice of the decision to the enrollee and provider when an MA organization downgrades an enrollee from receiving inpatient to outpatient services or when an MA organization denies payment for services after such services were rendered but before a request for payment is submitted. We agree that an enrollee cannot be financially liable for more than the applicable cost-sharing for a service upon receiving plan-directed care.

Medicare Prescription Payment Plan

We support CMS codifying established requirements allowing enrollees to opt in to the Medicare Prescription Payment Plan (MPPP) in 2025, the 24-hour effectuation requirement, and processing time requirements for electronic election requests. Further, we support CMS in pursuing rulemaking to codify the requirements of the MPPP program for 2026 and subsequent years.

We support CMS's proposed regulatory changes to the MPPP, including requiring PDP sponsors and MA organizations offering Part D plans to provide enrollees the option to elect to pay cost-sharing under the plan in capped monthly amounts, making MPPP information required content for Part D sponsor websites, and adding the MPPP to the list of Part D requirements waived for the Limited Income Newly Eligible Transition program.

We support the proposed requirement for Part D sponsors to effectuate election requests received via phone or web in real-time for 2026 or future years, as the benefit to Part D enrollees outweighs any potential burden on other interested parties.

Ensuring equitable access to behavioral health benefits

Recognizing that parity in access to behavioral health and substance abuse benefits improves health care treatment for beneficiaries and protects them from discrimination,[32] several states and the federal government have passed laws requiring certain insurers to cover mental health and substance abuse care at the same level as care for other health conditions.[33] Medicare

[31] Jeannie Fuglesten Biniek, Nolan Sroczynski, and Tricia Neuman, "Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022," KFF, August 8, 2024, available at https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/.

[32] Thomas McGuire, "Achieving Mental Health Care Parity Might Require Changes In Payments And Competition," *Health Affairs*, 35 (6) (2016): 1029-1035, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC5026763/.

[33] Jessica Kirby and Sean Slone, "Mental Health Insurance Parity: State Legislative and Enforcement Activities," (Lexington, KY: The Council of State Governments), available at https://www.csg.org/wp-content/uploads/sites/7/2021/09/Mental_Health_Parity.pdf; Center for Medicare & Medicaid Services, "The Mental Health Parity and Addiction Equity Act (MHPAEA)," (Washington), available at

beneficiaries should at minimum receive the same parity protections that were guaranteed to enrollees in group plans by the Mental Health Parity and Addiction Equity Act of 2008.[34]

We agree with the proposal to require MA and Medicare Cost Plans in-network cost-sharing for categories of mental health and substance use disorder services be no greater than that in traditional Medicare. As a principle, MA enrollees should not be paying more to access services than they would in traditional Medicare. Unless MAOs can affirmatively demonstrate that the administrative burden would make the changes unworkable, CMS should move to apply these proposed changes to the behavioral health cost-sharing standards beginning in contract year 2026, not 2027.

Medicare Advantage and Part D medical loss ratio standards

Extreme health care consolidation, driven by vertical integration, necessitates that CMS must change its thinking about MLR standards. According to the American Medical Association, in 2022, among the nation's largest metropolitan statistical areas, 71 percent of MA markets were highly concentrated.[35] In fact, only two insurers, UnitedHealthcare (the insurance division of UnitedHealth Group) and Humana, accounted for nearly half (47 percent) of all MA enrollees nationwide in 2024.[36]

As detailed in a December 2024 CAP report, consolidation among health insurers is eroding competition, making MLRs easier to game and therefore less meaningful.[37] For example, UnitedHealth Group (UHG), including through its subsidiary, Optum, is alleged to employ or be affiliated with 10 percent of all physicians in the United States, and a 2024 STAT investigation reports that UHG pays its own physician groups more than it pays others.[38] Under current rules, those payments would count toward the insurer's MLR, even though they are also revenue for the parent company. This is a blatant conflict that CMS should take into account when considering MLR rules.

With that in mind, we strongly encourage CMS to require that MA plans and parent companies report to the agency the full scope of contracts the organization has with related and unrelated parties as well as any reimbursement arrangements included in those contracts that could influence or induce higher coding intensity or clinical activity designed to drive higher

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https://www.cms.gov/marketplace/private-health-insurance/mental-health-parity-addiction-equity, (last accessed January 2025).

[34] Centers for Medicare & Medicaid Services, "The Mental Health Parity and Addiction Equity Act (MHPAEA)," (Washington), available at https://www.cms.gov/marketplace/private-health-insurance/mental-health-parity-addiction-equity, (last accessed January 2025).

[35] American Medical Association, "Competition in Health Insurance: A comprehensive study of U.S. markets," (Washington: 2024), available at https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf.

