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Matthew Eyles

President & Chief Executive Officer

February 13, 2023

Administrator Chiquita Brooks-LaSure Centers for Medicare & Medicaid Services (CMS) Attention: CMS-4201-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications ("Proposed Rule")

Dear Administrator Brooks-LaSure:

Americans agree: The Medicare Advantage (MA) and Part D programs are enormously successful models of public/private partnerships that offer choice, competition, and innovation in their coverage and care. These programs deliver high-quality, affordable coverage and care to tens of millions of America's seniors and people with disabilities. AHIP¹ welcomes the opportunity to comment on the Proposed Rule, which would have significant impacts on these programs.

More than 30 million Americans have chosen MA – almost half of those eligible for Medicare. MA plans deliver better services, better access to care, and better value than the original Medicare program. Enrollees in MA are more racially and ethnically diverse and are more satisfied with their coverage than those in original Medicare. MA also enjoys strong bipartisan support.² And more than 50 million enrollees are receiving robust access to prescription drugs through Part D plans.³ Despite exorbitant launch prices for new drugs and out-of-control drug price increases on existing medicines, Part D plans have kept premiums steady by negotiating lower costs with drug manufacturers and pharmacies, using available, tested and effective cost management and negotiating tools.

¹ AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

² See, e.g., the recent <u>letter</u> to CMS from a bipartisan group of more than 60 Senators.

³ More than 27 million receive their Part D coverage through MA plans.

To build on these successes, AHIP supports a number of proposals that would strengthen consumer protections while retaining flexibility, choice, competition, and value. At the same time, we are concerned that certain proposals would reduce funding or increase costs without benefiting seniors and people with disabilities. Further, the sweeping changes under consideration here, when combined with recent statutory changes and other payment and regulatory changes either finalized or proposed elsewhere, will increase financial and operational uncertainties and create new barriers to the continued availability of high-value, affordable coverage. Accordingly, we urge CMS to consider how the combined impacts of these numerous changes could inhibit innovation, increase confusion and complexity, and ultimately harm seniors and people with disabilities. We also urge CMS to consider regulatory approaches that will ensure stability and value for the tens of millions of people these programs serve. The following is a summary of key areas of support and concern, with more information in our attached detailed comments.

Key Proposals We Support Include:

- New Marketing Requirements That Would Protect Medicare-Eligible Americans Without Unduly Burdening Access to Help in Choosing Medicare Options. AHIP appreciates CMS' efforts to enhance federal requirements designed to protect Medicare-eligible Americans from misleading advertising, and to reduce confusion and abrasion. AHIP supports many of CMS' proposals to add new marketing standards and oversight requirements to the robust rules already in place. However, as discussed in our attached detailed comments, CMS should reconsider how certain proposals such as mandated waiting periods for meetings with trusted agents and brokers could unduly inconvenience seniors and people with disabilities who face social barriers, mobility challenges, or rely on trusted family members or caregivers who have limited availability to participate in multiple sessions with the Medicare-eligible person. In addition, we believe certain proposals require longer implementation timelines than CMS has proposed given the need for additional CMS guidance, revised materials and/or updated training.
- New Prior Authorization Standards That Clarify MA Flexibilities Without Unduly Limiting the Ability to Promote High Value Care. We appreciate that CMS recognizes utilization management tools like prior authorization (PA) are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. Numerous studies have found Americans frequently receive inappropriate care in a variety of settings for many different medical procedures, tests, and treatments. PA can ensure care is delivered in the most appropriate setting, at the most appropriate frequency, and by the most appropriate provider. At the same time, health insurance providers have been working hard to

⁴ The Institute of Medicine has confirmed that geographic variations in spending are substantial, pervasive, and persistent over time and there is little to no correlation between spending and health care quality. In a national survey of over 2,000 physicians, most (64.7%) reported at least 15-30% of medical care is unnecessary.

make PA more efficient, more effective, and less burdensome. We support CMS proposals that build on these efforts by clarifying the scope of permissible PA, increasing transparency, and (in a separate proposed rule) expanding electronic PA. However, in our detailed comments we urge CMS to retain long-permitted flexibilities in the MA program so plans can encourage the delivery of high-quality care in safe, cost-effective alternative settings that are covered in the original Medicare program. We also are concerned about the feasibility of implementing new restrictions and process mandates for 2024 given MA bid cycle and operational needs.

• Provisions That Would Promote Health Equity. AHIP continues to strongly support CMS' efforts to advance health equity. We support provisions in the Proposed Rule such as enhancing digital health literacy and using quality improvement program activities to reduce disparities in health and health care. We also support CMS' efforts to develop a health equity index reward in the Star Ratings Program but have concerns with methodological and design issues in the index proposed by CMS. Additionally, we recommend that CMS improve enrollee data collection and align data collection standards across programs.

Key Areas of Concern Include:

• Star Ratings Program Changes That Would Not Increase Quality but Would Reduce Benefits or Increase Premiums. We have serious concerns with proposed changes to the Star Ratings program, including proposals to eliminate the reward factor and limit application of the hold harmless policy for the improvement measures, which would make it more difficult for MA plans to obtain funds to offer more choices, expand supplemental benefits, and keep premiums low. We are also concerned that implementation of Inflation Reduction Act (IRA) changes in Part D could further negatively affect certain Star Ratings measures and plan performance due to factors outside of plan control. While we appreciate CMS proposing to decrease the weight of survey measures relative to the weight of clinical outcome measures as AHIP has previously recommended, the overall impact of the Star Ratings proposals would be higher premiums and/or reduced benefits for enrollees, impacts that would disproportionately affect seniors and people with disabilities in underserved communities without increasing quality.

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⁵ In July 2022, AHIP posted a comprehensive report on how health insurance providers have delivered on their commitments to improve PA for patients and providers. This report follows up on the 2018 Consensus Statement among providers, health insurers, and other stakeholders recommending opportunities to improve the PA process. ⁶ At the same time, we encourage CMS to review separate comments that AHIP members may submit on this topic so the agency more fully appreciates the investments MA plans have made to improve patient experience and their perspectives on the potential implications of the proposed change. We also urge CMS to continue working with the Agency for Health Research and Quality (AHRQ) and National Committee for Quality Assurance (NCQA) to research longer-term solutions to improve the CAHPS survey and response rates.

- New Network Requirements That Would Fail to Account for Provider Shortages and Related Factors. Every day, health insurance providers work with people, providers, and communities to ensure access to mental health care and support through methods such as coordinating and integrating mental health with medical and physical health care, expanding access to telehealth appointments, and reducing the stigma associated with mental health conditions. We also recognize that with more Americans of all ages seeking mental health care, capacity is being stretched to its limits. AHIP and our member organizations have developed specific policy recommendations to improve access, care, and equity for patients. Certain CMS proposals build on these efforts such as promoting continuity of care for behavioral health services through MA care coordination programs. However, we have significant concerns that proposals to apply new time and distance standards to three behavioral health specialty types and to impose appointment wait time mandates for behavioral health and primary care fail to appropriately account for provider shortages and other factors outside plan control. A more flexible approach is needed to accommodate these reasonable factors and avoid placing unreasonable expectations or burdens on providers.
- Proposed Changes to Part D Medication Therapy Management (MTM) Program Requirements That Would Be Costly and Disruptive. Given major changes to Part D taking affect under the IRA, CMS should not be mandating a rapid increase in staffing and administrative structure to implement proposed expanded eligibility criteria for MTM programs. Before any such changes are made, additional analysis is needed to assess the effectiveness of the MTM program and alternative methods already being used by plans and contracted providers. However, if the proposal is finalized, we urge that changes be phased in over time.

Overall Concerns with Magnitude of Proposed Changes Affecting MA. In addition to our comments on the specific provisions in the Proposed Rule, it is important to consider them on a combined basis and in the context of a broader set of policy changes affecting the MA program.

• Taken together, CMS in one plan year is making (or proposing to make) sweeping changes affecting critical components of the MA program without a comprehensive assessment of the combined impacts of those measures. The sheer magnitude of changes in the Proposed Rule is extensive, with major proposals affecting key MA elements including utilization management, marketing, and Star Ratings. At the same time, there are other major changes outside the Proposed Rule affecting the MA program: the recently issued final Risk Adjustment Data Validation rule; the significant proposed changes in the interoperability rule that will affect the MA program; and proposed major changes relating to the risk adjustment model and other payment components in the 2024 Advance Notice.

⁷ https://www.ahip.org/resources/a-vision-for-improved-mental-health-care-access-for-every-american.

- We are concerned that CMS has not considered how provisions applying similar approaches to different policy objectives could adversely affect enrollees. For example, the Proposed Rule would expand situations in which MA plans must proactively conduct outreach to members after a primary care or mental health provider leaves a network. This change should not be considered in a vacuum; adding more outreach to the robust proactive communications that MA plans already conduct (e.g., care coordination activities, claims/appeals processes, etc.) creates the risk that seniors and people with disabilities come to view the combined impacts of these contacts as overly aggressive and intrusive rather than helpful.
- The changes are taking place while plans are working to implement the biggest changes to the Part D program since its inception due to the recently enacted IRA. Changes in Part D can have significant impacts on MA organizations, including increasing the cost of providing Part D coverage as supplemental benefits, and focusing organizational time and resources on comprehensive implementation efforts.
- These provisions are on top of the numerous changes that have been made to the MA and Part D programs in prior years, some of which are now being undone under the Proposed Rule. It means MA plans are required to devote significant resources each year to implementation, training, provider contracting, communications, and other actions resources that could otherwise be used to provide additional benefits to enrollees.

The cumulative impact of those factors is significant. They create tremendous uncertainty that inhibits planning and investments in long-term innovations. These changes impose higher administrative costs due to factors outside of plan control. Compliance is more challenging when systems and training requirements must be constantly updated, particularly when paired with extremely short implementation deadlines that fail to reflect MA and Part D bidding cycles and operational and contracting needs. The accumulated changes also create more confusion and complexity for enrollees, family members, agent/brokers, and providers. **Ultimately, all these factors combine to increase program costs, limit choice, reduce supplemental benefits, and/or increase premiums.**

As the MA program continues to grow, we urge CMS to account for how so much uncertainty and change can undermine the ability of MA plans to continue offering innovative, affordable options to seniors and people with disabilities. We recommend that CMS seriously consider options to bring more stability to the program by limiting the number and scope of changes, extending implementation timelines, and other approaches. We look forward to discussing those strategies with CMS.

The Value of Medicare Advantage

MA delivers better services, better access to care, and better value through innovative, patient-centered programs that improve quality and reduce costs for seniors and the most vulnerable Americans with disabilities.

Care for diverse and vulnerable populations. Medicare Advantage plans care for a growing share of Medicare beneficiaries dually eligible for Medicare and Medicaid benefits. In 2019, 44% of dual-eligible beneficiaries were enrolled in MA, up from 25% in 2013⁸, and research shows dual-eligibles enrolled in MA have greater health needs than those in original Medicare. MA also serves a more racially and ethnically diverse population. In 2020, 30% of MA enrollees were minorities, compared with 20% of those in original Medicare. Minority populations are especially prevalent among those who choose MA plans that combine both medical and prescription drug coverage with monthly premium beyond the standard Part B premium.

In 2020, over half of all racial and ethnic minorities were enrolled in MA, up dramatically from 2006, when only about a third of minorities chose MA.¹² Recent research shows MA plans have made substantial progress in reducing health disparities for racial and ethnic minorities and rural populations across key health measures such as getting an annual flu vaccine, diabetic eye and kidney exams, and access to preventive and ambulatory services.¹³

Greater care coordination and more comprehensive benefits. MA plans work with their members to prevent, detect, and manage chronic conditions through programs that better integrate and coordinate care compared to original Medicare. MA plans also provide more comprehensive benefits than original Medicare. Some of these essential benefits include integrated dental, hearing, and vision coverage along with innovative telehealth options. In recent years, MA plans began offering new types of benefits that address various social barriers to better health, such as wellness programs and nutrition, transportation, and in-home caregiver services, and the availability of these benefits has grown tremendously. In 2022, 1,034 plans offer a new type of health-related benefit designed to help support enrollees such as in-home support services, home-based palliative care, adult day services, or caregiver support, and

⁸ Murphy-Barron, C, Pyenson, B, Ferro, C, et. al. "Comparing the Demographics of Enrollees in Medicare Advantage and Fee-For-Service Medicare." Milliman. October 2020.

⁹ NORC at the University of Chicago. "Analysis of COVID-19 Impact on Medicare Advantage and Fee-for-Service Beneficiaries." May 2021.

¹⁰ AHIP. "Medicare Advantage Demographics Report." January 2023.

¹¹ NORC analysis of June 2021 CMS Medicare enrollment and demographic data, conducted for AHIP. December 2021.

¹² Trish, E, Valdez, S, et. al. "Substantial Growth In Medicare Advantage And Implications For Reform." Health Affairs. 42. No 2 (2023): 246-251.

¹³ RAND Health Care. "Trends in Racial, Ethnic, Sex, and Rural-Urban Inequities in Health Care in Medicare Advantage: 2009-2018." December 2021.

increase of 111% since the benefits were first made available in 2020. ¹⁴ The availability of special supplemental benefits for chronically ill Americans – benefits like nutrition support, transportation for non-medical needs, or structural home modifications to support independent living – have grown even faster, increasing by almost 400% to more than 1200 plans in 2022. ¹⁵

More financial security. All MA plans deliver affordable coverage to members by capping annual out-of-pocket costs while individuals with original Medicare coverage alone are exposed to extraordinarily high cost-sharing. MA premiums continue to decline, falling 8% from 2022 to an average of \$18 a month in 2023. ¹⁶ Further, the Medicare Payment Advisory Commission (MedPAC) reports that in 2023, 99% of those eligible for Medicare have an option to enroll in a MA plan that offers drug coverage for no additional cost. ¹⁷

Better health outcomes. MA has been shown to provide better quality of care on various clinical quality measures ¹⁸, reduce hospital admissions and readmissions as well as patient days spent in rehabilitation facilities and nursing homes ^{19,20,21}, and lower hospital use in the last days of life. ²² Peer-reviewed research has found that MA plans outperform original Medicare across a range of metrics, including better access to preventive care and better clinical outcomes. ²³ For example, MA enrollees are more likely to receive important preventive services like annual wellness exams and cognitive screenings than their counterparts in original Medicare. ²⁴

¹⁴ ATI Advisory. "New, Non-Medical Supplemental Benefits in Medicare Advantage in 2022." January 2022. Accessed at https://atiadvisory.com/wp-content/uploads/2022/01/Plan-Year-2022-Medicare-Advantage-New-Non-Medical-Supplemental-Benefits.pdf.

¹⁵ Id

¹⁶ CMS. CMS Releases 2022 Premiums and Cost-Sharing Information for Medicare Advantage and Prescription Drug Plans. September 2021. Accessed at https://www.cms.gov/newsroom/press-releases/cms-releases-2023-premiums-and-cost-sharing-information-medicare-advantage-and-prescription-drug.

¹⁷ Medicare Payment Advisory Commission. "The Medicare Advantage Program: Status report and mandated report on dual-eligible special needs plans." January 2023 Public Meeting.

