January 27, 2025

Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

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

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; 89 Fed Reg 99340 (Dec. 10, 2024) CMS-4208-P

The Center for Medicare Advocacy (CMA) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality health care. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with longer-term conditions. CMA's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues annually. Additionally, CMA provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care.

II. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program

Coverage of Adult Vaccines

We support the codification of the requirements related to $0 cost-sharing for adult vaccines recommended by ACIP under Part D for 2026 and each subsequent year.

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

We support the codification of the requirements related to appropriate cost-sharing for covered insulin products under Part D for 2026 and each subsequent plan year.

Medicare Prescription Payment Plan

CMS states that it "does not have authority to implement the Medicare Prescription Payment Plan through program instruction authority beyond 2025. As such, we are pursuing rulemaking to codify the requirements of the program for 2026 and subsequent years" (p. 99355). We support CMS' proposal to codify existing guidance, along with the proposed modifications. We also encourage CMS to add information about LIS, Medicare Savings Programs and SPAPs to materials accompanying the MPPP Election Request form so that beneficiaries can be educated

earlier in the process and before making an MPPP enrollment decision. Similarly, we ask CMS to add information about LIS retroactivity to the Notice of Voluntary Termination, Notice of Failure to Pay, Involuntary Termination Notice and the Billing Statement in order to provide timely information about accessing LIS assistance – including for past costs – for individuals facing prescription drug affordability issues.

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

Part D Coverage of Anti-Obesity Medications (AOMs) and Application to the Medicaid Program (p. 99375)

CMS proposes to reinterpret the Medicare statute to permit coverage of anti-obesity medications for the treatment of obesity when such drugs are indicated to reduce excess body weight and maintain weight reduction long-term for individuals with obesity. In so doing, CMS would be aligned with existing policies under which the agency permits Part D coverage for drugs that would otherwise be excluded when they are being used to treat certain specific diseases (e.g., drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia). CMS' revised interpretation would recognize obesity to be a chronic disease based on changes in medical consensus. However, CMS would not consider that interpretation to extend to individuals who are overweight but do not have obesity, as overweight is not considered a disease. Therefore, CMS would continue to exclude anti-obesity medications from Part D coverage when being used in individuals who are overweight but without obesity or another condition that is a medically accepted indication. Because CMS' proposal reinterprets the Medicaid statute, this reinterpretation would also apply to the Medicaid program.

CMA strongly supports this proposal and commends CMS for taking the necessary steps to address the growing obesity epidemic by expanding coverage for AOMs under both the Medicare and Medicaid programs. Given all of the impacts that obesity can have on overall health, including being a primary risk factor for many chronic illnesses, including type 2 diabetes, and being associated with increased risk for a number of types of cancer, if finalized, this proposal could lead to significant savings of health care costs for both individuals and the federal government.

Network Transparency for Pharmacies (p. 99381)

CMS proposes two new provisions to promote better service to Part D beneficiaries and prevent instability in pharmacy networks by promoting transparency in pharmacy network contracts. The first provision would require Part D plans (or first tier, downstream, or related entities, such as PBMs, acting on the Part D sponsors' behalf) to provide contracted pharmacies with information about which Part D plans they are in-network for before open enrollment and on request thereafter. The second would require Part D sponsors (or first tier, downstream, or related entities, such as PBMs, acting on the Part D sponsors' behalf) to allow pharmacies to terminate their network contracts without cause after the same notice period that the sponsor is allowed to

terminate pharmacy network contracts without cause. We support these proposals that will allow Part D enrollees to be better informed about contracted pharmacies; this will particularly aid rural enrollees and those with transportation challenges.

Part D Medication Therapy Management (MTM) Program Eligibility Criteria

CMS proposes to expand the reference to Alzheimer's disease on the list of core chronic diseases to include other dementias. We support this proposal.

Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights To Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs

We share CMS' belief that pharmacies, particularly small, unaffiliated pharmacies, lack the ability to negotiate reciprocal termination terms on their own. 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.

The fact that Part D sponsors can terminate pharmacy contracts without cause, however, is unfair as it denies pharmacies the expected benefit of a contract. Further, the six largest pharmacy benefit managers (PBMs), which make up 96 percent of the PBM market, are vertically integrated with mail order and specialty pharmacies, placing them in direct competition with independent pharmacies. There is evidence from investigative reports that these PBMs may have taken steps to deprive independent pharmacies of revenue to force them to close. Already, approximately 10 percent of rural, 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.

Administration of Supplemental Benefits Coverage Through Debit Cards (p. 99384)

CMA has long held concerns regarding MA plans' use of debit cards for administering both mandatory supplemental benefits for all MA enrollees and mandatory supplemental benefits available as Special Supplemental Benefits for the Chronically Ill (SSBCI). Many private MA plans heavily promote "flex cards" or debit cards in their advertisements, though the amounts on the cards, permitted uses, and other details vary by plan. The cards can be appealing to beneficiaries who struggle to cover their out-of-pocket costs each month, as they can sometimes be used to purchase items such as groceries and over-the-counter medications. We have heard anecdotally that the extensive marketing of the flex cards by MA plans, coupled with beneficiaries on tight budgets facing high out-of-pocket costs, has led to beneficiaries seeking out plans with the highest flex card amounts, regardless of the other benefits or networks in a plan. At CMA, we urge beneficiaries, particularly those who are dually eligible for Medicare and Medicaid, to proceed with great caution when selecting their Medicare coverage, and to consult

with their local SHIP program for unbiased advice. However, real oversight of these cards and MA marketing must come from CMS. Therefore, we appreciate the increased oversight proposed in the rule.

