Humana Inc.
500 W. Main St.
Louisville, KY 40202-2946
www.humana.com

January 27, 2025

Jeff Wu, Acting Administrator
Cheri Rice, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted electronically via regulations.gov

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

Dear Acting Administrator Wu and Acting Deputy Administrator Rice:

This letter is in response to the "Medicare Program; Contract Year 2026 Policy and Technical Changes" proposed rule as issued by the Centers for Medicare & Medicaid Services (CMS) on December 10, 2024.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. Humana currently serves approximately 6.2 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 2.2 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As one of the nation's top contractors for MA, we are distinguished by our long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the MA program as their safety net – receive integrated, coordinated, quality, and affordable care through our plans. Our perspective is further shaped by the comprehensive medical coverage we provide for Medicaid beneficiaries in nine states.

Humana looks forward to working with the new administration to deliver on President Trump's commitment to reduce unnecessary regulations and to decrease administrative burdens. We believe that CMS can take an important step forward in this effort by adopting the following changes to the proposed rule:

- **Part D Coverage of Anti-Obesity Medications (AOMs) and Application to the Medicaid Program –** Humana agrees there is a need to address the increasing prevalence of obesity in the United States and that newer AOMs are a potential tool to address morbidity and mortality associated with obesity, when paired with lifestyle modifications and used adherently. However, we disagree with the proposed reinterpretation of the Part D statutory exclusion of "agents

when used for . . . weight loss". Congress must amend the Part D statute to allow for coverage of agents when used for weight loss and prescribed solely for the treatment of obesity. Additionally, State Medicaid programs already have the option to extend coverage for AOMs to include treatment for obesity, and this coverage decision should continue to remain with the states.

- **Medicare Prescription Payment Plan (MPPP) –** Although Humana supports CMS efforts to promote affordable access to drug therapies, we believe CMS should establish additional mechanisms under the program to encourage participants to adhere to their monthly payments whenever possible and minimize program abuse. We also oppose proposed changes to previous guidance on the MPPP until program experience is available to guide such modifications, especially when such changes minimize plan flexibility or create undue burden. We see a need for at least one year's experience with the MPPP to gauge both the reaction of first-time participants and our responsibilities as a Part D plan sponsor.

- **Marketing of Supplemental Benefits –** Humana appreciates CMS's desire to ensure that advertisements accurately depict the benefits offered, and we support efforts to prevent misleading communications to beneficiaries; however, we are concerned that prohibiting the marketing of specific allowance amounts of supplemental benefits or the mechanisms of card usage will intentionally withhold vital information that beneficiaries rely on to make informed decisions. In an effort to address these concerns, Humana suggests revising the proposed guidelines to prevent only the advertisements that falsely claim "free money," while still allowing for the clear and factual presentation of essential plan details.

- **Health Equity Index Reward –** While Humana supports efforts to address barriers to quality health outcomes for vulnerable and underserved populations, we strongly urge the Trump Administration to withdraw the implementation of the Star Ratings Health Equity Index (HEI) for the 2027 Star Ratings and delay its implementation until at least two years of plan-level data for the industry are made publicly available. with adequate time to respond and prepare before the measurement period begins. We have serious concerns that CMS has not adequately shared the data required for plans to fully understand the methodology and their performance for their plans and the industry on the HEI, even as the agency has publicly stated it would. In fact, only one year of data has been shared and only days before the measurement period began, leaving plans virtually no time to understand their performance. It is vital that the Star Ratings are an accurate and reliable reflection of of plan quality and it is imperative that plans have the necessary data to enhance performance. Humana strongly recommends that CMS delay implementation of the HEI and and maintain the current reward factor for the 2027 Star Ratings.

We hope that you consider our comments as constructive feedback aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to beneficiaries, focused on improving their total health care experience. If you have any questions, please do not hesitate to reach out to me at mhoak@humana.com and 571-466-6673.

Sincerely,

Michael Hoak
Vice President, Public Policy

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

II.A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D (§§ 423.100 and 423.120)

CMS proposes to codify the Inflation Reduction Act's requirement that the Medicare Part D deductible shall not apply to, and there is no cost-sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.