¹⁸ Agarwal, R., Connolly, J., Gupta, S., et al. Comparing Medicare Advantage And Traditional Medicare: A Systematic Review. *Health Affairs* 40(6): 937-944. June 2021.

¹⁹ Kumar, A., Rahman, M., Trivedi, Amal, N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoSMed* 15(6): e1002592.

²⁰ Jung D., DuGoff E., Smith M., Palta M., Gilmore-Bykovskyi A., Mullahy J. Likelihood of hospital readmission in Medicare Advantage and Fee-For-Service within same hospital. *Health Serv Res.* 2020;55:587–595.

²¹ Schwartz, A., Slaoui, K., Foreman, R., et al. Health Care Utilization and Spending in Medicare Advantage vs. Traditional Medicare: A difference-in-difference analysis. Jama Health Forum. 2021.

²² Sungchul, P., Teno, J., White, L., Coe, N. Effects of Medicare advantage on patterns of end-of-life care among Medicare decedents. Health Serv Res. February 13, 2022.

²³ DuGoff, E., Rabak, R., Diduch, T., et al. Quality, Health, and Spending in Medicare Advantage and Traditional Medicare. *The American Journal of Managed Care* 27(9). September 2021.

²⁴ Jacobson, M., Thunell, J., and Zissimopoulos, J. Cognitive Assessment at Medicare's Annual Wellness Visit in Fee-For-Service and Medicare Advantage Plans. *Health Affairs* 39 (11): 1935–1942. November 2020.

Research also suggests that MA does a better job in addressing complex care needs than original Medicare. In one cross-sectional study of 1.8 million Medicare beneficiaries, those enrolled in MA had lower rates of hospital stays, ED visits, and 30-day readmissions. Overall, the study found that among Medicare beneficiaries with complex care needs, those enrolled in MA had lower rates of acute care utilization, suggesting that managed care activities in MA may influence the nature and quality of care provided to these beneficiaries.²⁵

Studies have also found better outcomes for patients with specific chronic diseases when they are covered by MA. When compared to patients with original Medicare, MA members with end stage renal disease have lower mortality and reduced utilization. ²⁶ Further, MA members with diabetes and cardiac disease experienced fewer emergency room visits and hospitalizations and better quality scores compared with those covered under original Medicare. ²⁷ Lastly, MA members who experience a hip fracture have shorter lengths of stay and fewer hospital readmissions. ²⁸

Cost efficiency for seniors and taxpayers. For many years, average MA plan bids for delivering the basic Medicare benefit have been well below original Medicare costs — 83% of original Medicare, based on the latest MedPAC estimates. Research provides examples of how MA plans achieve these savings: for example, through more efficient prescribing of Part B drugs and MA enrollees receiving care from more efficient providers. Further, according to MedPAC, average payments to MA plans in 2023 are projected to be on par with original Medicare costs while MA offers supplemental benefits and enhanced financial security for seniors. In fact, in areas where MA enrollment is higher relative to original Medicare, additional MA enrollment leads to slower original Medicare costs and spending growth as

²⁵ Antol, D., Schwartz, R., Caplan, A., Casebeer, A., Erwin, J., Shrank, W., Powers, B. Comparison of Health Care Utilization by Medicare Advantage and Traditional Medicare Beneficiaries with Complex Care Needs. JAMA Health Forum. 2022.

²⁶ Powers, B., Yan, J., Jingsan, et al. The Beneficial Effects of Medicare Advantage Special Needs Plans for Patients with End-Stage Renal Disease. *Health Affairs* 39(9): 1486–1494. September 2020.

²⁷ Landon, B., Zaslavsky, A., Saunders, R., et al. A comparison of relative resource use and quality in Medicare Advantage health plans versus traditional Medicare. *American Journal of Managed Care* 21(8): 559-566. August 2015.

²⁸ Kumar, A., Rahman, M., Trivedi, Amal N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoSMed* 15(6): e1002592. June 2018.

²⁹ Medicare Payment Advisory Commission. January 2023 Public Meeting Presentation. January 2023.

³⁰ Anderson, K., Polsky, D., Dy, S., et. al. Prescribing of low-versus high-cost Part B drugs in Medicare Advantage and traditional Medicare. *Health Serv Res.* 2021.

³¹ Medicare Payment Advisory Commission. January 2023 Public Meeting Presentation. January 2023.

providers employ MA practice patterns and care guidelines for their remaining original Medicare patients. 32,33,34,35

Leading the way in value-based care. MA plans are leading the way in leveraging value-based payment arrangements, working with providers to bring better quality and more affordable care to patients. In 2021, more than half (58%) of health care payments from MA plans were tied to alternative payment models in 2020, compared to 47% in original Medicare and 40% overall. And research shows that these alternative payment arrangements mean MA patients get higher value care. One recent study found that those enrolled in MA received 9.2% fewer low-value services than those in original Medicare. The MA enrollees in health maintenance organizations and those in primary care organizations reimbursed within advanced value-based payment models had the lowest rates of low-value care. Another study showed MA plan value-based payment arrangements with providers resulted in lower costs, improved patterns of utilization, and higher survival rates.

High satisfaction. A recent survey finds continued high satisfaction with the MA program with 94% of senior voters with MA reporting satisfaction with their health care coverage. A strong majority of senior voters with MA are satisfied with access (95%) and affordability (90%) of medical care through their MA coverage. Among rural voters with MA, nearly all (96%) are satisfied with access of medical care through their MA coverage. Nine in ten voters with MA are satisfied with their prescription drug coverage (90%, including 60% very satisfied) and preventive services they receive (92%, including 64% very satisfied). Nine in ten (93%) voters with MA would recommend their coverage to their families or friends based on their personal experience. ³⁹

² Johnson, G., Figuero, J., Zhoi

³² Johnson, G., Figuero, J., Zhou, X., et al. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9): 1707-1715. September 2016.

³³ Callison, K. Medicare managed care spillovers and treatment intensity. *Health Economics* 25(7):873-887. July 2016.

³⁴ Baicker, K., Robbins, J. Medicare payments and system-level health-care use: The spillover effects of Medicare managed care. *American Journal of Health Economics* 1(4):399-431. October 2015.

³⁵ Baicker, K., Chernew, M., Robbins, J. The spillover effects of Medicare managed care: Medicare Advantage and hospital utilization. *Journal of Health Economics* 32(6):1289-1300. December 2013.

³⁶ Health Care Payment Learning & Action Network. APM Measurement: Progress of Alternative Payment Models. November 2022. Available at: https://hcp-lan.org/apm-measurement-effort/2022-apm/.

³⁷ Boudreau, E., Schwartz R., Schwartz, A., Navathe A., Caplan, A., et.al. Comparison of Low-Value Services Among Medicare Advantage and Traditional Medicare Beneficiaries. *JAMA Health Forum.* 2022;3(9):e222935. doi:10.1001/jamahealthforum.2022.2935.

³⁸ Mandal, A. Tagomori, G., Felix, Randell V. et al. Value-based contracting innovated Medicare Advantage healthcare delivery and improved survival. *American Journal of Managed Care* 23(2): e41-e49. February 2017. ³⁹ Morning Consult National Poll. December 6-9, 2022. Available online at: https://medicarechoices.org/americans-like-ma-2023/.

Seniors and the most vulnerable Americans with disabilities deserve to know they can count on the essential benefits and affordable, high-quality coverage they need to stay healthy. That's why more than 30 million Americans – some 46% of all those eligible for Medicare – choose MA – with a recent study in *JAMA Health Forum* finding that more Americans are switching to MA plans from original Medicare. ⁴⁰

Conclusion

Again, we appreciate the opportunity to comment on the Proposed Rule and your continued commitment to partner with MA and Part D plans. Attached are detailed comments on the foregoing proposals and other provisions in the Proposed Rule. Our recommended changes are designed to maintain and grow strong and stable MA and Part D programs so the millions of seniors and people with disabilities who rely on them continue to receive the high-quality, coordinated care they deserve. We look forward to continuing to work together on policies that ensure affordable and innovative choices in MA and Part D to improve the health and well-being of Americans.

Sincerely,

Matthew Eyles

Matthew Eyles

President & Chief Executive Officer

⁴⁰ Unuigbe, A., Cintina, I., Koenig, L. Beneficiary Switching Between Traditional Medicare and Medicare Advantage Between 2016 and 2020. *JAMA Health Forum*.3(12):e224896. December 29, 2022.

AHIP Detailed Comments Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

General comment on effective date for new requirements

The MA and Part D Proposed Rule for CY 2024 codifies a number of existing provisions of MA and Part D guidance and adds a significant number of new requirements. It appears that the new provisions are generally effective for 2024 with some exceptions (e.g., certain Star Ratings proposals).

Discussion and Recommendations:

Given the volume and complexity of the changes proposed to take effect for CY 2024, CMS should provide MA plans with more time to implement the new requirements included in the Proposed Rule. By the time this rule is finalized, plans may have only several weeks to fully assess all of the changes to existing program requirements, adequately reflect these changes in their 2024 bids, modify contracts, and make systems and other operational changes needed to meet the 2024 effective date. We therefore urge CMS to delay the effective date to 2025 or later for new regulatory requirements that are finalized under this rule and are not required by statute or existing rules to take effect by 2024, including but not limited to:

- Proposed changes to MA plan use of utilization management (UM) policies and tools. Given the volume and complexity of the expansive set of proposed changes, as discussed in more detail below, we urge CMS to delay until 2026 the effective date of new regulatory requirements focused on UM that are finalized under this rule. A 2026 effective date would also align with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving PA proposed rule⁴¹ that also impacts MA plans.
- Changes to Part D Medication Therapy Management (MTM) program requirements. For reasons we detail in our comments below, AHIP recommends CMS not proceed with implementing the proposed MTM Program eligibility requirements. However, if CMS decides to proceed with expanding enrollment in the program in a final rule, we urge it to be done via a gradual/phased-in approach that allows plan sponsors sufficient time to adapt and scale up to better accommodate these new requirements. AHIP believes that—at a minimum—this approach is less disruptive (and costly) to enrollees, the Medicare program, and plans than simply adopting these changes as proposed and increasing enrollments by 64% in less than a year. These additional burdens would also be imposed at the same time as

⁴¹ 87 FR 76238, December 13, 2022.

program changes imposed by the Inflation Reduction Act (IRA) provisions and other significant CMS policy changes are being implemented into Medicare.

- Changes to the MA network standards and provider directories. We recommend CMS delay the requirement for the addition of the proposed new directory data elements until solutions like CMS' National Directory of Healthcare Providers & Services (NDH) are further explored and implemented to address the inherent challenges of provider directories. We also recommend CMS provide plans more time, up to CY 2025, to meet the new network adequacy requirements for behavioral health (BH) services. Workforce shortages and other factors outside plan control should also be addressed through a modified network adequacy exceptions process.
- Changes to the marketing requirements that rely on issuance of sub-regulatory guidance in advance of 2023 annual enrollment period (AEP). Given the breadth and scope of the proposed changes to the marketing rules, we are concerned that by the time the final rule and sub-regulatory guidance are released, plans and their partners may not have sufficient lead time to implement all of the finalized marketing related changes impacting the AEP for CY 2024. We recommend CMS consider a 2025 effective date to ensure successful implementation.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§§ 422.503(e), 422.504, 422.510 and 422.514)

CMS proposes to extend its regulatory prohibition on dual-eligible special needs plan (D-SNP) "look-alikes" to the segment level in cases where an MA plan benefit package (PBP) includes multiple segments with different benefit designs. In a conforming change, CMS proposes to provide itself with authority to sever the D-SNP "look-alike" segment from the related MA plan, which would allow the remaining segments of that MA plan to continue (along with any other MA plans offered under the same contract).

CMS proposes to identify existing MA plans as D-SNP "look-alikes" if they either project dual enrollment of at least 80% in their bids or have actual enrollment that exceeds the same regulatory threshold. Currently, the standard for existing plans is based only on actual enrollment. CMS specifies that the change would take effect for 2024.

Finally, CMS proposes to add regulatory language that would expressly permit termination of an MA contract when the contract meets the criteria for a D-SNP "look-alike" plan.

Discussion and Recommendations:

While AHIP has raised concerns in the past with the "look-alike" policy, the proposal to apply it to plan segments that meet the test for D-SNP "look-alike" plans would be a logical extension of such policy, and we appreciate the conforming change to allow remaining segments of the plan and other plans under the same contract to continue.

We also reiterate our prior concerns about the policy's failure to distinguish between full-benefit and partial-benefit dual eligibles for purposes of identifying D-SNP "look-alike" plans. While we understand the concern of CMS and states that "look-alike" plans may result in the diversion of full-benefit dual eligibles from integrated D-SNPs, partial-benefit dual eligibles are not eligible for Medicaid benefits (except for coverage of Medicare cost sharing) and cannot benefit from integrated D-SNPs to the same extent as full-benefit dual eligibles. Moreover, partial dual eligibles can benefit from the tailored care management approaches used by many MA plans and the supplemental benefits that MA plans can offer, especially special supplemental benefits for the chronically ill (SSBCI). Therefore, we continue to urge CMS to reconsider the practice of including of partial dual eligibles in calculating the 80% threshold for "look-alike" plans.

Regarding the proposed authority for CMS to terminate a MA contract that includes a plan that meets the criteria for a "look-alike" plan, we urge CMS to provide details regarding the circumstances under which it would use that authority instead of taking more incremental measures to achieve compliance with the "look-alike" policy.

Another issue noted by some of our members is that confusion can arise when crosswalk transactions are processed between segmented and non-segmented plans due to the variety of permissible scenarios. We understand that in some cases, crosswalk transition plans for 2023 were approved by CMS but MA plans later experienced incorrect denials during the plan crosswalk process despite the prior approval. With respect to crosswalking, we recommend the agency provide full details of requirements and status of approvals in the CMS Health Plan Management System (HPMS).

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (§ 423.38)

CMS proposes to align the timeframe for use of the Part D special enrollment period (SEP) based on new Medicare Part B general enrollment period (GEP) enrollment effective date parameters stemming from the Medicare enrollment statutory changes made by the Consolidated Appropriations Act, 2021(CAA).

Discussion and Recommendations:

We support CMS' proposal to align the timeframe for use of the Part D SEP based on new Medicare Part B GEP enrollment effective date parameters.

C. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38)

CMS proposes to add corresponding exceptional condition SEPs for MA and Part D enrollment to align with the Medicare enrollment statutory changes made by the CAA. Therefore, individuals who use an exceptional condition SEP to enroll in premium Part A and/or Part B would be provided an opportunity to enroll in a MA or Part D plan, provided that the individual meets applicable eligibility requirements for the plan.

Discussion and Recommendations:

We support CMS' proposal to align the Part C and Part D SEPs with the Medicare exceptional condition enrollment.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

CMS proposes the following changes for CY 2024 to support the advancement of health equity in MA:

- <u>Equitable access</u> Current regulations require that MA coordinated care plans ensure that
 covered services are provided in a culturally competent manner to all enrollees, including
 those with limited English proficiency or reading skills, and diverse cultural and ethnic
 backgrounds. CMS proposes to specify additional populations to whom this requirement
 would apply.
- <u>Improvements to provider directories</u> CMS proposes to add two new required data elements to MA provider directories: providers' cultural and linguistic capabilities (including American Sign Language (ASL)) and notations for providers waived to treat patients with medications for opioid use disorder (MOUD).
- <u>Digital health education</u> CMS would require MA plans to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits. Plans would also be required to make information about their programs available to CMS upon request.