We strongly support the CMS proposal to prohibit MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered. Current advertisements can lead consumers to focus on the cash value of the card, while disregarding other key aspects of the plan, such as other benefits, whether the beneficiary qualifies for supplemental benefits, or whether their providers are in the plan's network. We agree with CMS that the advertisements can "potentially giv[e] false impressions that the card itself is the benefit…" We believe that limiting the advertisements surrounding these cards will help potential enrollees review all aspects of the plan and make a more informed choice that better matches their health needs. CMA also appreciates the clear language in this rule, reiterating that the cards are not the benefit in themselves; they are the mechanism for providing the benefit, "[t]he debit card itself is not a supplemental benefit; rather, it is a tool used to administer coverage. . ."

While the advertisements, such as those on television, print and radio, should not include the details of the cards, as they can be misleading, we support strong requirements for plans to outline the benefits accessible through the cards, the manner in which they can be accessed, and any other pertinent information related to the cards in plan materials that are easily accessible for both potential enrollees and those already enrolled in the plan.

We agree with CMS's proposal to require MA organizations that use debit cards to administer a supplemental benefit to provide instructions for debit card use and customer service support to enrollees to answer questions or help with issues related to the administration of the card. Research demonstrates that many supplemental benefits are left unused by beneficiaries. A recent report in Science Magazine highlighted research examining data collected from over 76,000 Medicare beneficiaries between 2017 and 2021. They found that "nearly half of Medicare Advantage enrollees were not even aware that they had dental or vision coverage under their plans, raising concerns about the communication and transparency of insurance providers." [1]

It is possible that beneficiaries are unsure of how to access their benefits on the MA flex cards and are unsure of where they are able to use their cards. Requiring the plan to provide detailed information and customer service support could improve utilization of these benefits. The information must be accessible to beneficiaries living in rural areas with limited access to broadband/internet for communication.

Since benefits must be used in a plan year, we support the proposal for MA organizations to ensure the use of a debit card to administer a covered benefit is limited to the specific plan year. Beneficiaries should clearly understand that they cannot carry over benefits from one plan year to another. Clarity on this issue is critical, as a misunderstanding could encourage beneficiaries to remain enrolled in a plan for a subsequent year with the false belief that they can carry over those

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[1] ScienMag, Medicare Advantage Beneficiaries Show No Increase in Dental, Vision, or (Jan. 14, 2025).

benefits, even if that plan does not meet their health needs. In order to ensure that benefits are not left unused on the debit cards, we encourage CMS to require plans to notify beneficiaries of remaining balances on their cards before they expire, as well as how and where they can access these benefits. Underutilized benefits on the cards underscores the inherent issues with these cards and why they are a problematic mechanism for providing benefits.

Since 2024 CMA has been monitoring a troubling situation regarding the flex cards and their impact on eligibility for public benefits. After learning that some Connecticut low-income housing complexes were imposing rent increases on residents who are in MA plans with flex cards, we discovered that the contractors hired by the owners of the properties were counting the amounts on the cards toward income in rental assistance eligibility determinations. The contractors were citing the Department of Housing and Urban Development (HUD) policy, and counting the amounts on the cards regardless of whether the cards were even used by the beneficiaries.[2] These rent increases have been devasting for beneficiaries who are already living off very limited means. We have also heard from other advocates that other public benefits have been jeopardized by these cards as well. Leading Age, for example, reports multiple instances where individuals join Medicare Advantage plans for flex card benefits, not realizing that they will be disenrolled from the Program of All-Inclusive Care for the Elderly (PACE).[3]

HUD recently released guidance on this issue that echoes CMS language that the cards are simply a mechanism for administering a benefit, and are not a benefit in themselves that should be counted as income in public benefit determinations. The HUD guidance outlines that only funds from the cards actually used to pay for utilities or rent can be counted as income; all other funds or unused amounts must be excluded from income calculations for purposes of HUD assistance. The guidance from HUD states that "benefits or supports received ***and used*** for the purpose of paying rent and utilities – such as the supports that may be provided through an MA Plan with [Flex Cards] – must be included in the calculation of income." (emphasis in original).[4]

We urge CMS to require plans to disseminate this information broadly to their enrollees through plan materials and through the plan website wherever flex cards are mentioned. This information should also be included in the instructions and customer service support proposed in the rule (discussed above). Beneficiaries should receive a warning that cards used for rent and/or utilities will be counted toward their income calculations for public benefit purposes and may result in increases in rent. It is critically important that beneficiaries understand this when using their debit cards. Otherwise, those eligible for HUD assistance could inadvertently jeopardize their rental assistance. Due to the beneficiaries who contacted us at CMA, our focus has been on the impact of these cards on housing benefits. But, we encourage CMS to conduct a review of other

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[2] Center for Medicare Advocacy, Warning: MA Plan Flex Cards May Impact Housing Benefits of Low-Income Beneficiaries - Center for Medicare Advocacy (Oct. 3, 2024).
[3] LeadingAge, Letter to CMS regarding opportunities to strengthen Program of All-inclusive Care for the Elderly (PACE) participant protections against Medicare Advantage (MA) fraudulent and misleading marketing practices (July 25, 2024).
[4] U.S. Department of Housing and Urban Development, "Frequently Asked Questions (FAQ): HUD-assisted Housing and Medicare Advantage Supplemental Benefits," (January 2025).

public benefits that may be impacted by the flex cards. We urge CMS to require plans to include any other relevant warnings to beneficiaries that may impact their public benefits based on particular usage of the cards.