[36] Meredith Freed, Jeannie Fuglesten Biniek, Anthony Damico, and others, "Medicare Advantage in 2024: Enrollment Update and Key Trends," KFF, August 8, 2024, available at https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/.

[37] Natasha Murphy, "Trends and Consequences in Health Insurer Consolidation," Center for American Progress, December 4, 2024, available at https://www.americanprogress.org/article/trends-and-consequences-in-health-insurer-consolidation/.

[38] Bob Herman, "UnitedHealth Group now employs or is affiliated with 10% of all physicians in the U.S.," STAT, November 29, 2023, available at https://www.statnews.com/2023/11/29/unitedhealth-doctors-workforce; Bob Herman, Casey Ross, Lizzy Lawrence, and others, "UnitedHealth pays its own physician groups considerably more than others, driving up consumer costs and its profits," STAT, November 25, 2024, available at https://www.statnews.com/2024/11/25/unitedhealth-higher-payments-optum-providers-converts-expenses-to-profits/.

reimbursement. Furthermore, we recommend that CMS require MA organizations to disqualify profits or revenues brought in from contracted companies from counting as a qualifying MLR expense and report such disqualifications to the agency.

We agree with the proposal to reinstate the detailed MLR reporting requirements that were in effect for contract years 2014 through 2017, which required the submission of the underlying data used to calculate and verify the MLR and any remittance amount. In an era of increased complexity and hyper market concentration, this transparency is critical to ensure that the MA program is functioning as intended and meeting standards for Medicare sustainability.

We agree with the proposal to establish clinical or quality improvement standards for any provider incentives and bonus arrangements in order for those expenses to be included in an MLR numerator. CMS has taken similar action before. In "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023," CMS responded to issuer manipulation of quality improvement activity (QIA) reporting to raise MLRs and reduce rebates in marketplace plans by codifying existing MLR policy, stating that "only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes."[39]

We agree with aligning CMS regulations on QIAs with existing commercial and Medicaid requirements, which state that "only expenditures directly related to activities that improve health care quality may be included in QIA expenses." Further, as administrative costs do not deliver clinical value to patients, we agree with the proposal to prohibit them from quality improving activities counted toward the MA and Part D MLR numerator.

Annual health equity analysis of utilization management policies and procedures

As outlined in our May 2024 comment letter in response to the Request for Information on MA Data, waiting for prior authorization approvals, going through the process of appealing denials, and being denied care can lead to stress and anxiety for beneficiaries and can result in actual harm to patients' health.[40] It is important that beneficiaries understand how MA plans engage in utilization management, as there is a great deal of variation in prior authorization use across plans. In 2022, the number of prior authorization requests ranged from 0.5 to 2.9 requests per enrollee.[41] To that end, prior authorization intensity should be reported to beneficiaries and should be easily visible during enrollment when a prospective enrollee is comparing plan options through Medicare Plan Finder.

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[39] The Federal Register, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023," (Washington: 2022), available at https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.

[40] Center for American Progress, "Re: CMS-4207-NC–Medicare Program; Request for Information on Medicare Advantage Data," May 29, 2024, available at https://www.americanprogress.org/wp-content/uploads/sites/2/2024/07/CAP-Re-CMS-4207-NC-Medicare-Program-RFI-on-Medicare-Advantage-Data.pdf; The Federal Register, "Medicare Program; Request for Information on Medicare Advantage Data," (Washington, DC: 2024), available at https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

[41] Jeannie Fuglesten Biniek, Nolan Sroczynski, and Tricia Neuman, "Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022," KFF, August 8, 2024, available at https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/.

We appreciate CMS's responsiveness to our previous comments about collecting more–and more detailed–utilization management data.[42] We applaud the proposal to revise the required metrics for CMS's annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services. This will allow regulators to understand whether variances exist for particular groups of beneficiaries, including those with particular chronic conditions who may be disproportionately subject to utilization management techniques.

Relevant data must be easily accessible and understandable for enrollees and the public. Therefore, we agree with the proposal that the results of the health equity analysis include an executive summary. We suggest that the results of the health equity analysis, including the executive summary, should adhere to plain language principles, accessibility standards, and consumer-centered design standards and be required to be published on MA plans' websites in a uniform manner across all MA plans.

Having a mental health or substance use disorder diagnosis as a social risk factor

Mental health and substance use disorder can impact social determinants of health[43] and increase risk for cardiovascular disease,[44] diabetes,[45] obesity,[46] and other diseases.[47] According to the National Council for Mental Wellbeing's 2022 Access to Care Survey, 81 percent of adults who received substance use care and 67 percent of adults who received mental health care had difficulties accessing care.[48] To better support those in need of mental health and substance use care, we are in favor of adding "having 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.