• <u>Change to quality improvement program requirements</u> – CMS would require MA plans to incorporate one or more activities into their overall Quality Improvement Programs that help to reduce disparities in health and health care among their enrollees.

Discussion and Recommendations:

AHIP and our members strongly support the promotion of culturally competent care and equitable access to services for Medicare enrollees. We believe that everyone deserves affordable, high-quality health coverage and care. AHIP members have taken action to reduce disparities by addressing social drivers of health. Evidence shows that these solutions are working. For example, studies have found reduced health disparities for racial and ethnic minorities and rural populations served by MA plans across several key health measures, such as annual flu vaccines, diabetic eye and kidney exams, and access to preventive services. AA plans are also increasingly using expanded regulatory flexibility to offer more benefits, including non-medical services and supports, to enrollees in need to help address social drivers of health and advance health equity. Research demonstrates that services and interventions that address the health-related social needs of MA beneficiaries can result in improved quality of life, improved health outcomes, and reductions in unnecessary health care utilization.

In general, we support CMS' proposals to advance health equity. We ask CMS to ensure that the program requirements take into account data collection and other challenges that must be overcome for plans to identify individuals and populations facing health disparities and subsequently initiate activities and strategies to reduce such disparities. For example, some of the categories of underserved populations discussed under the agency's equitable access proposal are not clearly defined (e.g., religious minorities, areas with high levels of deprivation, people otherwise adversely affected by persistent poverty or inequality) or may present challenges to MA organizations with respect to beneficiary sensitivities around health plan collection of self-reported data (e.g., gender identity and sexual orientation). We therefore request that CMS consider the following comments and recommendations related to the health equity proposals:

- Equitable Access To ensure that services are provided in a culturally competent manner and enrollees have equitable access to services under the Medicare fee-for services (FFS) and MA programs, we recommend that CMS take the following additional steps:
 - + <u>Improve data standards</u>. Robust, accurate, actionable, and standardized demographic data is fundamental to advancing health equity. Current data content standards (whether from Office of Management and Budget, CMS, 2020 Census, or the 2011 Department of Health

⁴² RAND Health Care. "Trends in Racial, Ethnic, Sex, and Rural-Urban Inequities in Health Care in Medicare Advantage: 2009-2018." December 2021.

⁴³ Innovative-Approaches-to-Addressing-SDOH-for-MA-Beneficiaries-FINAL.pdf (bettermedicarealliance.org); SDOH-MA-IssueBrief-2021.pdf (ahip.org).

and Human Services' recommendations proposed in the Affordable Care Act), unfortunately continue to lead to varied, inaccurate, incomplete, or missing data, with significant percentages of respondents selecting "Other" because current data response options often do not align with how people identify themselves. To improve upon existing demographic data standards, AHIP convened diverse groups of health insurance providers and other stakeholders (e.g., patients representing different communities, providers, community-based organizations, and others) for over 18 months from 2020 to 2022 in a Health Equity Workgroup and employed an evidence-based and stakeholder-driven process to develop improved data standards⁴⁴ using culturally appropriate framing that align with how people identify themselves. We are encouraged by the updated draft standards published by the Office of Management and Budget (OMB) on January 27, 2023, and we will be submitting comments. We welcome the opportunity to continue to discuss our recommended demographic data standards⁴⁶ in more detail with CMS.

- + Improve data collection. Data collection through enrollment forms continues to be a critical part of efforts to address health equity and social drivers of health. We recommend CMS propose further changes to the Medicare FFS and MA enrollment forms to enable collection of more sociodemographic information directly from enrollees. AHIP and our members also welcome the opportunity to work with CMS to educate Medicare enrollees about the value of self-reported sociodemographic data and the guardrails for protecting the privacy and security of their data.
- + Support broader data collection through a phased approach. Sociodemographic data collected and reported by health plans, hospitals, clinicians, and other providers is critical in informing care and in identifying and reducing health disparities. We recommend CMS support incremental steps to facilitate broader data collection and reporting by stakeholders on a wider set of sociodemographic data. Plans, hospitals, clinicians, and other organizations will need to design, align, implement, test, evaluate, and revise data collection and application workflows. Accordingly, CMS should focus initially on a small number of social needs and/or demographic data elements with interoperable codes, and then add additional data elements in subsequent years in a phased approach.
- + <u>Support alignment of data standards</u>. A major challenge to equity efforts is that health plans, hospitals, and clinicians are following various federal and state data collection requirements on demographics and social needs. Varying data collection standards hinder

⁴⁴ AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf. ⁴⁵ 88 FR 5375, January 27, 2023.

⁴⁶ AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf.

efforts to aggregate, analyze, and enable apples-to-apples comparisons across markets and across health care entities and the ability to measure improvement. Having interoperable patient demographic data would allow the health care ecosystem to collect this data when most appropriate and convenient for patients and share the information with other partners with patients' consent to inform their care and population health management efforts, as well as to more effectively address disparities in access to care and outcomes. To promote interoperability across different standards and codes, AHIP mapped our demographic data standards to standardized codes (e.g., LOINC, SNOMED, ICD-10) and developed a data documentation framework that provides guidance on how frequently each question should be asked and how various responses should be coded.⁴⁷ We recommend CMS support alignment of demographic data standards at the ecosystem level through federal policy changes to advance health equity.

Incentivize use of standardized codes. Use of standardized codes by providers continues to lag. Many providers are still not aware of the availability and value of codes (such as Z codes, LOINC codes, or SNOMED codes) to document patients' health-related social needs. Many electronic health record (EHR) systems do not have easy ways to add Z codes to a patient's problem or diagnostic list. Providers also have concerns with adding Z codes to a patient's problem or diagnostic list because the provider may then feel responsible for addressing the patient's health-related social needs that occur outside of the clinician's office. We recommend CMS educate providers about the value of standardized coding. Additionally, CMS should consider developing incentive programs to increase provider use of standardized codes. CMS should also work with ONC to incentivize EHR system developers to implement modifications that facilitate the use of all available interoperable codes, including Z codes, LOINC codes, and SNOMED codes.

We also have the following comments and recommendations related to the other health equity proposals:

• Improvements to provider directories. MA plans work continuously to improve provider directories. Maintaining accurate directories is a shared responsibility between clinicians, facilities, and health insurance providers. Despite the best efforts of health insurance providers, including direct outreach to providers, electronic solutions, advanced analytics and artificial intelligence methods, and ongoing validation and audits, directories remain less than 100 percent accurate. Experience shows there are two formidable barriers to ensuring fully accurate provider directory information: (i) many providers do not consistently provide updates to their contact information, or they may provide inaccurate information; and (ii)

⁴⁷ AHIP letter, "Improving Demographic Data Standards to Advance Health Equity," October 2022. Available online at: https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf.

there is no single "source of truth" for provider information that can be leveraged to verify information contained in directories.

We believe a public-private partnership between the federal government, providers, payers, and solutions vendors is needed to streamline collection of directory information and improve directory accuracy. AHIP supports CMS' proposal to explore a National Directory of Healthcare Providers & Services (NDH) as indicated in our comments in response to CMS' request for information on development of an NDH. AHIP has recommended that CMS first work with stakeholders to develop the core set of provider directory data elements (such as languages spoken) supported by the NDH, as well as potential extension elements that may be required. A cohesive, national approach to building a technology-enabled infrastructure would help ensure accuracy of directories, reduce burdens on providers and plans, and improve efficiency. CMS should also conduct a provider directory education campaign to encourage providers to respond to questions from health plans related to provider directories and related provider information.

AHIP and our members appreciate the importance of non-English speaking patients or those with limited English proficiency being able to receive care in their preferred language. However, we have heard from AHIP members who operate Medicaid managed care organizations (which are already subject to a regulatory requirement regarding cultural and linguistic capabilities in provider directories), that despite good faith efforts to collect this type of data, many providers do not share information on the languages they speak or their cultural capabilities. Thus, when a provider returns a question about cultural and linguistic capabilities with a 'blank' data field, it is unclear whether this means that for example the provider only speaks English, or whether the information was simply not included. If this provision is finalized, we ask CMS to use its authority to encourage healthcare provider organizations to maintain this data for their own individual clinicians, so that accurate and complete information may be provided to MA organizations and other payors.

We also note that the prescribing of medications for opioid use disorder (MOUD) is an area that is evolving, particularly with the recent enactment of Section 1262 of the Consolidated Appropriations Act of 2023 (CAA), which removed the federal requirement for practitioners to submit a Notice of Intent (i.e., have a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder. Given the recent enactment of this legislative provision that likely will significantly expand the number of eligible prescribers, we recommend CMS not adopt its directory proposal related to prescribers of MOUD. CMS should first consider and analyze the impact of

⁴⁸ AHIP Press Release, "Working with CMS to Improve Provider Directories Accuracy," October 2022. Available online at: https://www.ahip.org/news/press-releases/ahip-looks-forward-to-working-with-cms-to-improve-provider-directories-accuracy.

the recent legislative change on its proposal and then modify its proposal with a new notice and comment opportunity.

For the reasons discussed above, AHIP recommends CMS delay the requirement for the proposed new directory data elements until solutions like an NDH are further explored and implemented to address the challenges of provider directories. If CMS moves forward and adopts these two new data elements for MA provider directories, we urge CMS not to penalize plans undertaking good faith efforts to collect information and improve their provider directories until the NDH or an equivalent solution is available to providers and plans.

• <u>Digital health education</u>. While telehealth helps increase safe access to care, especially during a pandemic, it can create or exacerbate disparities in access by leaving some populations behind. Research conducted prior to the pandemic revealed that older Americans, people residing in rural communities, vulnerable populations, racial and ethnic minorities, and people with lower socioeconomic means are disadvantaged by this "digital divide" and may be unable to take full advantage of telehealth opportunities. ⁴⁹ Many individuals face challenges to using telehealth, including a lack of access to the internet; an inability to afford the technologies needed to access telehealth, such as phones, computers, connectivity devices, and data plans; and a limited understanding of how to access virtual care. ⁵⁰

AHIP member plans embrace digital solutions that help increase access to care and want to ensure that the enrollees they serve can access safe and convenient care, regardless of where they live or their economic situation. To that end, many health insurance providers continue to work with their provider partners to bridge the digital divide. Low digital health literacy is a significant obstacle in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need.

We support CMS' proposal for MA plans to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy. Additionally, we appreciate and support CMS' proposal to provide MA plans with broad flexibility to design their own digital health literacy screening programs or procedures. Consistent with CMS' proposal to provide plans with broad discretion, we recommend that plans should be able to use a program that is narrow in scope during the initial years to meet this requirement. This would allow plans more time to assess and test various screening and educational tools and programs for feasibility and effectiveness. This flexible approach would also allow for innovation. There are currently different definitions, standards, and vocabulary related to digital health literacy, and the field continues to evolve.

⁵⁰ Id

⁴⁹ AHIP Issue Brief, "Bridging the Digital Divide for Consumers." Available online at: https://www.ahip.org/documents/202011-AHIP_IB-DigitalDivide.pdf.

We also encourage CMS to develop a working group comprised of AHIP members and other stakeholders that could come together to consider and discuss research-driven standards, studies, and examples of effective programs to improve digital health literacy.

• Change to quality improvement program requirements. Quality improvement programs are an important vehicle for MA plans to develop and execute activities designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved. MA plans are already addressing disparities and gaps in care for underserved populations through a variety of quality initiatives. We appreciate and support CMS' proposal to provide MA plans with broad discretion in the types of activities they can develop and implement to meet this proposed new quality improvement program requirement.

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

CMS proposes several changes to MA program requirements intended to improve access to behavioral health (BH) services in MA including the following:

- Addition of three new BH specialty types to network adequacy standards. CMS proposes to add clinical psychology, clinical social work, and prescribers of MOUD to network adequacy time and distance evaluations.
- Application of telehealth credits to the three new BH specialty types. CMS proposes to apply the 10-percentage point telehealth credit policy to help MA plans satisfy network adequacy requirements for the three new BH specialty types listed above.
- Addition of BH services to care coordination programs. CMS proposes to add BH services to
 the list of services for which MA plans must have a care coordination program in place to
 ensure continuity of care.
- Codification of appointment wait time standards for primary care and BH services. CMS proposes to codify in regulation appointment wait times recommended in sub-regulatory guidance for primary care services and to also extend these suggested wait times to BH services: (i) urgently needed services or emergency—immediately; (ii) services that are not emergency or urgently needed but require medical attention—within 1 week; and (iii) routine and preventive care—within 30 days.

Discussion and Recommendations:

AHIP members are committed to ensuring that MA enrollees have access to the covered BH services they need. Americans are continuing to experience a dramatic increase in BH needs, including in the areas of mental health and substance use disorders (SUD). The increase in demand is outpacing the supply of BH professionals. The Government Accountability Office's (GAO) October 2022 report⁵¹ on the BH professional workforce in the U.S. included the following findings: (i) approximately half of U.S. counties did not have an active psychiatrist or addiction medicine specialist; (ii) more than 150 million people live in federally designated mental health professional shortage areas; and (iii) in the near future, the U.S. will face shortages of mental health providers ranging from 14,280 to 31,109.

In the face of these challenges, MA plans have taken important steps to optimize the existing workforce and improve access to BH services including the following:

- <u>Understanding consumers' experiences accessing BH services</u>. In June 2022, AHIP conducted a nationwide survey⁵² of enrollees in MA plans and other kinds of health coverage to understand their experiences accessing care, whether their treatments were covered by insurance, and if insured patients were satisfied with the results. The survey results make it clear: an overwhelming majority of individuals report being satisfied with the mental health care they sought and received through their health insurance providers. Key findings from AHIP's survey included: (i) nearly all respondents who sought mental health care for themselves or someone within their household over the past two years received treatment; (ii) nearly 3 in 4 insured Americans (73%) found it easy to get the care they needed; (iii) more than two-thirds of respondents were able to find an appointment with a provider in less than a month; and (iv) 9 in 10 reported being satisfied with the mental health support they received, including half who said they were very satisfied.
- Access to behavioral telehealth services. MA plans also continue to advance a variety of
 solutions to further improve access to BH services, including expanding access to telehealth
 and digital tools for BH services. Telehealth and digital tools can help Medicare enrollees
 better engage in their health by offering convenience and flexibility. That is why AHIP
 strongly supports CMS' proposal to apply telehealth credits to the three new BH
 specialty types as discussed below.
- <u>BH integration</u>. Another area of focus for health insurance providers has been integrating mental health support into primary care settings. For example, health insurance providers have promoted collaborative care and enhanced care coordination models by providing primary care clinicians with tools and training to identify and care for their patients' mental

⁵¹ Behavioral Health: Available Workforce Information and Federal Actions to Help Recruit and Retain Providers. Government Accountability Office. October 21, 2022.