CMA also appreciates CMS clarifying through regulatory text that "all coordinated care plans are required to cover benefits, including supplemental benefits, at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs in accordance with the standards set forth in our rules and regulations. This is required for all benefits, regardless of how they are administered." We agree with CMS that this has been inconsistently applied by plans, and we support the proposal to require MA organizations to have processes for delivering all MA organization covered supplemental benefits to enrollees. We encourage CMS to provide robust oversight to ensure plan compliance with this requirement.

Despite the improvements in oversight of the flex cards, as well as limitations on marketing of the cards proposed in this rule, we continue to have concerns about how the cards drive consumer behavior and their impacts on essential public benefits. While this rule allows for the flexibility to use alternatives to the flex cards, which we support, we urge CMS to explore requiring plans to use alternative methods for providing supplemental benefits.

Non-Allowable Supplemental Benefits for the Chronically Ill (SSBCI) (p. 99390)

CMS proposes a non-exhaustive list of non-primarily health related items or services that do not meet the standard of having a reasonable expectation of improving or maintaining the health or overall function of the enrollee standard as described in section 1852(a)(3)(D)(ii)(I) of the Act and at CMS regulations at § 422.102(f)(1)(ii), meaning such items and services are not permissible SSBCI. We agree with CMS that codifying this "non-exhaustive list of examples of items or services that do not meet these standards provides transparency and greater certainty for MA organizations and enrollees about the rules that govern these benefits, which is necessary and appropriate to ensure that supplemental benefits coverage is properly furnished by all MA organizations that choose to offer these supplemental benefits" (p. 99391). As noted in comments to the eligibility for SSBCI above, we are concerned that MA supplemental benefits, including SSBCI, are used to maximize enrollment in plans rather than enrollee health.

Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) and Technical Changes to the Definition of Chronically Ill Enrollee (p. 99392)

We strongly support CMS' proposal that plans must demonstrate that an enrollee has met all three of the criteria of being a "chronically ill enrollee" set forth in 422.102(f)(1)(i)(A) through the use of an objective process. We urge CMS to require plans to post such information on their websites. We also support the clarification that the presence of a chronic illness or chronic condition alone is not sufficient to satisfy all of the statutory criteria to qualify as a chronically ill enrollee.

Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence (p. 99396)

CMS proposes to revise 42 CFR 422.112(a)(8) to require MA plans to ensure services are provided equitably, irrespective of delivery method or origin, whether from human or automated systems. The agency also clarifies that in the event that an MA plan uses AI or automated systems, they must comply with section 1852(b) of the Social Security Act and 42 CFR 422.110(a) and other applicable regulations and requirements and provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status.

Absent prohibiting the use of AI or automated tools/algorithms to make coverage decisions (as discussed below), we strongly support this proposal to require MA plans to provide equitable access to services in the event that they use AI or automated systems. Given existing rules applicable to MA plans concerning prior authorization and the use of AI or algorithms, we also urge CMS to go much farther in their efforts to rein in plan behavior. Despite the extensive changes to prior authorization requirements outlined in the 2024 rule, we regularly encounter MA plans that fail to meet these existing guidelines. Existing oversight of MA plans' abuse of prior authorization is insufficient; this new requirement will be meaningless without adequate enforcement, and meaningful consequences for plan non-compliance.

In our extensive comments to the proposed 2024 rule,[5] we asserted that CMS must explicitly prohibit MA plans from using of AI or algorithmic tools to make coverage determinations. Some policymakers have similarly called for a prohibition on the use of AI/algorithmic tools and software to make coverage denials "until a systematic review of their use can be completed" (see the June 2024 bipartisan, bicameral Congressional letter discussed below).

While we are aware that the use of AI and algorithmic tools does hold some promise in the healthcare sector, making coverage determinations is not in this category. In short, such products have been used to improperly deny care. For example, in October 2024 Senator Richard Blumenthal (D-CT), Chair of the U.S. Senate Permanent Subcommittee on Investigations, released a 54-page report[6] regarding its ongoing investigation of Medicare Advantage plans' Prior Authorization and on-going denials. The report highlighted how three major insurers: UnitedHealthcare, Humana, and CVS "intentionally use prior authorization to boost profits by denying post-acute care." Many of the denials analyzed by the committee increasingly rely on artificial intelligence (AI), not health care experts, to make coverage decisions.

If neither Congress nor CMS prohibits the use of AI or algorithmic tools to make coverage decisions – specifically coverage denials – there are many more consumer protections that

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[5] Center for Medicare Advocacy comments to Proposed 2024 Part C & D rule (February 13, 2023), available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

[6] See https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf; also see, e.g., *CMA Alert* titled "Senate Subcommittee Report Details Medicare Advantage Coverage Denials" (Oct. 24, 2024).

should be instituted in order to better ensure that MA enrollees are protected and MA plans are held accountable.