> **Humana Comment:** Humana believes vaccination is one simple and effective way older adults can work toward achieving their best health. We support the Inflation Reduction Act's elimination of cost-sharing for adult vaccines recommended by the ACIP and the proposed rule's provisions codifying those requirements.

II.B. Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D (§§ 423.100 and 423.120)

CMS proposes to codify definitions and requirements included in the Inflation Reduction Act and previous regulatory guidance. Specifically, CMS proposes to define "covered insulin product applicable cost-sharing amount" as an insulin product covered under a PDP or an MA-PD plan prior to an enrollee reaching the annual out-of-pocket threshold during plan year 2026 and each subsequent plan year, with cost sharing equal to the lesser of: $35; an amount equal to 25 percent of the maximum fair price established for the covered insulin product; or, an amount equal to 25 percent of the negotiated price of the covered insulin product under the PDP or MA-PD plan.

> **Humana Comment:** Humana supports efforts to ensure Medicare Part D enrollees have access to affordable insulin products. We participated in the Part D Senior Savings Model through our Insulin Savings Program (ISP), a precursor to the Inflation Reduction Act's provisions that limit enrollee cost sharing for covered insulin products. We support the proposed rule's provisions that codify definitions and requirements on this topic included in the Inflation Reduction Act and previous regulatory guidance.

II.C. Medicare Prescription Payment Plan (MPPP) (§§ 423.137, 423.2265, 423.2267, and 423.2536)

II.C.1. Background (§§ 423.137, 423.2265, 423.2267, and 423.2536)

CMS proposed and finalized two pieces of informal guidance on the MPPP program, as well as model communication materials for the program, in 2024. CMS does not have authority to implement the MPPP through program instruction authority beyond 2025 and proposes to codify existing requirements for the program for plan year 2026 and subsequent years.

> **Humana Comment:** Humana supports the policy goal of establishing the MPPP as a mechanism to allow Part D enrollees to spread significant costs over time in lieu of a single larger expense. We submitted comments on parts one and two of the initial CMS guidance on MPPP in September 2023 and March 2024, respectively, and appreciate CMS's desire to ensure that program operations for plan year 2026 are consistent with those established for plan year 2025.
>
> Although we understand that CMS does not have explicit authority to implement the MPPP through program instruction beyond 2025 and must take action to codify existing program parameters, we caution that programmatic changes for plan year 2026 should be kept to a minimum. Plan sponsors are still in the process of gauging member interest in the MPPP and do

not yet have concrete experience administering the program. Humana recognizes that the MPPP will necessarily evolve over time once experience begins to accrue, and we encourage CMS to identify program adjustments capable of streamlining the participant experience and minimizing plan sponsor burden. We look forward to working closely with CMS to improve the MPPP experience in 2026 and beyond.

II.C.2(a). Basis, Scope, and General Rule (§§ 423.137, 423.2265, 423.2267, and 423.2536)
CMS proposes to define "OOP costs for the Medicare Prescription Payment Plan" as the cost sharing amount the Part D enrollee is directly responsible for paying. Additionally, CMS proposes to define "remaining OOP costs owed by the participant" to be the sum of OOP costs for the Medicare Prescription Payment Plan that have not yet been billed to the program participant. CMS proposes to define "OOP costs for the Medicare Prescription Payment Plan" as the cost sharing amount the Part D enrollee is directly responsible for paying. Additionally, CMS proposes to define "remaining OOP costs owed by the participant" to be the sum of OOP costs for the Medicare Prescription Payment Plan that have not yet been billed to the program participant.

Humana Comment: Humana appreciates the inclusion of these new definitions in the proposed regulations. While CMS has previously indicated that only patient-incurred costs would be eligible for inclusion in participant out-of-pocket (OOP) balances under MPPP, these definitions add additional clarity about the subset of costs eligible for the program. We concur with CMS that only costs directly incurred by a participant should be included in the balance owed by that participant.