⁵² AHIP Mental Health Access Survey. June 2022. Available online at: https://www.ahip.org/resources/ahip-mental-health-access-survey-june-2022.

health needs. This allows primary care clinicians to be better equipped to integrate physical and mental health care, treat mild/moderate conditions, and consult with or refer patients to specialists when appropriate. We continue to encourage CMS to consider the inclusion of the Collaborative Care Model (CoCM) and other enhanced care coordination approaches to support BH integration in future Center for Medicare and Medicaid Innovation (CMMI) demonstration models.

• AHIP Board of Directors Statement of Commitment. On August 23, 2022, AHIP's Board of Directors released a new Statement of Commitment⁵³ and a detailed advocacy vision⁵⁴ to further improve access to mental health care and SUD treatment for every American. These commitments build on health insurance providers' extensive history of improving access to effective, high-quality care and treatment choices, while offering new solutions for public sector and private market partners to work together to overcome barriers that persist.

In addition to noting the concerted efforts by AHIP and our members to improve access to and quality of BH services, we have the following specific comments and recommendations in response to several BH related provisions included in the proposed rule.

Addition of three new BH specialty types to network adequacy standards. Regarding clinical social work, we ask CMS to clarify that all disciplines that fit within this category (e.g., licensed independent social workers) would be countable toward meeting adequacy standards. We are concerned, however, about the ability of the current exceptions process under the MA program to address legitimate network challenges that MA plans may face with the proposed addition of the three new BH specialty types (clinical psychology, clinical social work, and prescribers of MOUD) to the MA network adequacy standards. For example, MA plans could face challenges meeting the time and distance standards due to a variety of factors, including but not limited to provider shortages, contracting practices, geographic issues, and other unique community characteristics or health care needs. Plans should also be able to use other provider specialty types (e.g., mental health counselors, licensed therapists, nurse practitioners, etc.) to satisfy the BH related network adequacy requirements. Accordingly, if CMS were to finalize this proposal, the factors discussed above should be incorporated into the exceptions process for network adequacy, in addition to the justifications allowed under current rules. We also urge CMS to provide more time for plans to meet the standards by delaying the effective date until CY 2025.

⁵³AHIP Board of Directors Statement of Commitment. August 2022. Available online at: https://www.ahip.org/resources/ahip-board-of-directors-statement-of-commitment-improving-access-to-and-quality-of-mental-health-and-addiction-support.

⁵⁴ AHIP Statement, "A Vision for Improved Mental Health Care Access for Every American." Available online at: https://www.ahip.org/resources/a-vision-for-improved-mental-health-care-access-for-every-american.

In addition, as noted above, the prescribing of MOUD is an area that is evolving, particularly with the recent enactment of Section 1262 of the CAA, which removed the federal requirement for practitioners to submit a Notice of Intent (i.e., obtain a waiver commonly referred to as an "X-Waiver") to prescribe medications, like buprenorphine, for the treatment of opioid use disorder. Given the recent enactment of this legislative provision that significantly expands eligible prescribers, we recommend CMS not adopt its proposal related to prescribers of MOUD. CMS should first consider and analyze the impact of the recent legislative change on its proposal and then modify its proposal with a new notice and comment opportunity.

- Application of telehealth credits to the three new BH specialty types. Expanding access to
 BH care through telehealth, virtual visits, and other innovative uses of technologies can
 connect people to the BH support they need. If CMS finalizes this proposal, AHIP strongly
 supports CMS' related proposal to apply the 10-percentage point telehealth credits to
 the three new BH specialty types (clinical psychology, clinical social work, and
 prescribers of MOUD).
- Addition of BH services to care coordination programs. AHIP and our members support the goal of including BH services as part of MA plans' care coordination programs. However, we recommend CMS provide additional time for plans to secure and implement the necessary contracts to add BH services to existing care coordination programs. We urge CMS to delay implementation of this proposal to CY 2025.
- Codification of appointment wait time standards for primary care and extension to BH services. As discussed earlier, provider availability for BH can vary considerably based on a number of factors outside of plan control. Those and other factors can also affect appointment wait times for BH and primary care providers (PCPs). That is why we appreciate CMS' current guidelines in Chapter 4 of the Medicare Managed Care Manual (MMCM) that provide examples of reasonable appointment wait times for PCPs and also recognize that plans should have the flexibility to consider other factors, including "the enrollee's need and common waiting times for comparable services in the community."⁵⁵ We are concerned that the proposal to mandate requirements for primary care without the flexibilities identified in the MMCM, and extending such requirements to BH, would place additional burden on providers and may discourage them from participation in MA plan networks in the future. The expiration of the COVID-19 public health emergency (PHE) declaration could also impact providers and plans in meeting these standards, especially for BH services. For example, if federal rules such as the Ryan Haight Act are reinstated, inperson appointments would be required (in lieu of telehealth) for addiction services or to prescribe controlled substances for BH conditions. We urge CMS not to adopt strict rules

⁵⁵ Chapter 4 of the Medicare Managed Care Manual, Section 110.1.1, Provider Network Standards.

for appointment wait times and continue to provide plans with flexibility in meeting these network standards consistent with current sub-regulatory guidelines.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS currently requires MA plans to make a good faith effort to provide notification to MA enrollees at least 30 calendar days before the effective date of termination of a provider network participation contract. The rule currently applies to enrollees who are patients seen on a regular basis by the provider whose contract is terminating. (CMS proposes to codify sub-regulatory guidance that defines "regular basis" as "enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated".) However, for PCPs, the notice requirement applies to all enrollees who are patients of that PCP. CMS is proposing to modify these rules and to specify the requirements for the content of the notification to enrollees about a provider contract termination. Specifically, CMS proposals would:

- Preserve the phrase "good faith effort" for enrollee notification timeframes for for-cause provider contract terminations but remove "good faith effort" for no-cause provider contract terminations. CMS reasons that MA organizations should be able to meet a CMS established enrollee notification requirement in these no-cause cases on a timely basis.
- For patients of terminating PCPs: (i) extend the notice requirement to all enrollees who have ever been patients of these terminating PCPs (not just current patients); (ii) increase the notice requirement from 30 to 45 calendar days; and (iii) require both written and telephonic notice for contract terminations (the standard is written only for other provider types). MA organizations would be required to continue attempting to reach the enrollee by telephone to provide notice of the termination of the provider from the network when a call goes unanswered.
- Apply those same special rules for terminating PCPs to terminating BH providers.

CMS is also soliciting comment on two issues: 1) how many telephonic attempts are required to notify enrollees of a provider termination, and 2) whether an enrollee who is impacted by a provider contract termination should be eligible for an SEP.

Discussion and Recommendations:

While AHIP supports efforts to ensure enrollees have accurate, up-to-date information about their MA plan, including providers leaving the plan's network, we have several concerns with the proposals described here:

- The assumption that notification can always be provided at least a certain period of time before a no-cause termination ignores the reality that in many cases, providers fail to provide adequate notice when choosing to leave the network. The plan can have limited ability to enforce a timely notice requirement in a network contract, as the key enforcement tool removal from the plan network is the very action the provider has taken. We urge CMS to retain the "good faith" standard when the provider is the party terminating the contract.
- Requiring notification to any enrollee who has ever seen a terminating BH provider or PCP is unreasonable. An enrollee who receives notification of a provider termination after having seen the terminating provider only once, several years ago, is likely to view the notification as wasteful rather than helpful. While CMS cites continuity of care and the need to preserve ongoing provider relationships as justification for the expanded notification requirements for BH and PCPs, an individual who is no longer a current patient by definition does not have an ongoing relationship and is unlikely to be under an existing care plan with the provider. Therefore, CMS should retain the existing notification requirements with respect to which patients should be contacted. At a minimum, CMS should limit the notification requirements to enrollees who have seen the terminating BH provider or PCP in the past year.
- The proposal to require notification by phone every time a primary care or BH provider leaves the plan's network may be unhelpful and unwelcome by many enrollees. As CMS notes elsewhere in the proposed rule, many enrollees already report receiving too many phone calls. There is a significant risk that many will view a phone call notifying them of a provider termination for which they have already received written notice (and for a provider they may have not interacted with for years) as unnecessary and bothersome. Moreover, members may be more likely to misinterpret multiple phone calls as 'spam' calls that have nefarious intent. We also note that the requirement would add administrative burdens relating to messaging, tracking, and receiving increased call center inquiries following unanswered calls and voicemails. This will increase plan costs, which ultimately could have negative impacts on bids and benefits. The proposal also ignores the reality that providers leaving a plan's network are likely to contact affected patients who have approaching appointments.

We urge CMS to withdraw this proposal and retain existing regulatory requirements that require enrollee notification by mail. Written notices provide enrollees with the time needed to digest the information and decide on the best action based on the information provided and offer an opportunity for the individual to share clear, accurate information with caregivers or trusted advisors for assistance in decision-making. In the event CMS finalizes the requirement for plans to notify enrollees by phone whenever a BH or PCP the individual has ever seen leaves the plan's network, we also ask

that CMS clarify how this requirement interacts with the recent announcement from the Federal Communications Commission of enforcement of rules that limit certain calls made to a residence.⁵⁶

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

CMS proposes a number of significant changes related to UM and prior authorization (PA) requirements under MA including:

- Permitted uses of PA. CMS proposes to specify that MA plans are permitted to use PA for one or more of the following purposes: (i) to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; (ii) for basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1) (which includes the permissible coverage criteria in the regulations; the assessment of whether an item or service is reasonable and necessary under the Medicare statute; the enrollee's medical history, physician recommendations and clinical notes; and involvement of the MA organization's medical director as appropriate); or (iii) for supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.
- Adherence to Medicare FFS guidelines. CMS would specify that MA plans must comply with general coverage and benefit conditions included in original Medicare laws, including coverage criteria for inpatient admissions, requirements for coverage of Skilled Nursing Facility (SNF) Care and Home Health Services, and Inpatient Rehabilitation Facilities (IRF) coverage criteria. CMS indicates this would require MA plans to follow specific coverage criteria established in applicable Medicare statute, regulations, national coverage determinations (NCDs), and local coverage determinations (LCDs), when making medical necessity determinations.
- Ability to use internal plan coverage criteria for other benefits. Under the proposal, when
 coverage criteria are not fully established in applicable Medicare statute, regulation, NCDs or
 LCDs, MA plans would be permitted to create and use internal coverage criteria to make
 medical necessity determinations provided certain conditions are met:

 $^{^{56} \}underline{\text{https://www.federalregister.gov/documents/2023/01/20/2023-00634/limits-on-exempted-calls-under-the-telephone-consumer-protection-act-of-199}.$

- + The coverage criteria would have to be based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. (The proposal would define "widely-used treatment guidelines" and acceptable clinical literature.)
- + MA plans would need to provide a public summary of evidence that was considered during the development of the plan's internal coverage criteria for medical necessity determinations, a list of sources of such evidence, and an explanation of the rationale supporting the adoption of the coverage criteria.
- Establishment of UM committee. CMS would require MA plans to establish a "Utilization Management Committee to review all utilization management, including prior authorization policies, annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines."⁵⁷
- Length of approvals and transition requirements. CMS proposes to require, with respect to basic benefits, that MA plans provide for an enrollee undergoing an active course of treatment: (i) approval of a PA request for the entire duration of the approved course of treatment, and (ii) for an enrollee who enrolls in an MA plan (including enrollees new to a plan and new to Medicare), a minimum 90-day transition period when the active course of treatment had previously started, even if furnished by an out-of-network provider. The proposal says that the MA plan "must not disrupt or require reauthorization" for such active course of treatment during the 90-day transition period.

CMS explains several important implications of the proposed changes – for step therapy and for existing coverage flexibilities in areas such as discharges from acute care hospitals.

First, when MA plans are required to adhere to specific Medicare guidelines, step therapy would be permitted only to the extent the step therapy is permitted under the original Medicare guidelines. (At the same time, CMS indicates that MA plans could still use PA to deny coverage for a particular item or service if it is not reasonable and necessary based on the medical necessity determination requirements in the Medicare guidelines.) Conversely, when MA plans are allowed to create internal coverage criteria under CMS' proposal, step therapy would be permissible - if current evidence in widely used treatment guidelines or clinical literature require another item or service to be provided first. CMS also notes this proposal does not affect Part B drugs for which existing rules authorize use of step therapy in certain cases.

Second, CMS specifies in the preamble that MA plans would be restricted in the ability to limit "when and how" they cover basic Medicare FFS benefits. ⁵⁸ CMS explains that "when care can

⁵⁷ 87 FR 79452 at pages 79454-79455.

⁵⁸ 87 FR 79452 at page 79502.

be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the [Medicare coverage rules]."⁵⁹ This restriction applies even to cases where an MA plan denies a particular item or service and redirects the enrollee to a different clinically appropriate item or service. CMS acknowledges this would be narrower than current policy, established in a June 2000 final rule, which provided that "...when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided."⁶⁰ Thus, for example, if an enrollee in an MA plan is "discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for [Medicare FFS coverage of] SNF care."⁶¹

CMS also requests comments on early termination of services in post-acute care settings by MA plans and other possible changes to better manage incentives between MA plans and post-acute care providers to deliver the best possible care for Medicare beneficiaries. Additionally, CMS encourages MA plans to adopt gold carding programs that would allow providers to be exempt from PA and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with a plan's gold carding requirements.

Discussion and Recommendations:

AHIP has the following comments and recommendations in response to CMS' expansive set of UM proposals:

<u>Background on value of PA</u>. AHIP appreciates CMS' acknowledgement in the proposed rule that UM policies are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care under MA. Our members support the use of evidence-based clinical policies, including those specified under Medicare FFS rules and guidelines, to ensure the right care is provided to MA enrollees at the right place, and at the right time.

PA is one of many tools health insurance providers use to promote safe, timely, evidence-based, affordable, and efficient care. MA plans and other health insurance providers have adopted a range of evidence-based UM tools, including PA, to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient. Under the supervision of medical professionals, PA can reduce inappropriate

⁵⁹ 87 FR 79452 at page 79507.

⁶⁰ Id.

^{61 87} FR 79452 at page 79502.

care by catching unsafe or low-value care, or care not consistent with the latest clinical evidence. Low-value or otherwise inappropriate care can contribute to potential harm to patients and unnecessary costs.

The evidence showing the value of PA is clear. For nearly two decades, numerous studies have documented that Americans frequently receive inappropriate care in a variety of settings for many different medical procedures, tests, and treatments. The Institute of Medicine has confirmed that geographic variations in spending are substantial, pervasive, and persistent over time and there is little to no correlation between spending and health care quality. Needless medical tests are unsupported by evidence, causing harm and wasting billions. In a national survey of over 2,000 physicians, most (64.7%) reported at least 15-30% of medical care is unnecessary. A January 2023 study also demonstrates how savings associated with PA far exceed the administrative costs.

The MA program rules support the use of PA as a critical tool to ensure Medicare enrollees receive safe, effective, and appropriate care. Moreover, CMS has repeatedly recognized PA as an important tool to protect patients and has taken a number of actions to thoughtfully expand its use under original Medicare. Additionally, in response to recommendations from the GAO⁶⁶ and the Medicare Payment Advisory Commission (MedPAC),⁶⁷ original Medicare has implemented evidence-based guidelines and PA for outlier professionals to address the overuse and misuse of imaging services, which can expose patients to unnecessary and potentially harmful radiation, unnecessary surgery and office visits, undue stress, and add wasteful costs to the health care system.