In November 2023, 30 House members wrote CMS urging the agency to increase oversight of AI and algorithms used to determine coverage in MA plans.[7] We concur with the recommendations made in the letter, and reproduce the recommendations here:

> **Absent prohibiting the use of AI/algorithmic tools outright, it is unclear how CMS is monitoring and evaluating MA plans' use of such tools in order ensure that plans comply with Medicare's rules and do not inappropriately create barriers to care.** In order to ensure proper oversight of MA plans, we urge CMS to take the following measures:
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> - Require MA plans to report prior authorization data including reason for denial, by type of service, beneficiary characteristics (such as health conditions) and timeliness of prior authorization decisions;
> - Compare "guidance" generated by these tools with actual MA coverage decisions (e.g., compare naviHealth projected length of stays in a skilled nursing facility with the actual approved lengths of stay by the MA plan to assess whether such tools are, indeed, being used to make coverage determinations);
> - Assess the frequency of denials related to the same individual in the same episode of care by analyzing data from Quality Improvement Organizations (QIOs) and Independent Review Entities (IREs) that process Medicare appeals to identify trends in MA appeals regarding hospital discharges, skilled nursing facility discharges and home health terminations;
> - Assess how and to what extent initial prior-authorized AI determinations for services are adjusted to account for unanticipated changes in a patients' condition (according to advocates and providers, initial determinations are not generally adjusted);
> - Require attestation from MA plans and contractors (including care management firms such as naviHealth, myNexus) that their coverage guidelines are not more restrictive than traditional Medicare (with enforcement if this proves not to be true);
> - Given concerns about the homogeneity of patient testing populations when developing AI or algorithmic software in other settings, assess the data plans are relying on to make these determinations or assessments, and whether plans are inappropriately using race/other factors in these algorithms.
> - Assess whether the AI/algorithms are "self-correcting," by determining whether, when a plan denial or premature termination of services is reversed on appeal, that reversal is then factored into the software so that it appropriately learns when care should be covered.

[7] See Rep. Nadler Press Release: "Nadler, Chu Lead Colleagues in Urging CMS Increase Oversight of Artificial Intelligence and Algorithms Used to Determine Coverage in Medicare Advantage Plans" (Nov. 3, 2023); also see the letter.

Many of the same House members joined a bicameral, bipartisan letter to CMS in June 2024 on the same subject.[8] The letter urged the agency to take the measures outlined in the November 2023 letter (reproduced above) and offered additional, specific recommendations for CMS, including:

- Clarify the specific elements that must be contained in denial notices;
- Establish an approval process to review AI and algorithmic tools and their inputs to ensure the integrity of their use, and conduct a review of algorithm and AI tools currently being used;
- Prohibit the use of AI/algorithmic tools and software from use in coverage denials until a systematic review of their use can be completed;
- Clarify how CMS distinguishes between use of algorithms or software that account for individual circumstances and those that do not; specify what criteria, methods, or data will be used to determine this distinction; and clarify how this requirement will be enforced and communicated to plans;
- Clarify when MA organizations are able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits; and
- Impose a minimum time period during which MA plans cannot issue a termination notice after their prior termination decision has been reviewed by a Medicare contractor.

There is bipartisan interest in addressing the problems of AI/algorithms surrounding MA plans' coverage decisions. In December 2024, the House of Representatives released a report titled "Bipartisan House Task Force Report on Artificial Intelligence".[9] In an analysis of the use of AI to make "Health Insurance Decisions," the report talks about some of the promise of AI use in healthcare, but then states:

> However, stakeholders have criticized the implementation of AI tools by health insurers for insurance decisions for a lack of transparency in coverage decisions. While Medicare Advantage insurers have flexibility in Medicare benefit design, questions have been raised about the use of AI systems created to predict estimated lengths of stay based on statistical metrics and then rejecting patient requests for care that exceeded this length, even if supported by caregiver opinion. […]
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> There is potential to use AI as a medical management tool in some instances, but there are concerns that these applications could create unnecessary denials and lack of access to necessary treatments when AI produces inaccurate or biased results.

While CMS' proposals "to require MA plans to ensure services are provided equitably, irrespective of delivery method or origin, whether from human or automated systems" are welcome, they must be accompanied by more stringent standards and plan accountability.

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[8] See, e.g., Rep. Chu Press Release: "Reps. Chu, Nadler & Sen. Warren Lead Bicameral Letter to CMS Urging Oversight of Artificial Intelligence and Algorithms Used in Medicare Advantage Coverage Decisions" (June 25, 2024); also see letter.

[9] Bipartisan House Task Force Report on Artificial Intelligence (Dec. 2024); also see Speaker Johnson's press release (Dec. 17, 2024).

Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors (p. 99398)

In an effort to enhance transparency with respect to in-home service contractors, CMS proposes to: 1) codify definitions of community-based organizations (CBOs) and in-home or at-home supplemental benefit providers and direct furnishing entities; 2) require plans to identify, within the provider directory, which providers and direct furnishing entities meet the proposed definition of a CBO; 3) require plans to identify in-home or at-home supplemental benefit providers and direct furnishing entities, including those that provide a hybrid of services (both in-home or at-home, and in-office services), either through a subset list within the provider directory or through a separate list comprising in-home or at-home supplemental benefit providers and direct furnishing entities; and 4) clarify existing policy by stating that all direct furnishing entities must be included within the provider directory. We support these proposals.