Guardrails for artificial intelligence

In 2019 and 2020, executive orders from the Trump Administration called for building public trust and confidence in artificial intelligence (AI) technologies and called on agencies to ensure

[42] Center for American Progress, "Re: CMS-4207-NC–Medicare Program; Request for Information on Medicare Advantage Data," May 29, 2024, available at https://www.americanprogress.org/wp-content/uploads/sites/2/2024/07/CAP-Re-CMS-4207-NC-Medicare-Program-RFI-on-Medicare-Advantage-Data.pdf.

[43] Margarita Alegría, Amanda NeMoyer, Irene Falgas, and others, "Social Determinants of Mental Health: Where We Are and Where We Need to Go," *Curr Psychiatry Rep.,* 20 (11) (2018), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC6181118/.

[44] Rebecca C. Rossom, Stephanie A. Hooker, Patrick J. O'Connor, and others, "Cardiovascular Risk for Patients With and Without Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder," *Journal of the American Heart Association*, 11 (6) (2022), available at https://www.ahajournals.org/doi/full/10.1161/JAHA.121.021444.

[45] Chun-Jen Huang, Herng-Chia Chiu, Mei-Hsuan Lee, and others, "Prevalence and incidence of anxiety disorders in diabetic patients: a national population-based cohort study," *General Hospital Psychiatry*, 33 (1) (2011): 8-15, available at https://www.sciencedirect.com/science/article/abs/pii/S0163834310002045?via%3Dihub.

[46] David B. Allison, John W. Newcomer, Andrea L. Dunn, and others, "Obesity Among Those with Mental Disorders: A National Institute of Mental Health Meeting Report," *American Journal of Preventive Medicine*, 36 (4) (2009): 341-350, available at https://www.sciencedirect.com/science/article/abs/pii/S0749379709000245.

[47] Chris Delcher, Daniel R. Harris, Nicholas Anthony, and others, "Substance Use Disorders and Social Determinants of Health from Electronic Medical Records obtained during Kentucky's 'Triple Wave'," Pharmacology Biochemistry & Behavior, (2022), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10082996/.

[48] National Council for Mental Wellbeing, "2022 Access to Care Survey Results," (Washington: 2022), available at https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf

that AI is accurate, reliable, and effective.[49] In 2022, the White House Office of Science and Technology Policy issued the Blueprint for an AI Bill of Rights, which called for the right to be protected from unsafe or ineffective systems.[50] We applaud CMS's focus on equal opportunity, justice for the American people and culturally competent care. We agree with the proposed policy to make clear 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.

We agree that MA organizations and their third party contractors that use AI tools or automated systems in any manner are responsible for ensuring that the usage of such tools complies with all existing Medicare policies, including, but not limited to, providing culturally competent care to all enrollees in a non-discriminatory manner and that usage of AI tools complies with internal coverage criteria rules.

Promoting informed choice—expanding agent and broker requirements regarding Medicare savings programs, Extra Help, and Medigap

Given the gravity of the choice beneficiaries make when choosing MA or Part D plans, we applaud CMS's proposed changes to ensure they have an accurate picture of their enrollment options and help them make informed decisions when considering their health care coverage.

We agree with the proposals to include Low-Income Subsidy (LIS) eligibility criteria as an additional topic that agents and brokers must address before enrolling a beneficiary in an MA, MA-PD or Part D plan; to require that agents and brokers review, prior to a beneficiary's enrollment in an MA, MA-PD, or Part D plan, existing resources for state programs, including MSPs that can help with health care costs; to require that agents and brokers pause to ask the beneficiary, prior to finalizing the enrollment, whether the beneficiary has any remaining questions related to the beneficiary's enrollment in a plan; and to put the newly proposed and existing requirements into a more organized and reader-friendly format.

Broker communication regarding Medigap

Outside an initial 12-month window (and barring some extenuating circumstances), Medigap carriers in 46 states can deny a policy to an MA enrollee who wants to switch to traditional Medicare. This is because outside of that window, Medicare beneficiaries lose their guaranteed issue rights for Medigap and become subject to medical underwriting–a practice that no longer exists for the vast majority of health insurance plans thanks to the Affordable Care Act. For such enrollees, the loss of guaranteed issue Medigap rights can make choosing MA over traditional Medicare an effectively irreversible decision, even if they are not satisfied with their MA coverage, because of the high financial risk associated with traditional Medicare enrollment absent a supplemental policy. Examples of enrollees not understanding this phenomenon are

[49] The Federal Register, "Maintaining American Leadership in Artificial Intelligence," (Washington: 2019), available at https://www.federalregister.gov/documents/2019/02/14/2019-02544/maintaining-american-leadership-in-artificial-intelligence; The Federal Register, "Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government," (Washington: 2020), available at https://www.federalregister.gov/documents/2020/12/08/2020-27065/promoting-the-use-of-trustworthy-artificial-intelligence-in-the-federal-government.