In July 2022, AHIP posted a comprehensive report⁶⁸ on how health insurance providers have delivered on their commitments to improve PA for patients and providers. This report follows up

⁶² AHIP Medical Management Resources. Available online at: https://www.ahip.org/issues/medical-management.

⁶³ Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care; Board on Health Care Services; Institute of Medicine; Newhouse JP, Garber AM, Graham RP, et al., editors. Variation in Health Care Spending: Target Decision Making, Not Geography. Washington (DC): National Academies Press (US); 2013 Oct 1. Summary. Available from: https://www.ncbi.nlm.nih.gov/books/NBK201637/.

⁶⁴ Lyu H, Xu T, Brotman D, Mayer-Blackwell B, Cooper M, Daniel M, et al. (2017). "Overtreatment in the United States." PLoS ONE 12(9): e0181970. https://doi.org/10.1371/journal.pone.0181970.

⁶⁵ Brot-Goldberg, Z., Burn, S., Layton, T., Vabson, B. "Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare." January 2023.

⁶⁶ GAO Report. "Medicare: CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending." Available online at: https://www.gao.gov/products/gao-18-

^{341#:~:}text=GAO%2D18%2D341%20Published%3A,or%20items%20like%20powered%20wheelchairs.

⁶⁷MedPAC Chapter 10: Medicare Coverage Policy and Use of Low-Value Care (June 2018 report). Available online at: https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-jun18 ch10 medpacreport sec-pdf/.

⁶⁸ AHIP report available online at: https://www.ahip.org/documents/AHIP-1P-Consensus-Statement-Actions-072722-FINAL.pdf

on the 2018 Consensus Statement⁶⁹ among providers, health insurers, and other stakeholders recommending opportunities to improve the PA process. Since then, health insurance providers have taken and continue to take concrete actions to help achieve the shared goal of making PA more efficient, more effective, and less burdensome.

Below we identify specific proposals we support, as well as concerns and recommendations on other proposals. We recommend that CMS work with plans and providers to ensure these processes work as effectively as possible. Health insurance providers are continually improving PA programs to reduce physician and enrollee burdens and improve outcomes for patients. We also urge CMS to adopt policies that encourage widespread provider adoption of electronic prior authorization (ePA) technology and look forward to submitting recommendations to increase adoption of ePA by providers in our comments in response to CMS' Advancing Interoperability and Improving PA proposed rule.⁷⁰

Proposals we support:

- Clarification of standards. Despite the importance of PA and the steps health insurance providers have taken to make PA more efficient, more effective, and less burdensome, we acknowledge that providers and others continue to raise concerns about the burdens and impacts of PA along with questions about the scope of permissible PA. For that reason, we support CMS providing additional clarity about the scope of permissible PA. However, as noted below, we are concerned that certain aspects of the proposal would eliminate long-permitted flexibilities which have allowed MA plans to encourage high-quality, cost-effective care alternatives. We also have other concerns about the proposal, including the proposed effective date for implementing new restrictions and process mandates relating to PA that are discussed in more detail below.
- Public summary of evidence requirement. We support CMS' requirement for plans to make publicly available the evidence that they considered during the development of their internal medical necessity coverage criteria. CMS should also provide plans with flexibility for meeting the requirement for making this information publicly available. This proposal would increase transparency into MA plans' medical necessity decision making and ensure consumers and others are better informed about the evidence-based coverage criteria that MA plans use to make medical necessity determinations.
- <u>Establishment of UM committee</u>. In the preamble, CMS indicates that its proposed requirement for MA plans to establish a UM committee would enable the UM committee to

⁶⁹ 2018 Prior Authorization Consensus Statement. Available online at: <u>2018 Prior Authorization Consensus</u> Statement.

⁷⁰ 87 FR 76238, December 13, 2022.

operate similarly to a plan's Pharmacy and Therapeutics (P&T) committee. CMS would require plans to meet committee membership requirements outlined in the rule but would also provide plans with flexibility to define the structure and appropriate additional responsibilities of the UM committee. We support CMS' proposal to provide flexibility for plans to meet this requirement but also recognize that plans may need more time to identify qualified committee members. CMS notes that MA plans could establish a UM committee that largely mirrors their P&T committee. We recommend that CMS also clarify in the final rule that to support efficiencies, MA plans could also use their UM committee to meet the existing P&T committee requirements. Additionally, we recommend CMS permit MA plans, or the parent organization of one or more MA plans, to use one UM committee to serve multiple MA plans when the MA plans are offered under the same legal entity.

Proposals that raise concerns:

• Adherence to Medicare coverage guidelines – in general. AHIP members have expressed concerns about circumstances under which coverage criteria specified under original Medicare are not fully established or are ambiguous. Required adherence to questionable clinical criteria under original Medicare could lead to worse patient health outcomes, higher costs for the Medicare program, and fewer affordable, high-quality plan choices for beneficiaries. While the proposed rule permits the use of internal plan criteria when original Medicare coverage criteria are not fully established, we further recommend CMS ensure the agency has a process in place to consider questions and provide clarity on which Medicare guidelines fail to meet the regulatory requirement and therefore permit use of internal plan coverage criteria.

We have also heard concerns about guidelines that may be in place but do not reflect current medical or scientific evidence or literature. In such cases, there could be increased risks of patients receiving low value care and experiencing adverse health impacts. We urge CMS to ensure that NCDs are timely reviewed to reflect the most recent medical or scientific evidence or literature. We further encourage CMS to ensure that Medicare Administrative Contractors (MACs) are timely reviewing LCDs to ensure that they are also based on the most recent medical or scientific evidence or literature.

Finally, we have serious concerns that the proposal would require MA plans to follow "coverage criteria for inpatient admissions at 42 CFR 412.3." That regulatory provision includes CMS' "two-midnights" policy for determining when an individual qualifies for an inpatient admission under original Medicare. CMS guidance acknowledges that the two-midnights rule is a "Medicare claims processing procedure" and CMS has said it would not interfere with how MA plans and contracted hospitals establish their criteria for determining

inpatient admissions as compared to observation stays. ⁷¹ The proposal would reverse this approach, thereby interfering with MA/hospital contracting and likely raising costs for delivering MA benefits. Moreover, applying the two-midnights rule to MA enrollees would not expand coverage for items or services, but could (depending on plan design) actually impose higher cost sharing liabilities on enrollees. We also note that unlike original Medicare, MA plans have the authority and commonly cover a skilled nursing facility stay without a preceding three-day inpatient admission, further limiting any benefit the proposal could have in terms of coverage for post-acute care. We urge CMS to modify any final provision to carve out the two-midnights policy from Medicare coverage requirements to which MA organizations must adhere.

- Limits on use of step therapy. There are medical conditions that may have several medical coverage or medication options. Although their clinical effectiveness may be the same, the patient safety considerations and coverage costs may be very different. Step therapy enables an enrollee to obtain the item, service, or medication they need, but at a lower cost. In 2019, CMS acknowledged the value of step therapy when the agency affirmatively permitted MA plans to apply step therapy to manage Part B drugs. 72 In August 2018, CMS stated that "using step therapy plans could ensure that a senior who is newly diagnosed with a condition begin treatment with a cost-effective biosimilar before progressing to a more costly drug therapy should the initial treatment be ineffective. By implementing step therapy along with care coordination and drug adherence programs in MA, it will lower costs and improve the quality of care for Medicare beneficiaries."73 We urge CMS to consider more flexibility to allow step therapy by MA plans that reflects current medical or scientific evidence or literature, even if not expressly permitted under specific original Medicare guidelines. We strongly support CMS' continued flexibility with respect to step therapy for Part B drugs and believe similar benefits to patients and taxpayers could be realized for other items and services.
- Post-acute care and similar limits on use of PA. We have very serious concerns with CMS' proposal to eliminate more than 20 years of flexibility under the MA program to limit "when and how" original Medicare covered benefits are covered. This proposal would undermine efforts to move towards value-based care and would increase overall costs under the program and thereby adversely affect enrollees and taxpayers without improving patient health outcomes. CMS' Medicare FFS demonstrations have shown that care can be delivered in more than one way or in more than one type of setting. For example, CMS' Comprehensive Care for Joint Replacement Model and Bundled Payments for Care Improvements Model have shown that greater use of home health care instead of institutional post-acute care can

⁷³ Id.

⁷¹ 78 FR 50495 at page 50934.

⁷² CMS Fact Sheet. Available online at: https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

reduced costs without harming patient outcomes. These results have also been discussed in peer-reviewed publications, and these strategies have been implemented by many organizations, including accountable care organizations. A recent Kaiser Family Foundation assessment of post-acute care utilization research found that MA enrollees use less institutional post-acute care in comparison to original Medicare enrollees, with similar or slightly better outcomes. MA plans play a vital role in ensuring that their enrollees have access to high-quality, cost-effective care. Limiting plan flexibilities to manage post-acute care would undermine efforts to move towards value-based care and increase costs without improving patient health outcomes. We therefore urge CMS to not adopt policies that would place limits on plan flexibility to manage post-acute care.

• 90-day transition period coverage requirement. In the preamble, CMS explains that its 90-day transition period coverage proposal "mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage." CMS also proposes to define an active course of treatment as "a course of treatment in which a patient is actively seeing the provider and following the course of treatment."

We are very concerned about the implementation challenges, including the broad coverage scope, associated with the 90-day transition period coverage requirement. The proposed requirement to cover transitional care without the ability to apply PA could increase the risk of fraud, waste and abuse and could have other unintended consequences for the program. We also believe that the 2024 proposed effective date is premature. In its Advancing Interoperability and Improving PA proposed rule RCMS' proposal to require a Payer-to-Payer application programming interface (API) to facilitate exchange of information between payers regarding a PA coverage decision for an active course of treatment does not take effect until 2026. We believe this exchange capability should be operational prior to the implementation date for this new coverage requirement. We strongly recommend CMS delay and not finalize the 90-day transition period coverage requirement proposal until unintended consequences are addressed and until the Payer-to-Payer API is fully functioning. If CMS decides to finalize this proposal, we urge the agency to apply a 2026 effective date.

⁷⁴ Ochieng, N. and Biniek, J. "Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature." September 2022. Available online at: https://www.kff.org/report-section/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature-report/.

⁷⁵ Barnett ML, Wilcock A, McWilliams JM, et al. "Two-year Evaluation of Mandatory Bundled Payments for Joint Replacement." *N Engl J Med*. 2019;380(3):252-262.

⁷⁶ 87 FR 79452 at page 79505.

⁷⁷ 87 FR 79452 at page 79714.

⁷⁸ 87 FR 76238, December 13, 2022.

- Full course of treatment requirement. The proposed definition and preamble discussion related to "course of treatment" is broad in scope. It is unclear whether this proposed coverage requirement applies to a continuity of care period or would require approval in perpetuity. We are concerned that it may be misinterpreted to mean that there is no clear time limitation and potentially no limitation on a provider continuing to furnish services that are outside the scope of the original coverage approval. This uncertainty could allow for inappropriate coverage. This lack of clarity could also increase risk for fraud, waste and abuse and costs for beneficiaries and the health care system as a whole. We recommend CMS clarify in the final rule its definition and coverage expectations related to a "course of treatment." CMS should also provide examples of what is and is not permissible to ensure that treatments that are not medically necessary under Medicare FFS guidelines are not required to be covered under this policy. It is also unclear whether a plan would be required to approve the exact course of treatment included in the original coverage request. This clarity is needed to ensure consistent application of CMS' policy. We believe CMS policy should also ensure that plans have the ability to approve periodic courses of treatment consistent with their internal plan coverage criteria. Additionally, we recommend that in the final rule, CMS make it clear that its transition coverage requirement is limited to 90 days. CMS should allow a plan to work with their MA enrollee after the 90-day transition period to find an in-network provider to continue their care.
- Encourage use of gold carding programs. Health insurance providers remain committed to improving the PA process. As part of health insurance providers' long-standing commitment to the 2018 Consensus Statement and continued process improvements, AHIP recently surveyed health insurance providers on the use and impact of gold carding programs with a focus on how these programs impact patient care. AHIP's research⁷⁹ found that the use of gold carding has increased since 2020—and gold carding programs are most effective when they are used selectively and are continually re-evaluated to ensure patients are receiving the high-quality care they deserve. Additional findings included: (i) health insurance providers are using gold carding programs more frequently to improve efficiency and speed; (ii) gold carding programs work better for some services than others; (iii) gold carding programs include providers with sufficient PA volume and low denial rates; (iv) frequent reviews of provider performance are vital; (v) gold carding programs have mixed reviews; and (vi) concerns about care quality for patients and challenges with implementation are top reasons for discontinuing gold carding programs. AHIP agrees that gold carding can be helpful in targeting PA requirements where they are needed most and reducing the

⁷⁹ AHIP Survey on Gold Carding Programs. July 2022. Available online at: https://www.ahip.org/resources/new-survey-effective-gold-carding-programs-are-based-on-evidence-and-value-for-patients.

administrative burden on high-performing health care providers. AHIP considers gold carding programs to be a contract issue between a plan and a network provider. As such, and given the varied experience and customized nature of effective gold carding programs, AHIP does not support the mandating of these programs under MA.

• Effective Date. Given the volume and complexity of the changes CMS proposes to make under the UM requirements section of the regulation, MA plans should be provided at least two additional years to implement any finalized requirements. As previously indicated, by the time this rule is finalized, plans may only have several weeks to fully assess all the changes to existing program requirements, adequately reflect these changes in their 2024 bids, modify contracts, and make systems and other operational changes needed to meet the 2024 effective date. Moreover, if the proposal for establishment of a UM committee is finalized, each plan committee would be required to review and possibly have to modify all UM policies to ensure that they are consistent with MA program rules. This work would be considerable and time-consuming. We therefore urge CMS to delay the effective date to 2026 for new regulatory requirements focused on UM, including the establishment of a UM committee, that are finalized under this rule. A 2026 effective date would not only provide plans with sufficient time to meet new requirements, but also aligns with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving PA proposed rule⁸⁰ that impacts MA plans.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS asks for stakeholder feedback on whether the agency should issue additional guidance on the definition of "cash equivalent" within the context of MA rewards and incentives programs and the use of gift cards that may be redeemed only at specific retailers.

Discussion and Recommendations:

AHIP supports the use of rewards and incentives programs as a means of encouraging healthy behaviors and promoting the efficient use of health care resources among MA enrollees. We appreciate CMS' ongoing commitment to providing guidance to MA organizations on the design and use of such programs to drive better health outcomes.

We believe additional guidance on the definition of "cash equivalent" within the context of rewards and incentives program would be helpful, and ask CMS to clarify rules on the offering of gift cards that can be redeemed at specific retailers or a specific category of items or services as reward items. As CMS notes in the rule's preamble, there are currently

^{80 87} FR 76238, December 13, 2022.

several different interpretations on the permissible use of such gift cards. Additional guidance from CMS will ensure that MA organizations are able to provide appropriate incentives and rewards as part of efforts to improve enrollee health and wellness.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

Current regulations state that if an MA organization expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. CMS proposes to require that for adverse medical necessity decisions, coverage determinations would have to be reviewed by a licensed physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the service at issue. Under the proposal, the health care professional would not need to be the same specialty or sub-specialty as the treating physician or health care professional; CMS indicates that plans would have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition.