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

CMA commends CMS for proposing to align MA and Cost Plan in-network cost-sharing with Traditional Medicare for intensive outpatient (IOP) services, MH specialty services, opioid treatment program (OTP) services, outpatient SUD services, partial hospitalization (PHP), psychiatric services, and inpatient hospital psychiatric services. As CMS has noted in the proposed rule, beneficiaries in Traditional Medicare pay only 20% coinsurance for all services (with zero cost sharing for OTP services), while MA enrollees may be charged up to 50% coinsurance for the same SUD and MH services. CMS's data shows that approximately one in four MA plans have higher cost-sharing for MH specialty and psychiatric services than Traditional Medicare, and individuals in these plans would save an average of $7 per visit under the proposed change. The potential impact for access to SUD services is even greater: more than two in five MA plans have higher cost-sharing for outpatient SUD services than Traditional Medicare, and individuals in these plans would save an average of $30 per day under the proposed change. Notably, 71% of MA plans have higher cost-sharing for OTP services than Traditional Medicare, and individuals in these plans would save an average of $47 per visit. These costs add up quickly for individuals who attend treatment daily and weekly, and these numbers show that many MA enrollees with SUD are currently spending thousands of dollars out-of-pocket annually to access SUD treatment.

While these costs would be minimal for MA and Cost Plans, these savings would be life-changing for Medicare beneficiaries with SUD and MH conditions. Among Medicare beneficiaries with SUD, one of the most commonly reported reasons for not receiving treatment were financial barriers.[10] Additionally, the U.S. Department of Health & Human Services Office

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[10] William J. Parish et al., "Substance Use Disorders Among Medicare Beneficiaries: Prevalence, Mental and Physical Comorbidities, and Treatment Barriers," American Journal of Preventative Medicine 63(2), (Aug. 2022), https://www.sciencedirect.com/science/article/abs/pii/S0749379722001040.

of Inspector General found that Medicare beneficiaries with opioid use disorder who receive the low-income subsidy are almost three times more likely (26% compared to 9%) to receive medications to treat their opioid use disorder than beneficiaries without the subsidy, identifying the high Part D cost-sharing (averaging $268/annually for those without the subsidy, compared to $19/annually for those with the subsidy) as a potential explanation for this disparity.[11]

We emphasize the comments from our colleagues at the Legal Action Center, in strongly supporting CMS's proposed rule to align MA and Cost Plan in-network cost-sharing with Traditional Medicare for SUD and MH services, and we encourage CMS to consider other ways to limit the financial burdens associated with SUD and MH care in MA and Part D plans. Specifically, we recommend CMS eliminate cost-sharing for other outpatient SUD services under MA plans and medications for opioid use disorder (MOUD) under Part D, to align with the current $0 cost-sharing for the OTP benefit, so that Medicare beneficiaries have a more meaningful choice in where and how to get treatment. To the extent that CMS does not currently have this authority, we encourage CMS to work with Congress to accomplish this goal through legislation. Medicare beneficiaries are currently more likely to access SUD services and MOUD in office-based settings than OTPs,[12] and we believe removing the financial burdens for beneficiaries would achieve CMS's desired impact of improving access to behavioral health care and meeting beneficiaries where they are.

Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures (p. 99422)

CMA supports CMS's proposals to add an executive summary of the results of the health equity analysis of the utilization management policies and procedures and disaggregate metrics by each covered item and service. We also strongly support CMS's suggestion to add having a MH or SUD diagnosis as a social risk factor for this analysis. Recent claims and encounter data research by RTI International found exceptionally high MA denial rates for SUD treatment. In 2020, MA plans denied 45.3% of claims for inpatient hospital treatment with a primary diagnosis of SUD, compared to 3.3% in Traditional Medicare; and they denied 10.9% of hospital outpatient treatment claims with a primary diagnosis of SUD, compared to 2.2% in Traditional Medicare.[13] The inclusion of having a MH or SUD diagnosis as a social risk factor for this analysis would help to address this disparity, and fill one of the many critical gaps presented by Medicare's lack of protections under the Mental Health Parity and Addiction Equity Act. We continue to urge CMS to work with Congress to apply the Parity Act to Medicare, including MA and Part D plans. In the meantime, it is critical that all MA plans evaluate data on how their utilization management policies and procedures may disproportionately affect access to MH and SUD services and items, and take the necessary steps to reduce such barriers. We believe that this is something that MA plans would be able to operationalize through the claims data, or however they currently assess these metrics for enrollees with disabilities as already required.

[11] U.S. Department of Health & Human Services Office of Inspector General, "The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern," (Dec. 2023), https://oig.hhs.gov/oei/reports/OEI-02-23-00250.pdf.
[12] *Id.*
[13] "Under-Diagnosed and Under-Covered: Claims Data Reveal Significant Medicare Gaps in SUD Treatment in 2020," Legal Action Center (Oct. 2024), https://www.lac.org/assets/files/RTI-Claims-Data-Issue-Brief-final.pdf.

Medicare Advantage Network Adequacy (p. 99424)

We generally support CMS' efforts to "ensure consistent and equitable access to healthcare services for all Medicare Advantage enrollees" (p. 99425). However, we continue to regularly hear about MA plan enrollees facing provider networks that are not adequate to meet their needs.

As we have periodically raised since the rules were changed,[14] we urge CMS to revisit network adequacy standards that were weakened in the final 2021 rule. These provisions should be rescinded, specifically: the reduction in the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards; the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers; and the elimination of time and distance limits from network adequacy requirements for dialysis facilities.[15]

In addition, as we periodically state,[16] in order to improve access to acute and post-acute care for MA enrollees, we urge CMS to include inpatient rehabilitation facilities (IRFs), comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility-specialty types that are subject to MA network adequacy evaluations per 42 CFR §422.116(b)(2).