[50] The White House, "Blueprint for an AI Bill of Rights: Making Automated Systems Work For The American People," (Washington), available at https://bidenwhitehouse.archives.gov/ostp/ai-bill-of-rights/ (last accessed January, 2025).

so common that it has earned the moniker,[51] "The Medigap Trap."[52] To ensure that every enrollee is fully informed when making the choice between traditional Medicare and MA, it is therefore necessary that beneficiaries are provided comprehensive information about the extent to which that choice impacts their Medigap guaranteed issue rights.

Accordingly, we strongly agree that agents and brokers should be required to discuss with beneficiaries the potential impact enrolling into an MA plan can have on Medigap federal guaranteed issue (GI) rights and convey that the beneficiary generally has 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.

We agree that CMS must clarify penalties for when agents and brokers do not explain these impacts on Medigap guaranteed issue rights. However, penalties for brokers should also come with restitution for enrollees who had information withheld when making their choice. To that end, we suggest that a SEP should be triggered when brokers or agents are found to have not been in compliance with the rule that allows a beneficiary to purchase Medigap policy with guaranteed issue rights if they so choose.

Additionally, agents and brokers should be required, not merely "encouraged," to use CMS-developed materials to communicate important information to beneficiaries about relevant state programs and provide information on state laws regarding Medigap guaranteed issue rights for those states where the agent or broker is licensed.

Finally, as we called for in our May 2024 comment letter in response to the Request for Information on MA Data,[53] brokers should also be required to proactively disclose their financial incentives/relationships for enrolling beneficiaries in a given plan. Beneficiaries deserve to know whether brokers are financially benefiting (and therefore financially motivated) from the recommendations they are providing. Transparency is critical for ensuring consumer trust and confidence in the information that brokers are providing.

Conclusion

We applaud CMS for proposing rules to protect Medicare beneficiaries without placing an undue burden on the Medicare program, MA organizations, FDRs, agents, brokers, or other affected parties. We appreciate the agency clarifying existing rules regarding the scope of MA coverage, internal coverage criteria, excessive prior authorization use and inappropriate claims denials by MA organizations, broker communications about Medigap guaranteed issue rights, and more.

We appreciate the many modifications in this proposed rule that reflect our previous comments in response to the Request for Information on MA Data, which demonstrate the agency's

[51] Sarah Jane Tribble, "Older Americans Say They Feel Trapped in Medicare Advantage Plans," KFF, January 5, 2024, available at https://kffhealthnews.org/news/article/medicare-advantage-medigap-enrollment-trap-switch-preexisting-conditions/; Sarah Jane Tribble, "Older Americans Say They Feel Trapped in Medicare Advantage Plans," National Public Radio, January 3, 2023, available at https://www.npr.org/2024/01/07/1223353604/older-americans-say-they-feel-trapped-in-medicare-advantage-plans.

[52] Matthew Cunningham-Cook, "The Medicare Advantage Trap," The American Prospect, November 29, 2023, available at https://prospect.org/health/2023-11-29-medicare-advantage-trap/.

[53] The Federal Register, "Medicare Program; Request for Information on Medicare Advantage Data," (Washington: 2024), available at https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

commitment to using evidence and facts from the public to guide its rulemaking and to ensure that it is acting in the best interest of Medicare beneficiaries.[54]

Together, MA and Medicare Part D provide coverage for tens of millions of older Americans and people with disabilities.[55] To meet the needs of these Medicare enrollees while protecting them from potential harm, the agency must not only issue thoughtful rules, but also provide strict enforcement of those rules. It is vital that enforcement of these rules includes both penalties to MA organizations that are serious enough to deter misconduct and poor performance and protections for enrollees, including SEPs that empower enrollees with the ability to make new coverage choices when they have been misled by inaccurate network directories or failures of agents or brokers.

Thank you for the opportunity to comment on this Request for Information, and we appreciate your consideration of our comments. For any questions regarding this comment letter, please contact Andrea Ducas at aducas@americanprogress.org.

Sincerely,

Center for American Progress

[54] Center for American Progress, "Re: CMS-4207-NC–Medicare Program; Request for Information on Medicare Advantage Data," May 29, 2024, available at https://www.americanprogress.org/wp-content/uploads/sites/2/2024/07/CAP-Re-CMS-4207-NC-Medicare-Program-RFI-on-Medicare-Advantage-Data.pdf; The Federal Register, "Medicare Program; Request for Information on Medicare Advantage Data," (Washington: 2024), available at https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

[55] Centers for Medicare & Medicaid Services, "Medicare Monthly Enrollment," (Washington: 2024), available at https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment; Juliette Cubanski, "A Current Snapshot of the Medicare Part D Prescription Drug Benefit," KFF, October 9, 2024, available at https://www.kff.org/medicare/issue-brief/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/.