Discussion and Recommendations:

AHIP agrees that health care professionals making coverage decisions should have the expertise in the field of medicine or health care that is appropriate for the service at issue. We also strongly support CMS' decision not to require the case reviewer involved to be of the exact same specialty or sub-specialty as the treating physician. Such a restrictive approach would not only be cost-prohibitive but would be highly problematic. In the proposed rule, CMS provides an example of a qualified reviewer. CMS explains that "if a plan intends to deny a request for a home nebulizer, the organization determination request should be reviewed by a health professional with respiratory expertise, such as a respiratory therapist." We also believe that the language in the final rule should provide sufficient flexibility to support plan use of a physician specialized in for example internal medicine for this particular case. Internal medicine physicians are also familiar with the reasons why a home nebulizer may be medically necessary, such as for severe asthma or Chronic Obstructive Pulmonary Disease (COPD) and can order them.

⁸¹ 87 FR 79452 at page 79510.

We therefore strongly support CMS' intent to allow flexibility for a plan to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition, and to not require an exact match between the service requested and the qualifications of the reviewer. We urge CMS to modify the final regulatory text to make this flexibility and plan discretion clear.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

CMS proposes to codify its longstanding prohibition of midyear benefit changes for MA and Part D. Additionally, CMS proposes to require Part D sponsors to: (i) refund incorrect collections of premiums and cost sharing, and (ii) recover underpayments of premiums and cost sharing.

Discussion and Recommendations:

Given that the COVID-19 PHE declaration may end in 2023, certain COVID-19-related waivers and flexibilities may also end at that time. We recommend that CMS permit plans that have made mid-year benefit changes in 2023 to extend those changes through the end of the contract year. This approach would ensure that enrollees do not lose a benefit during the plan year and enable plans to continue their efforts to ensure that enrollees have access to their benefits and necessary care.

N. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503)

CMS proposes to codify that it does not evaluate or issue a notice of determination when an entity submits a substantially incomplete application. CMS also proposes to codify the definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of its MA or Part D application.

Discussion and Recommendations:

AHIP supports codifying the definition of a substantially incomplete application. However, the proposed language does not make clear what constitutes a plan's good faith efforts to provide all required documentation. We ask CMS to provide additional clarity on what evidence is acceptable to demonstrate that the plan has made best efforts to provide all necessary documentation.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

CMS proposes to require MA organizations and Part D sponsors to provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area and in accessible formats on request. CMS also proposes to extend this translation requirement to SNP enrollee individualized plans of care. In addition, the proposal would require that FIDE SNPs, HIDE SNPs, and applicable integrated plans translate all Medicare materials that would require translation into any languages required by their capitated Medicaid managed care contract in addition to language(s) required by the Medicare standard. CMS solicits feedback on the scope of this requirement, specifically whether other types of D-SNP plans should be required to meet this requirement as well.

Discussion and Recommendations:

We strongly support CMS' goal to ensure access to important information and materials for Medicare enrollees who have limited English proficiency or need auxiliary aids or services. This proposal applies to a broad range of written beneficiary materials. We have heard concerns about individual cases where it may be difficult to translate and provide a document to a beneficiary under tight timelines (e.g., braille translations could take several weeks). For those circumstances, the plan uses alternative means (e.g., verbal) to communicate the information with their beneficiary to not only meet timeliness standards, but also to appropriately balance the need for quick communication with the beneficiary. We recommend CMS ensure that the requirement included in the final rule provides plans with flexibility and supports their best efforts to provide translated materials timely and ability to use alternative arrangements when needed to meet timeliness standards. Given the concerns raised above, we also ask CMS to establish a workgroup comprised of plans and other stakeholders that can come up with options for meeting this objective while balancing the need to communicate with beneficiaries quickly in certain circumstances.

We support the concept of making SNP member care plans accessible to all members but as proposed, we are concerned with both the length of time translation of care plans could take as well as the potentially high costs of translation on a standing basis. Based on figures provided in CMS' Special Needs Plan Comprehensive Report for January 2023, the average SNP enrolls over 4,000 members; and in D-SNPs, the average is 5,825. Instead of requiring each care plan be translated on a standing basis, we believe it would be appropriate and more cost-effective to have a care team member verbally review the care plan in the member's chosen language following updates to the care plan. This approach would have the added benefit of improving member understanding and adherence to the care plan as they would have a team member to review the plan with them and the opportunity to ask questions. Following such a review, if the member requested written translation, the plan could then be required to translate the care plan into the member's requested language. We urge CMS to modify its proposal to permit SNPs to have a care team member verbally review the care plan in the member's chosen language. If after

such review the member requests translation, the plan should be required to translate the care plan into the requested language.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

CMS proposes numerous changes related to the content of advertisements and other marketing encounters; new plan oversight rules relating to agents and brokers; and other new marketing rules, including new limits on scheduling of meetings. A number of those proposals and AHIP's comments are highlighted below.

Discussion and Recommendations:

America's older adults and people with disabilities deserve MA plans that continue to deliver better services, better access to care, and better value. And as they make choices about their coverage, Medicare enrollees should be protected from bad actors who engage in misleading advertising and marketing tactics. They should have clear, accurate, easy-to-understand information about MA plans to help them select the coverage option that best meets their needs. Open and honest information about their plans is essential to MA's ability to deliver high levels of satisfaction to enrollees. The industry is committed to ensuring truth in advertising and marketing practices.

Accordingly, AHIP and our members generally support CMS' proposals, which, when added to the robust oversight regime already in place, would protect beneficiaries from misleading advertising and reduce consumer confusion and abrasion.

We are concerned however that several of CMS' marketing related proposals could adversely impact beneficiaries and the resources they rely upon to make the right plan choice to best meet their health care and other needs. Several proposals also do not adequately account for needed implementation time. In addition to complying with state licensing and other requirements, agents and brokers are required to be trained and tested annually on Medicare program rules and regulations and on the specific plan benefits they sell. As members of their local communities, agents can also help plans connect with diverse Medicare populations, including racial and ethnic minorities, to ensure that they have the information and resources they need to inform their Medicare coverage selections. Proposals that unnecessarily limit or impose barriers on access to agents and brokers may prevent consumers from getting educated on critical information they need to make informed decisions. In addition, certain proposals, including those relating to marketing materials, will require the release of more detailed sub-regulatory guidance and may require training and implementation steps that will be difficult to complete if the final rule applied them to marketing for the 2024 plan year.

We have the following specific comments and recommendations on these and certain other proposals:

• Separation of education events from marketing. CMS proposes several changes to the marketing rules which are intended to separate educational events from marketing events. Specifically, CMS proposes to: reinstate the prohibition on accepting Scope of Appointment (SOA) cards or the collection of beneficiary contact information at educational events; prohibit MA plans and agents from setting up future marketing appointments at educational events; prohibit marketing events from taking place within 12 hours of an educational event in the same location; and prohibit personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary.

CMS explains that these changes would help to "alleviate the pressure a beneficiary may feel to stay for a marketing event and will protect beneficiaries from undue pressures to enroll in a plan for which they may not be interested or a plan that does not best meet their health care needs." We are concerned that these proposed changes would have the opposite effect; they could deprive Medicare enrollees the ability to have in-person interactions and conversations, which studies suggest Medicare enrollees strongly prefer. 83

We also are concerned that de-linking education events from marketing could adversely impact dual eligible individuals and result in health inequities. Our members have shared that a higher share of dual eligible individuals enroll through face-to-face encounters with agents and brokers. At the same time, they often face unique challenges such as lack of access to transportation services and technology that makes it difficult to schedule multiple meetings; it is critical that they have access to information and resources in one interaction. The proposed 12-hour wait time after an educational event and 48-hour wait time after completion of an SOA could therefore impose absolute barriers on attending a subsequent meeting, potentially limiting their ability to choose a plan that best meets their health care and other needs. The wait times could also adversely impact beneficiaries who need to make a plan selection but are facing an immediate enrollment deadline. For these reasons, we strongly recommend that CMS not adopt its proposals that would separate educational events from marketing, including the provisions that prohibit marketing events from taking place within 12 hours of the educational event in the same location; and personal marketing appointments from taking place until after 48 hours have passed from the completion of the SOA. If CMS does finalize its proposal to require a 48-hour wait time

^{82 87} FR 79452 at page 79530.

⁸³ Rivera-Hernandez M., Blackwood K.L., Mercedes M., Moody K.A. "Seniors Don't Use Medicare.Gov: How Do Eligible Beneficiaries Obtain Information about Medicare Advantage Plans in the United States?" BMC Health Services Research 21, 146, February 2021; Shupei, Yuan, Syed A. Hussain, et. Al. "What do they like? Communication Preferences and Patterns of Older Adults in the United States. The role of technology, Educational Gerontology, 42:3, 163-174, 2016.

after completion of an SOA, we urge the agency to permit plans to add an opt-out choice on the form if the beneficiary wishes or needs to meet with the agent sooner than 48 hours.

- Timelines. In general, CMS does not explicitly indicate the effective date for these proposed changes in marketing rules, which suggests the intent would be for those proposals to apply for the marketing period for plan year 2024. However, plans must have access to all necessary marketing guidance and sufficient lead time to implement changes for CY 2024. In order for plans to meet this deadline, CMS would have to issue the final rule and provide MA plans with any required sub-regulatory operational guidance by early May 2023 at the latest. This would include sub-regulatory guidance for the new third-party marketing organization (TPMO) related requirements (e.g., disclaimers, submission of marketing materials directly to CMS, waivers that apply to EGWPs). CMS also indicates that it would provide more detailed sub-regulatory guidance on questions and areas that would have to be covered during the pre-enrollment discussion with an enrollee. MA plans will also need time to assess the changes in order to develop advertising materials and submit them to CMS for approval; and for agent/brokers to obtain training and modify their processes to reflect the numerous provisions in the proposed rule. Given the breadth and scope of the proposed changes, we are concerned about the timing of these changes, especially if CMS is considering a CY 2024 (Fall 2023 Annual Enrollment Period (AEP)) effective date. If CMS is unable to issue the final rule and required sub-regulatory guidance by April/May 2023, we recommend that CMS delay the effective date to CY 2025 (Fall 2024 AEP).
- Agent/Broker oversight. CMS proposes to require MA plans to establish and implement an oversight program that monitors agent and broker activities, identifies non-compliance with CMS requirements, and requires plan reporting of non-compliance to CMS. In the preamble, CMS explains that an acceptable oversight program includes: "the review of internal grievances, 1–800–MEDICARE complaints, random samplings of past audio calls, listening to sales/marketing/ enrollment calls in real-time, secretly shopping in-person education and sales events, and secretly shopping web-based education and sales events." In addition, CMS notes that plans should be able to identify non-compliant agents and brokers through these activities and would be expected to "quickly act, such as [pursuing] tailored training or disciplinary measures, based on the specific issues for each agent or broker" and also report the agent or broker non-compliance to CMS. AHIP members have already taken steps to improve oversight of agent and broker activities including implementing activities described above.

^{84 87} FR 79452 at page 79534.

⁸⁵ Id

⁸⁶ Id.

We appreciate CMS not proposing overly prescriptive requirements in regulation for MA plans to implement. We anticipate there are a number of clarifying questions that CMS will receive through the public comment process that should be addressed to ensure common understanding and consistent application. For example, we ask CMS to clarify whether reporting of agent/broker noncompliance would be limited to significant and/or repeated noncompliance actions. We also reiterate our previous recommendation that CMS not hold a MA plan liable for a non-compliant activity of a TPMO or other entity with whom the MA plan does not contract (directly or through a sub-contract). Finally, we continue to recommend that CMS establish a forum for engagement with AHIP, MA plans, the States, agents and brokers, and other TPMOs, and beneficiary advocates to discuss and address marketing-related concerns.

Q. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

In subsection Q.2.b.(3), CMS proposes new flexibility for Part D plans to make midyear formulary changes for certain drugs. Specifically, under this proposal Part D sponsors would be allowed to immediately substitute: (1) a new interchangeable biological product for its corresponding reference product; (2) a new unbranded biological product for its corresponding brand name biological product; and (3) a new authorized generic for its corresponding brand name equivalent.

Discussion and Recommendations:

AHIP and its members have long championed the use of generic versions of small molecule drugs as an alternative to more expensive brand/originator versions when they become available. Indeed, since the enactment of the Hatch-Waxman Act, nearly 90% of all drugs dispensed in the Medicare program are generics. The ability of Part D plans to use well-tested formulary management and negotiating tools, including the promotion of cost-effective and clinically appropriate generics, has been critical in plans' ability to keep Part D premiums steady despite exorbitant launch prices for new drugs and out-of-control drug price increases on existing medicines. While the dynamics of the biologic/biosimilars large molecule drug market are more complex, the prospect of growing numbers of interchangeable and biosimilar versions of brand biologics presents new opportunities for patients to obtain greater access to these expensive, but highly effective medicines. Accordingly, we appreciate and support CMS' efforts to provide plan sponsors with the flexibility to quickly make formulary changes regarding these follow-on biologics. This additional flexibility provides Part D plans with additional means to promote innovation, patient safety and cost effectiveness for consumers and taxpayers.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

⁸⁷ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_ch14_sec.pdf.

In general, Part D's statutory provisions impose certain requirements relating to MTM programs. For example, sponsors are required to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. To address its concerns that MTM is not being utilized to the fullest benefit for the broadest eligible patient populations in Medicare, CMS proposes several changes to the program's targeting criteria:

- CMS subregulatory guidance identifies 9 chronic disease targets for MTM programs, and current regulations provide plans flexibility in choosing which diseases to target. Under the proposal, Part D sponsors would be required to include all core chronic diseases in their targeting criteria. CMS would also codify the current 9 core chronic diseases in regulation and add HIV/AIDS for a total of 10 core chronic diseases.
- CMS would reduce the maximum number of covered Part D drugs a sponsor may require for MTM Program eligibility from 8 to 5 drugs while also mandating sponsors include all Part D maintenance drugs.
- Under its current methodology, the cost threshold for covered drugs is \$4,935 in 2023. CMS would revise the cost threshold methodology based on the average annual cost of 5 generic Part D drugs (e.g., \$1,004 in 2020).

Discussion and Recommendations:

AHIP and our members have long supported the use of MTM programs in Part D. Medication use in the Medicare population is significant, with patients currently averaging 54 prescriptions per member annually, ⁸⁸ with >50% of beneficiaries 65 and older taking four or more prescription drugs daily. ⁸⁹ The need to manage these treatments is a critically important task undertaken by plan sponsors and their contracted Pharmacy Benefit Managers (PBMs) to prevent adverse events and promote effective care. Accordingly, we appreciate CMS interest in expanding beneficiary enrollment in MTM programs.

However, we have the following significant concerns with the proposed changes to the MTM program criteria:

• As a threshold issue, CMS cites reports that only 9% of Medicare Part D enrollees are currently participating in MTM programs. CMS estimates that the proposed changes would

⁸⁸ https://www.cbo.gov/publication/57772#:~:text=Use%20of%20prescription%20drugs%20among,year%E2%80%94a%2013%20percent%20increase.