Promoting Informed Choice – Expand Agent and Broker Requirements Regarding Medicare Savings Programs, Extra Help, and Medigap (p. 99427)

To further promote informed enrollment decisions, CMS is proposing to expand the number of required topics that an agent or broker must cover before an individual's enrollment to ensure the individual is educated on important topics and options that may factor into their enrollment decision. CMS proposes requiring agents and brokers to discuss the individual's potential eligibility for the Low-Income Subsidy (LIS) and Medicare Savings Programs (MSPs), as well as the potential impact of MA enrollment on future Medigap guaranteed issue rights and where an individual might access additional information about these programs.

We strongly support these additions concerning what agents/brokers must cover, but we urge CMS to both expand the list of topics, and institute a meaningful process to ensure that such topics are, indeed, discussed, with appropriate penalties for non-compliance.

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[14] See, e.g., Center for Medicare Advocacy, HHS Transition Memorandum (December 2020), available at: https://medicareadvocacy.org/transition-memo-2020/#MA

[15] See, e.g., discussion in the Center's Weekly Alert "Final Rule for Medicare Parts C and D Includes Weakened Standards for Medicare Advantage Networks" (May 28, 2020), available at: https://medicareadvocacy.org/final-rule-for-medicare-parts-c-and-d-includes-weakened-standards-for-medicare-advantage-networks/.

[16] See, e.g., Center for Medicare Advocacy comments to Proposed 2024 Part C & D rule (February 13, 2023), available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

With respect to communications regarding Medigap plans, Medigap carriers in 46 states can deny a policy to an MA enrollee who wants to switch to traditional Medicare, outside of the initial open enrollment period and limited scenarios triggering guarantee issue rights. Outside of these limited time periods, 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.

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.

With respect to other topics that agents/brokers should be required to cover, we offer here and reiterate an excerpt from our comments to the 2024 proposed rule:[17]

> We strongly supported CMS' additions to the Pre-Enrollment Checklist (PECL) but suggested that CMS go further:
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> > We note that the current standardized PECL form (at Appendix 1 of the MCMG) currently does not address utilization management, including prior authorization. Given all of the challenges MA enrollees face with prior authorization, as addressed earlier in this proposed rule, this topic should be addressed in the PECL. In addition, while there is a prompt to review the provider directory in order to ensure one's providers contract with the plan, it should be disclosed that a provider can be terminated from the plan's network (or leave) the plan mid-year. This should be accompanied by a statement that an enrollee has a right to seek care outside of a plan's network when an in-network providers or benefits is unavailable or inadequate to meet an enrollees' medical needs, as discussed in section III.C. of this proposed rule, above. In addition, the checklist include a specific requirement that, if the prospective enrollee is a dual eligible, the plan or broker must provide a rudimentary explanation of whether benefits offered by the plan duplicate benefits already available to the individual through Medicaid.
> >
> > In order to ensure that agents and brokers do not continue to mislead or omit required information, CMS must ensure that this provision is enforced. We assume that such discussions would be recorded under current rules, which should help with respect to accountability. We also suggest that if it is found that an agent or broker did not

[17] CMA comments to the proposed 2024 rule are available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

review the requisite material, or materially mislead an individual concerning the content or subject matter of the PECL, that plans be forced to withhold any commissions earned from the sale of that product to the affected individual. Without teeth to enforcement and oversight, misconduct will likely continue at an unacceptable rate.

One way to enhance oversight and enforcement of agent/broker conduct would be to require that agents and brokers sign an attestation form that whatever product is being sold is appropriate for that beneficiary. Such an attestation is currently required for the sale of Medigap (Medicare supplemental insurance policies). [See subsequent discussion re: model NAIC language re: Medigap sales.]

We urge CMS to include these additional topics to be addressed and additional accountability measures to ensure compliance. It is our understanding that many agents have an app where they can "check the box" that they have met all Medicare requirements about counseling when enrolling people in plans. Such app (or apps) would probably just be updated to include CMS' proposed additional subjects, and many agents would just "check the box." CMS must ensure that there is more accountability than mere self-reporting on an app.

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. 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.

Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (p. 99430)

CMS proposes to further promote informed choice and transparency by requiring MA organizations to make provider directory data available to CMS to populate Medicare Plan Finder (MPF). Specifically, CMS proposes enhancing MPF with searchable provider information for all MA organizations and requiring that MA organizations attest to accurate provider directory data, make provider data available to CMS to populate MPF, and update the data accessed by MPF no later than 30 days after being notified of a change in provider information. To ensure the information in provider directories on Medicare Plan Finder is accurate, CMS would require plans to meet data compliance and quality checks, which will be outlined in upcoming technical guidance. We strongly support these proposed changes.

Promoting Informed Choice – Enhancing Review of Marketing & Communications (p. 99433)

To enhance CMS' oversight of the marketing and communications materials likely to influence an individual's enrollment decision, the agency proposes changes to their definition of

"marketing" to increase the number and type of advertisements that are required to be submitted to CMS and subject to review before their use. By broadening the "marketing" definition and CMS oversight, CMS asserts that it can better ensure that current or potential enrollees are not receiving misleading, inaccurate, or confusing information.