II.C.2(b). Calculation of the Maximum Monthly Cap on Cost-Sharing Payments (§ 423.137(c))
CMS proposes to codify the calculation standards established in the final part one MPPP guidance into the CFR for plan year 2026 and subsequent years.

Humana Comment: Humana supports CMS's desire to codify these existing definitions and standards related to the calculation of costs eligible for the MPPP.

II.C.2(c). Eligibility and Election (§§ 423.137(d) and 423.2267)
In this rule, for 2026 and subsequent years, CMS proposes to codify requirements for how Part D sponsors must process program election requests, including timing and notice requirements, procedures for collecting missing information on election requests, and requirements for retroactive election in the event the Part D sponsor fails to process an election within 24 hours at § 423.137(d)(4). These requirements are consistent with those set forth in parts one and two of the previous CMS guidance on MPPP.

CMS proposes to codify the 24-hour effectuation requirement at § 423.137(d)(4) for 2026 and subsequent years and also requests comment on a potential requirement for Part D sponsors to effectuate election requests received via phone or web in real-time for 2026 or future years.

CMS also proposes an automatic election renewal process for 2026 and beyond, wherein program participation continues into the next upcoming year automatically, provided the participant remains in the same PBP in the upcoming year, unless the program participant indicates otherwise. CMS further proposes to require Part D sponsors to send a renewal notice alerting the program participant that their participation in the program will continue into the next year unless they indicate that they would like to opt out for the upcoming year. This notice would be required to be sent out to program participants by

the end of the AEP and must include the Part D sponsor's program terms and conditions for the upcoming year and a reminder that the participant may opt out of the program at any time, including for the upcoming plan year. If an enrollee is switching Part D plans, including switching between two PBPs offered by the same Part D sponsor, the automatic election renewal process would not apply.

Humana Comment: Humana expects to be fully compliant with the 24-hour effectuation requirement originally established by the final part two guidance on MPPP for plan year 2025. Despite that, we are concerned about the potential volume of such elections and therefore caution CMS about employing a strict enforcement of this standard during the first year of MPPP operations. Furthermore, CMS should ensure that there are exceptions to this timeline for participation requests that are not processed electronically or telephonically, as we foresee situations in which it will not be possible to process a paper-based election received via mail within the proposed 24-hour timeline. While we anticipate working with CMS to facilitate successful implementation of the payment plan, we also encourage CMS to use careful discretion in seeking to enforce the myriad program provisions in plan year 2025.

We further caution CMS about establishing an expectation that MPPP participation requests can be processed in real-time. While we suspect some enrollees may benefit from an immediate effectuation, such as those who are presently seeking to fill a prescription with high OOP costs, we also anticipate administrative hurdles in implementing a truly real-time participation standard which would require participation or involvement from the pharmacy more directly, potential delays at the pharmacy counter, and investment from various downstream parties (claims processors, MPPP vendors, mail vendors, etc.).

In general, Humana supports CMS's concept of an automatic election renewal process under the MPPP. As plan sponsors and other stakeholders educate Part D beneficiaries about the MPPP, we anticipate that many of those beneficiaries will prefer to participate in the program beyond a single plan year and into subsequent years. A passive participation election wherein a beneficiary makes an affirmative participation election in a current plan year which then carries forward into subsequent years could streamline the participant experience and ensure that current MPPP participants are not caught off guard by future drug expenses.

However, we do not yet have practical program experience to gauge the interest of our members in such an approach. Since the MPPP only became operative on January 1, 2025, plan sponsors cannot yet know how beneficiaries will respond to the benefits and responsibilities associated with participation. Some beneficiaries who participate will undoubtedly benefit from the cost spreading effects of MPPP, while others may elect to participate despite having only modest annual drug expenses. For beneficiaries in the latter cohort, program participation may ultimately be more burdensome than beneficial as monthly bills replace traditional point-of-sale expenses.