⁸⁹ https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

increase MTM enrollment to 23%, close to its 2005 projection of 25% MTM enrollment. But the fact that MTM program enrollment rates do not match original projections does not, in our opinion, justify the expansion of eligibility criteria. More critically, focusing on the fact 9% of Part D enrollees are in MTM programs fails to account that other Part D enrollees receive medication care management through other means.

- + Plans offer a variety of services, which can range from activities like screening for drug interactions through claims adjudication to more direct enrollee engagement through UM tools, wellness checks, etc. As part of this, plans may employ physicians, pharmacists, nurses, and other clinical experts in-house to engage patients on managing their medications—especially when specialty and other high-cost or complex drugs are involved. Those activities can accomplish the same care quality and safety aims of the formal MTM program for patients outside the current eligibility criteria—and at potentially significantly lower costs.
- + Contracted physicians and pharmacists also conduct regular outreach on patient therapy adherence consistent with clinical standards of care and their provider contracts with plan sponsors.
- + We are concerned that enhanced MTM eligibility could generate overlapping outreach efforts that could overwhelm beneficiaries, including patients with cognition issues, to the point where it discourages patients from participating in similar activities with plans, physicians and pharmacies that have a record of success. Beneficiaries cannot be helped by MTM programs or other plan outreach efforts if they request to be placed on "do not contact" lists in response to these changes.
- In addition, the proposed rule does not offer clear evidence suggesting increased enrollment in the MTM program will improve patient care outcomes. Prior analyses in fact have raised questions about the level of benefits and savings under the MTM program. 90 We believe that before proposing to expand MTM program eligibility, CMS should provide an updated analysis that evaluates the effectiveness and costs of MTM programs and in comparison to the other non-MTM program-specific plan interventions/care management efforts noted above that may target the same (or similar) populations, before determining to expand MTM eligibility.
- As noted, CMS estimates that the proposed changes would result in significant increases in enrollment. The agency also estimates that costs would increase by \$336M annually, although CMS acknowledges that not all costs involved can be quantified due to the nature of

⁹⁰ https://innovation.cms.gov/data-and-reports/2022/mtm-fourth-evalrept.

administering these programs. While there is concern among our members that this estimate undercounts—perhaps significantly—those projected enrollment and cost burdens, even if those projections were to be proven accurate, we have serious concerns with CMS proposing to increase plan MTM costs by 64% in a single plan year, including the need for rapid increases in staffing and administrative infrastructure, at the same time plans are gearing up to devote significant resources to implementing major program changes resulting from the recently enacted IRA. In addition, CMS changes relating to pharmacy negotiated prices also take effect in 2024; we have noted our serious concerns with the impact of such changes as well. The combined impacts of these changes could further increase premium pressures and government costs.

AHIP members have also shared their concerns that it would be difficult—if not
impossible—to find enough pharmacists and other clinicians qualified to implement the
proposed MTM program expansion mandate. While plans may seek to contract with outside
vendors to help meet the added demand, a 2024 effective date would provide plans with
limited time to adequately assess the quality of services to be provided so they can ensure
high-quality services for patients and avoid abrasion, including potentially negative impacts
on Star Ratings scores.

Accordingly, AHIP strongly recommends CMS withdraw these proposed changes and instead conduct additional research of MTM and alternative methods, and provide the results for public review and comment, so stakeholders can better assess the implications of the changes. Subsequently, those findings should drive future engagement with stakeholders—clinicians, plan sponsors, beneficiary advocates, etc.—on how to revise eligibility criteria and/or other program changes going forward. However, if CMS chooses to finalize this proposal, we urge the proposed changes not be made effective for 2024, and that they be phased in over time to help mitigate potentially significant premium increases—especially in concert with pending IRA-mandated Medicare Part D changes to be implemented in the very near future.

W. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326I, 423.360(c), (§ 401.305(a)(2))

CMS proposes to revise the definition of when an MA plan or Part D sponsor has identified an overpayment by removing a reference to "reasonable diligence" and replace with language that gives the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act.

Discussion and Recommendations:

AHIP supports this proposal.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (§ 422.2)

CMS proposes a number of codifications and changes relating to "chronic condition special needs plans" (C-SNPs). For example:

- CMS would modify the definition of special needs individual to reflect a statutory change in the Bipartisan Budget Act of 2018 to the definition of a severe or disabling chronic condition.
- CMS would codify the list of chronic conditions that meet the statutory definition by including (with some modifications) conditions previously provided through sub-regulatory guidance and adding additional categories recommended by a panel of clinical advisors. Those new conditions would include conditions relating to obesity and related conditions, chronic gastrointestinal disease, and post-organ transplantation care and immunodeficiency and immunosuppressive disorders. Moreover, the proposal would add as chronic conditions certain functional needs that may be similar even if the underlying disease or chronic condition may differ. CMS provides the following examples: conditions that may cause cognitive impairment; conditions that may cause similar functional challenges and require similar services such as spinal cord injuries; chronic conditions that impair vision, hearing (deafness), taste, touch, and smell; and conditions that require continued therapy services in order for individuals to maintain or retain functioning. CMS also requests input on whether MA organizations require further guidance related to the functional needs categories.
- CMS would codify current guidance regarding MA plans' ability to offer C-SNPs focused on single or multiple chronic conditions. For C-SNPs that restrict enrollment to individuals with multiple commonly co-morbid and clinically-linked conditions (CMCLC), CMS would codify the currently approved set of five CMCLC and add three additional groupings recommended by the clinical advisor panel. CMS would also clarify that CMCLC C-SNPs may enroll eligible individuals who have only one of the qualifying conditions listed in the approved groupings.

Discussion and Recommendations:

We appreciate that CMS is proposing to modify, clarify and expand the current list of 15 chronic conditions to 22 conditions beginning in 2025. We believe this adjustment is appropriate and in keeping with developments in standards of care. As part of this proposal, we support including functional categories as chronic conditions so that individuals with similar kinds of functional

impairments can benefit from targeted models of care even though their underlying diagnoses may vary.

In terms of CMS' request for input on more guidance that may be needed on the new functional categories, we suggest that CMS take the approach of reviewing plan proposals for new C-SNPs organized around those functional categories and, based on that experience, determine whether additional guidance is needed. We note that the acuity or extent of functional impairments across a group of individuals may vary significantly. In that regard, CMS may wish to consider providing additional guidance on how and the extent to which an individual's level or degree of impairment should be considered as an element of eligibility criteria.

CMS also requests comments on the proposal to limit the regulatory definition of "severe or disabling chronic condition" to those conditions recommended by the panel of clinical advisors. We believe that it is appropriate to rely on the recommendations of a panel whose members have appropriate expertise and maintain currency with clinical innovation and standards of care.

G. Clinical Trial-Related Provisions (§§ 422.101 and 422.109)

CMS proposes to adopt regulations regarding MA plan coverage of clinical trials covered by Medicare under NCD 310.1 and as part of Category A or B Investigational Device Exemption (IDE) trials. CMS proposes to codify that an MA enrollee's in-network cost sharing must be included in the plan's maximum out-of-pocket calculation. CMS also proposes to specify that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan (nor create impediments to participation in such a trial).

Discussion and Recommendations:

AHIP and our member plans support Medicare coverage of clinical trial participation for beneficiaries across Medicare's coverage options. We appreciate CMS' efforts to ensure payment and coverage policies do not act as a barrier to such participation. We support the proposed regulations and clarifications relating to MA plan obligations regarding enrollee participation in covered clinical trials, including IDE trials. We encourage CMS to continue providing MA plans with information about clinical trials that qualify for Medicare coverage and MA plan responsibilities related to such trials.

O. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38)

CMS proposes two (2) revisions to the end date(s) for the SEP for a government entity-declared disaster or other emergency. First, in the case of a State or local emergency or disaster where a

specific end date of the emergency or disaster is not declared, the end date for the SEP may also be based on the emergency or disaster order automatically expiring pursuant to a State or local law, if such a law exists. Second, if no end date for the emergency or disaster period is specified, the SEP would end one year after the SEP start date.

Discussion and Recommendations:

AHIP supports the proposed revisions to the end dates for SEPs resulting from State or local emergency or disaster declarations. While SEPs for individuals affected by such disasters are important for protecting enrollees' ability to access care and needed benefits, the lack of clear end dates for SEPs lead to confusion and uncertainty. CMS' proposed specifications for SEP end dates in cases where the emergency or disaster end date is not clearly specified will provide certainty for both enrollees and plans.

AH. Gross Covered Prescription Drug Costs (§423.308)

To address a newly perceived ambiguity regarding interpretation of this term, CMS is proposing to revise its regulatory definition for Gross Covered Prescription Drug Costs (GCPDC) to fully "mirror" the statutory language in §1860D-15(b)(3) of the Social Security Act (SSA) by stripping the words "actually paid" from the regulatory definition in §423.308 in the Code of Federal Regulations (CFR). It is notable that the regulatory definition already mirrored the statutory language, but for the addition of the words "actually paid."

Discussion and Recommendations:

In the preamble, CMS states that this change "... would not constitute a change in policy or require a change in operations under Part D, and thus would not place any additional burden or reduce burden on Part D sponsors, nor result in government savings or costs." CMS also briefly notes that the GCPDC definition is incorporated into provisions of the IRA, specifically, those relating to new CMS negotiating authority for certain prescription drugs. While CMS explains at length why the change does not affect the calculation of reinsurance or have other Part D benefit implications, we believe the agency should also explain what, if any, effects the change could have under the IRA provisions such as the selection of drugs for negotiation or other implications. Without such explanation, it can be difficult for stakeholders to fully assess the consequences of the change or provide meaningful comment. Therefore, we urge CMS to explain the potential effects of this change under the provisions of the IRA.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

The MA Star Ratings program incentivizes plans to achieve high performance on quality and plays a vital role in helping millions of diverse individuals continue to have access to high-quality, coordinated care, affordable benefit offerings, and options they deserve and rely on. MA plans with Star Ratings of at least 4 stars receive increased funding as an incentive to achieve high performance. In turn, high performing plans use Star Ratings rebate funds to reduce cost-sharing and offer additional benefits to Medicare enrollees. For example, MA plans can offer dental, vision, and hearing aid benefits, as well as other benefits, including those that can address socioeconomic barriers to health. Star Ratings is also one of many factors reflected in the Medicare Plan Finder (MPF) tool to help Medicare enrollees choose between available plans in their service area.

Given the value of the Star Ratings program to MA enrollees, we have serious concerns about the combined impact of the proposed changes to the Star Ratings program that would make it more difficult for MA plans to achieve 4 or more overall Star Ratings. CMS estimates that its proposed changes would save a total of almost \$25 billion over 10 years. We offer comments below about specific components of these proposals but we emphasize our general concern that the cumulative impact of the proposed changes could result in reducing additional benefits offered by plans or increasing cost-sharing for Medicare beneficiaries without improving quality of care. Reducing supplemental benefit offerings in particular would run counter to the Administration's health equity goals, as supplemental benefits support plan efforts to advance them.

D. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

CMS proposes to make a number of measure-specific and other changes under this Star Ratings proposal:

- <u>Data Collection</u>. CMS proposes to add collection of data through alternative sources or modes of collection to the list of non-substantive measure updates that can be made without rulemaking under existing regulations. For example, if a web mode of survey administration is added to the current mail with telephone follow-up of non-respondents survey administration that is currently used for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey and the Health Outcomes Survey (HOS), CMS would consider this to be a non-substantive change that could be announced without going through the rulemaking process because, CMS reasons, there would only be a change in the method of collection and not a change in the information collected.
- Parts C & D Measures. CMS proposes to make a number of changes to the measures included in the Parts C and D measure set, including implementing risk adjustments for the three Part D medication adherence measures.

Discussion and Recommendations:

• <u>Data Collection</u>. While we support the addition of alternative modes of data collection to the Star Ratings program requirements, we do not agree that this change is non-substantive. Differing survey modalities have been shown to produce varying results, even when the same survey questions are asked. 91,92 Additionally, survey modality preferences differ by age groups, 93,94 which may also affect the population responding and, therefore, the survey results. We believe adding a web-based data source for the surveys, especially CAHPS, would likely increase the number of respondents which could have a significant impact on the numerator or the denominator and subsequently a plan's performance results. We therefore recommend that CMS finalize this policy change as a substantive change in accordance with existing Star Ratings rules that cover substantive updates.

Parts C & D Measures.

+ Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. CMS proposes to implement risk adjustment for the three Part D medication adherence measures based on sociodemographic status (SDS) characteristics for 2028 Star Ratings. CMS also proposes to implement other changes to these measures, including removing the adjustment for stays in inpatient (IP)/skilled nursing facilities (SNF), starting with the 2026 measurement year (2028 Star Ratings). To prepare for the application of SDS risk adjustment for the medication adherence measures, AHIP and our members recommend CMS provide more details on the risk adjustment methodology for these measures to allow for additional assessment and input. For example, information should be provided on whether plans will test against their own population or if vendors will test against the entire Medicare population and give plans the adjustment at the end of the period. Plans need to better understand these and other details to forecast performance and make other adjustments. Several AHIP members have also raised concerns about CMS' plans to remove the adjustment for IP/SNF stays from the medication adherence measures starting with the 2026 measurement year (2028 Star Ratings). CMS indicates that its analysis revealed that this change would have minimal impact on ratings. However, AHIP members are concerned that this change would be

⁹¹ Keeter, S. "Methods Can Matter: Where Web Surveys Produce Different Results than Phone Interviews." PewResearch.org. Available online at: https://www.pewresearch.org/fact-tank/2015/05/14/where-web-surveys-produce-different-results-than-phone-interviews/.

⁹² Christensen A, Ekholm O, et. al. "Effect of Survey Mode on Response Patterns: Comparison of Face-to-Face and Self-administered Modes in Health Surveys." Eur J Public Health. 2014.

⁹³ Palonen M, Kaunonen M, Åstedt-Kurki P. "Exploring How to Increase Response Rates to Surveys of Older People." Nurse Res. 2016.

⁹⁴ Gigliotti, L. and Dietsch, A. "Does Age Matter? The Influence of Age on Response Rates in a Mixed-Mode Survey." Human Dimensions of Wildlife. 2014.

impactful. We also recommend that CMS provide plans with more details on its analysis related to the removal of the IP/SNF stay adjustment prior to finalizing this proposed change.

+ Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures. CMS proposes to add these three Part D measures to the 2026 Star Ratings. These measures are currently on display. AHIP and our members have concerns with CMS' proposal to move these three measures from the display page to Star Ratings for 2026. While we recognize the potential harmful impacts associated with the use of these medication regimens in the Medicare population, we do not support adding these measures to Star Ratings as they may hamper a plan's ability to support appropriate medication use and ensure access to care. We have several concerns. First, we want to ensure that mental health conditions that may impact the use of these medications are appropriately accounted for and note that there are cases where concurrent use may be appropriate, which is not reflected in the measures' specifications. Second, we are concerned that concurrent use, defined under the specifications for these measures, as overlapping days greater than or equal to 30 days in the measurement period, may not provide plans with adequate time to assess whether the benefit of concurrent use outweighs the risk and to coordinate activities with prescribers. Third, some medications included in these measures would require dosage tapering and management of withdrawal symptoms which are clinical practices and patient safety measures that are also not accounted for in the measures' specifications. Finally, we believe CMS should delay the addition of these measures to Star Ratings due to the impact the proposed changes to the Part D Medication Therapy Management (MTM) eligibility requirements could have on plan performance on these measures if finalized. We urge CMS to delay adding these Part D measures to the Star Ratings until the concerns we and our members have raised are fully considered and addressed.