CMS states that broadening the definition of marketing would expand the scope of materials that must be submitted to CMS for review. While we are encouraged by CMS' effort to ensure that Medicare beneficiaries are better informed, CMA has long urged CMS to revisit its distinction between marketing and communications and their respective, corresponding requirements. As we have indicated in prior comments to CMS, we disagree with the agency's assertion that documents which may impact an enrollment decision, but are not intended to do so, don't qualify as marketing documents. If a beneficiary uses a plan-issued document to make enrollment choices, the sponsor's intent is irrelevant. Plan and agent/broker-issued content should be subject to stringent oversight by CMS to ensure accuracy and readability.

Enhancing Rules on Internal Coverage Criteria (p. 99455)

CMS intends to build upon and enhance the regulations from the CY 2024 MA and Part D final rule, specifically, the policies related to the use of internal coverage criteria, by defining the phrase "internal coverage criteria," establishing guardrails to preserve access to benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

CMS notes that the proposals in this rule have been informed by the utilization management audits CMS conducted throughout 2024 that will continue into 2025. Key proposals include defining the meaning of "internal coverage criteria" to clarify when MA plans can apply utilization management, ensuring plan internal coverage policies are transparent and readily available to the public, ensuring plans are making enrollees aware of appeals rights, and addressing after-the-fact overturns that can impact payment, including for rural hospitals. In addition, CMS notes that efforts are underway that will allow the agency to collect detailed information from initial coverage decisions and plan-level appeals, such as decision rationales for items, services, or diagnosis codes that will provide a better line of sight on utilization management and prior authorization practices, among many other issues.

While we asserted that MA plans should not be allowed to have any internal coverage criteria, particularly if it is "proprietary" and unavailable to the public, we nonetheless strongly supported CMS' efforts in the CY 2024 rule to attempt to rein in inappropriate MA plan coverage criteria that can be more restrictive than traditional Medicare rules.[18] We similarly support CMS' proposals in this rule, but assert that the agency must go further to adequately protect MA enrollees and hold MA plans accountable.

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[18] See CMA comments to the proposed 2024 rule are available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

Among other changes, CMS should broadly prohibit MA plans from using internal coverage criteria that limits access to benefits. Such criteria should only be used to expand access to coverage beyond current Medicare law, regulations and policy. Should CMS fail to issue such a prohibition, the agency should require that internal coverage criteria not violate civil rights law (e.g., such criteria should not automatically deny coverage because of an individual's advanced age, or developmental disabilities). Any denial of services should include the actual coverage criteria upon which the plan relies so that an MA enrollee can provide a meaningful challenge.

Further, we urge CMS to apply the same efforts to enhance transparency surrounding MA plans' decision-making to its contractors that administer the traditional Medicare claims and appeal processes, including Medicare Administrative Contractors (MACs), Independent Review Entities (IREs), Quality Improvement Organizations (QIOs). It is our understanding that these entities also may employ internal coverage criteria that are not included in Medicare statute, regulations or sub-regulatory guidance (for example, we have heard that Maximus uses InterQual criteria). These contractors should be prohibited from using internal coverage criteria, or, at the very least, disclose their use and post their content on their websites. Much of the rationale behind fostering transparency regarding MA plans' use of such criteria also apply to Medicare contractors, including the need for beneficiaries and providers to be informed about what rules and standards are being applied to decisions about claims.

As we noted in our comments to the proposed 2024 rule,[19]

> CMS should increase oversight of Medicare contractors, including the Quality Improvement Organizations (QIOs) and Independent Review Entities (IREs) that handle external review of MA appeals. Along with the Medicare Administrative Contractors (MACs) in traditional Medicare, we find that these contractors routinely issue incomplete and/or incorrect opinions and sometimes misapply or misinterpret the law, often to the detriment of Medicare beneficiaries seeking medically necessary, covered services. Extensive oversight and training of these contractors is required, as well as further training of Office of Medicare Hearings and Appeals' (OMHA) cadre of Administrative Law Judges (ALJs) and the Departmental Appeals Board (DAB) on Medicare coverage guidelines and MA plans' obligations to follow them.

Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (p. 99461)

CMS is proposing four modifications to clarify and strengthen existing regulations regarding MA organizations' coverage of and responsibility to provide all reasonable and necessary Medicare Part A and B benefits. We strongly support these modifications and note that they are generally consistent with principles of due process and with the agency's final rule creating processes in traditional Medicare for both retrospective and prospective appeals for eligible beneficiaries who

[19] Center for Medicare Advocacy comments to Proposed 2024 Part C & D rule (February 13, 2023), available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

disagree with their hospital's decision to reclassify them from inpatients to outpatients receiving observation services 89 Fed. Reg. 83240 (Oct. 15, 2024).

First, CMS is proposing to clarify the rule that if an enrollee has no further liability to pay for services furnished by an MA organization, a determination regarding these services is not subject to CMS' administrative appeal process. Specifically, CMS is clarifying that an enrollee's further liability to pay for services cannot be determined until an MA organization has made a determination on a request for payment. We appreciate the clarification that the "no further liability" limitation is *only* applicable if there's been a claim payment determination. We support this proposal and concur with CMS' observation that some MA organizations often improperly label adverse coverage decisions as "contractual denials" or "payment decisions" which can leave MA enrollees without an avenue to appeal decisions that directly affect their immediate medical care as well applicable cost-sharing. We also appreciate CMS' reference in footnote 252 to a state Medicaid agency's specific rights to appeal an adverse payment decision for a QMB or other full-benefit dual eligible, and that rights may exist even when 422.562(c)(2) would otherwise preclude a right to appeal.