We see a need for at least one year's experience with the MPPP to gauge the reaction of first-time participants. If the majority of initial MPPP participants make an affirmative election to participate again in plan year 2026, it could indicate strong satisfaction with the program and support use of a passive election process in future years. If, however, many (or most) initial participants do not elect participation for plan year 2026, a passive election approach could be counterproductive. **Accordingly, we recommend that CMS delay using an automatic election renewal process until at least plan year 2027**. Humana believes that beneficiary experiences

should guide changes to the MPPP election process and neither CMS nor plan sponsors can currently rely on any past program experience or participation data. Although we suspect an automatic election renewal process is likely to improve the participant experience over time, we also believe it is premature to establish such a process without an indication of initial beneficiary satisfaction.

II.C.2(d). Part D Enrollee Targeted Outreach (§ 423.137(e))

CMS proposes to maintain the criteria for Part D sponsor outreach prior to the plan year, during the plan year, and at the point-of-sale that were established in the final part one and final part two guidance for 2025. This includes use of the "Likely to Benefit Notice" and the pharmacy POS notification included in the previous guidance. CMS notes, however, that it plans to revisit these requirements in future rulemaking, as CMS gains program experience and can evaluate program data and operations. CMS seeks comments on potential changes to the outreach approaches included in this rule.

Humana Comment: We thank CMS for taking steps to finalize Part D sponsor outreach requirements for plan year 2026. Humana submitted comments on parts one and two of the initial CMS guidance on MPPP in September 2023 and March 2024, respectively, and in response to the proposed MPPP model communication documents in April 2024. We have been pleased that CMS has nimbly responded to stakeholder feedback on required communications to prospective MPPP participants and anticipate future revisions to these requirements as program experience accrues. We remain concerned about the possibility of participant confusion related to the new program and strongly support CMS's efforts to standardize communications whenever possible. Concurrently, we caution CMS in adopting "one-size-fits-all" outreach requirements and believe that plan sponsors should retain some flexibility in identifying and facilitating communications that best serve member needs.

Based on our initial implementation efforts, Humana believes the standard communication examples have been beneficial and ensured members are receiving consistent information from all plan sponsors. It will be informative to understand how much pharmacies and physicians utilize the model documentation, leave behind cards, etc. to inform members who may benefit about the program. We believe additional member research is necessary to understand if there are enhancements needed to improve members' understanding of the program.

Humana appreciates CMS's desire to revisit outreach requirements as MPPP experience dictates. We agree that beneficiary communication materials for the program must evolve to reflect the needs of our members. And while we believe that the model materials developed by CMS earlier this year provide a strong foundation for member outreach, we anticipate an iterative process aimed at beneficiary education that is capable of responding to insights gained during the initial years of MPPP operations.

II.C.2(e). Termination of Election, Reinstatement, and Preclusion (§ 423.137(f))

For 2026 and subsequent years, CMS proposes to maintain the requirement for Part D sponsors to send the notice of voluntary termination within 10 calendar days of receipt but require that the effective date of termination must be within 24 hours of receipt of the voluntary termination request.

CMS also proposes to make certain modifications to the timing requirements for the grace period and initial notice of nonpayment established in the final part one guidance. Specifically, in the final part one guidance, CMS stated that the grace period must begin on the first day of the month for which the

balance is unpaid or the first day of the month following the date on which the payment is requested, whichever is later. In this proposed rule, CMS proposes to change the date on which the grace period must begin to the first day of the month following the date on which the initial notice is sent. CMS seeks comments on whether to adopt this change or continue with the approach described in the final part one guidance.

CMS otherwise proposes to codify the existing standards for voluntary and involuntary terminations and preclusions set forth in parts one and two of the final MPPP guidance.