E. Measure Weights (§§ 422.166(e) and 423.186(e))

CMS proposes to lower the weight of patient experience/complaints and access measures from 4 to 2 beginning with the 2026 Star Ratings.

Discussion and Recommendations:

For several years, AHIP has recommended that CMS decrease the weight of CAHPS measures used in Star Ratings from 4 to 2. We have raised concerns about the current disproportionate weight for CAHPS measures in comparison to evidence-based clinical quality outcome measures. Reducing the weight of CAHPS measures to "2" would result in these measures being

weighted higher than process measures but not as high as clinical quality outcome measures. In addition, this change is consistent with one of the goals of CMS' Quality Strategy⁹⁵ and would align more closely with the weight these types of measures are given in other CMS quality programs. AHIP agrees with CMS' proposal to lower the weight of CAHPS measures from 4 to 2.

We also ask CMS to consider the comments submitted by AHIP members on this topic. In addition, we appreciate that CMS continues to work with the Agency for Health Research and Quality (AHRQ) and National Committee for Quality Assurance (NCQA) to research longer-term solutions to improve the CAHPS survey and response rates. Such potential approaches could include reducing the length of the survey; increasing sample size; and revising the questions to better reflect the current health care delivery system, including use of telehealth and non-physician clinicians. Additionally, removing questions from surveys addressing circumstances falling outside of a health insurance provider's control or with low reliability and/or validity would make room on the survey for questions that could be used to measure emerging quality issues and address health equity concerns without increasing the burden on respondents. We welcome the opportunity to engage with CMS on comprehensive evaluation and field testing of improvements to the CAHPS survey.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

CMS proposes to remove guardrails when determining measure-specific cut points for non-CAHPS measures starting with 2026 Star Rating.

Discussion and Recommendations:

In the preamble, CMS explains that the intent of the guardrails policy is to improve predictability and stability of Star Ratings measure cut points from one year to the next. CMS believes that the combination of the mean resampling and Tukey outlier deletion (set to take effect with 2024 Star Ratings) would provide "sufficient predictability and stability of cut points from one year to the next." In the preamble, CMS explains that the guardrails, which were created in the 2019 final rule, were intended to increase the predictability and stability of cut points because recent experience calculating Star Ratings during the PHE showed that they were unable to keep pace with any unanticipated changes in industry performance. As a result, CMS believes the guardrails policy is no longer necessary. We believe that CMS should not be making a permanent methodological change based on the extraordinary situation experienced during the recent public health emergency. We do not agree that the current use of mean resampling along with application of the Tukey outlier deletion (set to take effect with 2024 Star

^{95 83} FR 16440 at page 16521, April 2018.

⁹⁶ 87 FR 79452 at page 79626.

Ratings) would be an adequate substitute that increases cut point predictability and stability.

AHIP maintains that setting pre-determined cut points are the most effective way for CMS to improve predictability and stability under the Star Ratings program. Regarding value-based arrangements with providers, setting goals in advance of the measurement period is essential to helping plans and their network providers assess the effectiveness of their efforts to improve quality of care and reduce costs while maintaining high performance and rating levels. Moreover, setting cut points in advance of the measurement period reduces burdens on providers contracting with multiple plans who otherwise may face varying and conflicting quality performance metrics on the same quality measures. Setting cut points in advance of the measurement period would also support several CMS guiding principles for MA Star Ratings, including aligning Star Ratings with the current CMS Quality Strategy, ensuring contracts are treated fairly and equally, driving quality improvement, minimizing unintended consequences, and supporting transparency. Predictability, stability, and quality improvement.

The use of pre-determined cut points also aligns with principles of quality improvement. The Institute for Healthcare Improvement's (IHI) Model for Improvement is a widely accepted framework for quality improvement programs. 98,99 Setting quality aims and identifying measurement targets is the model's fundamental starting point. For the MA program, measure-specific cut points can serve as quality improvement aims. Additionally, pre-determined cut points could identify "stretch goals" that align with IHI's quality aims best practices to incentivize plans to identify and direct care toward populations experiencing health disparities that require individualized quality improvement solutions. Establishing pre-determined cut points for measures linked to clinical disparities can help plans set goals to aim quality improvement efforts toward populations with unique needs. Use of pre-determined cut points also empowers consumer choice as consumers are increasingly relying on categorical ratings and scores to inform their decisions. With the increasing number of MA plan choices that are available, pre-determined cut points could help clearly and meaningfully communicate the value of each MA plan to the beneficiary. For example, a beneficiary with diabetes may be most interested in choosing a plan with high Star Ratings on diabetes care measures.

We therefore do not support the elimination of the guardrails policy and the introduction of the Tukey outlier deletion (per our prior comments on this issue). Instead, AHIP recommends CMS assess and consider proposing the setting of cut points for Star Ratings

⁹⁷ Id

⁹⁸ Institute for Healthcare Improvement, "Science of Improvement: How to Improve." Available online at: https://www.ihi.org/resources/Pages/HowtoImprove/default.aspx.

⁹⁹ Langley, G., Moen, et. al. "The Improvement Guide: A Practical Approach to Enhancing Organizational Performance." 2nd Edition. April 2009.

measures well in advance of the measurement period. As discussed above, pre-determined cut points would enable MA plans and their network providers to better manage their quality care and health equity improvement efforts, allow for greater methodological transparency, and allow plans and their network providers to better understand the goals for each Star Ratings measure.

We also ask CMS to consider the comments submitted by AHIP members on this topic.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

CMS proposes to use a health equity index (HEI) in the Part C and Part D Star Ratings starting with the 2027 Star Ratings (which would include data from the 2024 and 2025 measurement periods). The HEI adjustment would reward contracts for obtaining high measure-level scores for the subset of their enrollees with specified social risk factors (SRFs). The SRFs included in the HEI would be low-income subsidy or dual eligibility (LIS/DE), or disability. CMS also proposes to eliminate the reward factor after 2026 Star Ratings, contingent on finalizing the addition of the proposed HEI reward.

Discussion and Recommendations:

We appreciate the details CMS has included in the regulation regarding the agency's HEI proposal. We support the goal of the HEI to further incentivize MA plans to focus on improving care for enrollees with SRFs. However, given the complexity of the proposal, we recommend CMS address questions raised about the HEI, perform additional modeling, and make additional changes as recommended below prior to finalizing and adding it to Star Ratings. We also oppose elimination of the reward factor, which could penalize high-performing plans.

We have the following specific comments and recommendations about CMS' HEI and reward factor proposals:

• HEI. AHIP members have many questions about the HEI methodology that would need to be addressed before its introduction into Star Ratings. For example, plans need to learn more about the contract level proportions of enrollees with SRFs that would be included in the HEI. In addition, plans need to review the stratified measure performance reported by SRFs that would be included in the HEI. Plans would also appreciate CMS' feedback and analysis on whether the HEI should be treated as an adjustment or separate measure in Star Ratings.

There are other aspects of the MA program that could impact a plan's HEI result that CMS should also address prior to finalizing this program requirement. For example, in the 2023

MA and Part D rule ¹⁰⁰, CMS finalized its proposal to create a pathway for states to require D-SNPs with exclusively aligned enrollment to hold a "D-SNP only" contract starting with plan year 2025. AHIP members have raised concerns about the impact on a plan's HEI result if D-SNP only contracts are compared to non-D-SNP contracts under the proposed HEI reward system. Concerns have also been raised about the impact of the HEI adjustments for contracts that are too small or have other characteristics that would disqualify them for a positive adjustment under the HEI. For example, a plan may have many enrollees with SRFs under a large contract, but the percentage may be too small to make the contract eligible for an HEI adjustment. Furthermore, plans may have contracts with many enrollees with other SRFs that would not be captured by the proposed HEI methodology.

Given these concerns, we urge CMS to delay the introduction of the HEI into Star Ratings. We believe CMS should first address all questions and issues raised about the HEI during this comment period. Next, CMS should pilot test the HEI for at least one performance year and provide plans with confidential feedback reports, and then seek additional public comments prior to finalizing and adding the HEI to Star Ratings. This approach would ensure plans have an opportunity to understand, assess and provide meaningful feedback to CMS to promote accuracy, reliability, and utility of the HEI and its results. We also ask CMS to consider specific comments about the HEI submitted by AHIP members.

• Reward Factor. CMS also proposes to eliminate the reward factor after 2026 Star Ratings. In the preamble, CMS explains that the reward factor was added to Star Ratings to provide "additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures." CMS further explains that over time the agency has established additional methodological changes (e.g., addition of Parts C and D quality improvement measures) to incentivize performance improvement across measures and therefore the reward factor is no longer needed. CMS further states that "[t]he removal of the current reward factor is contingent on finalizing the addition of the proposed HEI reward." 102

We have significant concerns regarding CMS' proposal to remove the reward factor from Star Ratings. Removal of the reward factor represents a significant change to the program and would result in penalizing consistently high-performing plans. CMS anticipates a 10-year Medicare savings estimate of \$5.13 billion with the addition of the HEI and elimination of the reward factor. Star Ratings for high-performing plans with a disproportionate share of enrollees with SRFs could be adversely impacted with the addition of the HEI and elimination of the reward factor. Lower Star Ratings for high-performing

^{100 87} FR 27704, May 9, 2022.

¹⁰¹ 87 FR 79452 at page 79626.

¹⁰² 87 FR 79452 at page 79627.

plans due to the elimination of the reward factor could also adversely impact Medicare enrollees by reducing additional benefits offered by plans or increasing cost-sharing requirements. We therefore oppose CMS' proposal to eliminate the reward factor and recommend the agency further analyze the potential adverse impacts of its proposal.

H. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

Under the current improvement measure hold harmless provision, Part C and Part D scores are calculated both with and without the improvement measures, and contracts with 4 or more stars are held harmless from having the highest rating reduced by the addition of the improvement measures. CMS now proposes to modify the Part C and Part D improvement measure hold harmless provision to limit its application to contracts with 5 stars only beginning with the 2026 Star Ratings.

Discussion and Recommendations:

In the preamble, CMS indicates its belief that the hold harmless provision is not needed for contracts with 4 or 4.5 Star Ratings because these plans "still have the potential to increase scores across measures and thus their Star Ratings." With this proposed change, CMS also anticipates a 10-year Medicare savings estimate of \$19.53 billion. ¹⁰⁴

Given the variability of Star Ratings cut points year to year, we are very concerned that with the proposed change to the hold harmless policy for the improvement measures, slight differences in performance on a small number of measures could have an inordinately adverse impact on a high-performing plan's overall Star Ratings. We are also concerned that Part D plans will be undergoing significant operational changes due to implementation of IRA provisions, which could lead to more challenges hindering plans' ability to achieve higher Star Ratings that are not necessarily indicative of performance or care quality. Although CMS views this policy change as a way to encourage continued quality improvement, it could result in penalizing high-performing plans. We believe that given the complexity and rigorous nature of the Star Ratings program, achieving and maintaining 4 stars takes tremendous effort and should not be discounted.

We are further concerned that CMS' proposed change to limit the application of the improvement measures' hold harmless policy could adversely impact MA beneficiaries. The existing hold harmless policy has driven quality improvement across measures. MA plans with a Star Rating of at least 4 stars receive increased funding as an incentive to achieve high performance. Plans use these funds to provide additional benefits and reduce beneficiary costsharing. Health plans that obtain the quality bonus payment for achieving 4-Stars or higher are

¹⁰³ 87 FR 79452 at page 79632.

¹⁰⁴ 87 FR 79452 at page 79702.

able to offer more robust supplemental benefits such as dental, vision, hearing aids, meals, nutrition, transportation, and in-home services and supports. These enhanced benefit offerings are also critical to addressing social drivers of health and advancing health equity. Limiting the offering of these benefits for disadvantaged populations would work against the Administration's health equity goals and could worsen disparities in health outcomes. Changes to the Star Ratings program should support, not take away, vital benefits. We therefore oppose CMS' proposal to modify the Part C and Part D improvement measure hold harmless provision and urge the agency to not adopt this policy change.

I. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

CMS proposes to modify its extreme and uncontrollable circumstances policy by no longer applying the "60 percent rule" starting with 2026 Star Ratings. The 60 percent rule excludes, for all non-CAHPS measures, the numeric scores for contracts with 60 percent or more of their enrollees living in a FEMA-designated Individual Assistance area when calculating cut points for non-CAHPS measures.

Discussion and Recommendations:

AHIP supports the removal of the "60 percent rule" for extreme and uncontrollable circumstances and recommends CMS adopt this proposal in the final rule.

Other Star Ratings Comments

AHIP has additional comments on other Star Ratings issues for CMS' consideration.

Discussion and Recommendations:

- Impact of IRA implementation on Star Ratings. We are concerned about the unanticipated impacts that implementation of IRA provisions will have on certain Star Ratings measures and plan performance. Beneficiary complaints and confusion as well as other factors outside of plan control could impact plan performance on various measures including, but not limited to, survey and administrative measures (e.g., complaints, disenrollment). We recommend that CMS consider applying a hold harmless policy for 2024 and 2025 Star Ratings years through an interim final rule or other mechanism to ensure that summary and overall Star Ratings for individual plans do not go down if lower performance results are likely due to IRA impacts.
- Part D MTM Program Completion Rate for CMR. CMS is proposing to make significant changes to the Part D MTM program requirements. Included are multiple changes to the enrollee targeting/eligibility criteria to improve access for enrollees CMS asserts could

benefit from these services. Accordingly, any of the changes that CMS finalizes related to the MTM program requirements should be considered as substantive changes under the Star Ratings program rules at §423.184. We recommend CMS address the impact of these substantive changes to the Part D MTM measure in a future rule for additional stakeholder input prior to finalizing the proposed changes to the MTM program requirements.

• Part C and Part D Members Choosing to Leave the Plan Measures. Several AHIP members have raised concerns about the impact of IRA implementation and other factors that could unfairly impact plan performance on the Part C and Part D Members Choosing to Leave the Plan measures. Under the IRA, Medicare enrollees who take insulin have access to an SEP in 2023 which could impact plan performance for the 2023 measurement year (2025 Star Ratings). Plans should not be penalized for member enrollment changes during this additional SEP, as such election changes have no bearing on the plan's performance but are due solely to statutory changes established by the IRA. There are also circumstances where an enrollee with an existing plan may select another plan under the same MA organization because their care and benefit needs have changed. For example, a member may choose to move to a D-SNP within the same parent organization or move from a PDP to a MA-PD due to changing life circumstances. If a plan assists a beneficiary to move to a product that may be more appropriate for their situation, the change should be excluded from the Members Choosing to Leave the Plan measures. We ask CMS to review and address the above issues that could impact plan performance on this Part C and Part D measure.