Second, CMS proposes to modify the definition of an organization determination to clarify that a coverage decision made by an MA organization contemporaneously with when an enrollee is receiving such services, including level of care decisions (such as inpatient or outpatient coverage), is an organization determination subject to appeal and other existing requirements. CMS specifically references situations in which an MA organization does not inform an enrollee of a concurrent review determination and the enrollee is not afforded the opportunity to appeal the decision (or have an appeal submitted on their behalf). We concur with CMS' observation that there is inconsistent misapplication of MA policies governing concurrent review creating variable outcomes for providers and enrollees. We agree with CMS that "the most appropriate and effective manner to address this issue is to clarify and strengthen the existing requirements related to organization determinations" (pp, 9964-5). We strongly support CMS' assertion that its "proposed clarification to the definition of organization determination is inclusive of all other types of services" (p. 99465). We also strongly agree with CMS' assertion that "[p]ut simply, a concurrent review decision (whether made unsolicited or in response to a request) is a coverage decision while a retrospective review decision (whether made unsolicited or in response to a request) is a payment decision" (p. 99465). We therefore strongly support the proposal to include concurrent reviews as a type of determination subject to the rules at 422.138(c). We also strongly agree with the clarification that "a decision by an MA organization made preservice, post-service, or concurrent with the enrollee's receipt of services in an inpatient or outpatient setting is an organization determination subject to the rules in part 422, subpart M which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights" (p. 94465). As a general matter and consistent with due process principles, enrollees should *not* be put in a position where they do "not know a change in [patient] status has occurred until they are required to pay the outpatient deductible and applicable costsharing" (p. 99464).

We also strongly support the directive that MA plans provide enrollees with notice of retrospective review decisions, before a decision on payment has been made, so that enrollees

may invoke their appeal rights and argue for, e.g., coverage of inpatient hospital services, which could change their cost-sharing amounts. In response to the request for comments on the type of notice MA organizations should utilize (p. 99466), we would point CMS to the Medicare Change of Status Notice recently created for implementation of appeals of patient status in traditional Medicare.[20] The MA notice could similarly state that the enrollee's hospital bill "may be lower or higher," due to the MA organization's decision, and that the "MA plan can give you more information." The notice could then describe how to start an appeal.

Third, CMS proposes to strengthen the notice requirements to ensure that a provider who has made a standard organization determination or integrated organization determination request on an enrollee's behalf, or when it is otherwise appropriate, receives notice of the MA organization's decision. We concur with CMS that "[w]e do not find a compelling reason that a provider should not receive notice of a standard organization determination when the provider submitted a request on behalf of an enrollee or when it is otherwise appropriate for the provider to receive notice of the determination" (p. 99467). We strongly support CMS' proposals to improve notice to providers.

Fourth, CMS proposes a change to the reopening rules to eliminate the discretion of an MA organization to reopen an approved authorization for an inpatient hospital admission. CMS limits the proposed clarification to organization determinations made by an MA organization that involve inpatient hospital admission decisions. We strongly support this proposed change and also urge CMS to consider applying similar considerations beyond decisions concerning inpatient admissions. The same rationale relying upon an admitting physician's expectations at the time of admission based on the known and documented clinical information can apply to other care settings, warranting greater deference to clinical decision-making rather than MA plan second-guessing concerning whether a given service should be covered.

Formulary Inclusion and Placement of Generics and Biosimilars (p. 99470)

In this proposed rule, CMS clarifies pursuant to these authorities that plan formularies must provide beneficiaries with broad access to generics, biosimilars, and other lower-cost drugs to be compliant with this requirement.

V. Improving Experiences for Dually Eligible Enrollees (p. 99485)

CMA agrees with CMS that despite improvements over the years, "there remain aspects of care for dually eligible individuals that can be misaligned, confusing, or duplicative even when a dually eligible individual is enrolled in Medicare and Medicaid managed care plans operated by the same parent organization." We applaud CMS for addressing some of these challenges to care for dually eligible beneficiaries through this proposed rule.

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[20] See https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative-bni/ffs-mcsn.

CMA supports the proposal to require that certain D-SNPs provide one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled. We agree that having a single card for both Medicare and Medicaid plans will reduce confusion regarding billing on the provider side, and confusion for beneficiaries, limiting beneficiary burden and making care more accessible for beneficiaries.

CMA supports the proposal of integrating health risk assessments. We agree with CMS that this integration would reduce confusion, assessment burden, and fragmentation for dually eligible individuals enrolled in certain D-SNPs, while also encouraging coordination of care since the assessment information will be found in one place.

We also strongly support making State Medicaid Agency Contracts (SMACs) public as SMACs contain critical information on what requirements are present for D-SNPs in a state regarding coordination and integration requirements. We also recommend that CMS require states to solicit meaningful public input from stakeholders in the SMAC development process through written and oral comment opportunities. We believe this is particularly important for dually eligible individuals with MH and SUDs, many of whom inadvertently lose access to the Parity Act protections associated with their Medicaid benefits when they enroll in these integrated plans that are not subject to Parity. We strongly recommend CMS work with Congress to require D-SNPs be subject to the Parity Act. In the meantime, however, this would enable stakeholders to advocate to states to adopt parity or comparable requirements in their SMACs to ensure dually eligible individuals have equitable access to MH and SUD care in D-SNPs.

Conclusion

Thank you for the opportunity to provide these comments. For additional information, please contact David Lipschutz DLipschutz@MedicareAdvocacy.org or Kata Kertesz KKertesz@MedicareAdvocacy.org at (202)293-5760.

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