> **Humana Comment:** Humana appreciates CMS's desire to clarify the grace period. However, moving the start of the 60-day grace period to begin on the date of the initial notice of nonpayment will extend the grace period by up to a month from the initial claim in some cases. This is not consistent with the previous guidance and would require an additional change in implementation of this program for plan sponsors and members. The proposed change will allow for potential program abuse, as members will have an additional period of time to reach their maximum out of pocket under the MPPP, with no requirement to repay the member cost sharing funded by the plan during this period. Humana encourages CMS to allow for more time to evaluate member behavior under the MPPP prior to making a significant shift related to the timing of the grace period.
>
> Humana continues to encourage CMS to balance the financial benefits of payment plan participation to enrollees with the potential for program abuse by participants who may never fulfill their financial responsibilities under the MPPP. We believe that CMS must establish additional mechanisms under the program to encourage participants to adhere to their monthly payments whenever possible. During the annual enrollment period for 2025, Humana has offered members electing MPPP participation the option of providing a payment method at the time of enrollment for expenses accrued during the plan year. We believe that having a payment method on file streamlines the payment process for participants while also lowering the financial risk to plan sponsors resulting from unpaid MPPP balances. We encourage CMS to consider any and all options aimed at ensuring that MPPP elections are made in good faith and that participants fulfill their financial responsibilities under the program.

<u>II.C.2(f). Participant Billing Rights (§ 423.137(g))</u>

CMS proposes to codify most of the MPPP billing and reconciliation requirements set forth in parts one and two of the final MPPP guidance.

In addition, CMS proposes to require that a plan sponsor follow its normal processes for adjustments and issuing refunds. CMS also proposes to modify the approach when Part D claims adjustments result in increased amounts owed by the participant; instead of stating that Part D sponsors "should" include the additional costs in the revised remaining OOP costs owed by the participant, we now propose that Part D sponsors "must" include the increased amount in this manner. Lastly, CMS proposes to define each MPPP billing period as a calendar month and establish requirements for the contents of MPPP billing statements.

> **Humana Comment:** Humana largely supports CMS's decision to codify these billing requirements with the proposed changes. In all matters related to MPPP, we have encouraged CMS to balance the use of uniform program standards with plan sponsor flexibilities to optimize the participant experience. CMS is proposing to require plan sponsors to include any additional

costs resulting from Part D claims adjustments in the revised remaining OOP costs owed by a participant. We would prefer for plan sponsors to retain flexibility in the application of these costs until we have at least one year of participant experience so that we can appropriately understand the impact of this proposed change on participants.

Humana also appreciates the proposed list of information that must be included in participant billing statements. Given the length of the billing statement and specific information required, Humana anticipates that the billing statements will likely only vary somewhat from one plan sponsor to another. Additional member experience and feedback during 2025 should direct whether a model billing statement for MPPP is needed.

II.C.2(h). Pharmacy POS Notification Process

CMS proposes to codify the POS notification requirements outlined in parts one and two of the final MPPP guidance. This includes detail on the POS notification threshold established in that guidance and parameters on use of the "Likely to Benefit" notice developed by CMS for use by plan sponsors.

Humana Comment: Humana continues to support CMS's efforts to ensure that individuals who are likely to benefit from the MPPP are informed of their participation options. We agree with CMS that payment plan participation should be targeted towards individual enrollees who incur, or can be expected to incur, substantial OOP costs under Part D, as those are the beneficiaries who are most likely to benefit from the payment plan. We also agree that Part D enrollees who incur high OOP costs early in the coverage year have the highest likelihood to benefit from participation in the payment plan. In keeping with the final parts one and two guidance on the MPPP, we agree that there will be instances when beneficiary notification at the point-of-sale is both appropriate and necessary.

At the same time, we remind CMS that plan sponsors have limited tools with which to compel pharmacies to provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" to a Part D beneficiary when that individual fills a prescription triggering the OOP POS notification threshold. Humana is working closely with contracted pharmacies to ensure compliance with this requirement but requests that CMS grant plan sponsors adequate time to establish effective protocols with pharmacies. As CMS notes in the final part two guidance, the POS notification to beneficiaries "in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee".[1] We see the need for an iterative process in which plan sponsors can continue to engage with pharmacies to ensure that beneficiaries have access to materials that facilitate an informed decision about MPPP participation. Humana anticipates that experience accrued during plan year 2025 will further illuminate pharmacy and beneficiary preferences in this regard and ask that CMS again use careful discretion in its enforcement activities related to the POS notification requirement.

II.C.2(i). Pharmacy Claims Processing (§ 423.137(j))

CMS proposes to codify the claims processing requirements outlined in parts one and two of the final MPPP guidance. In addition, CMS proposes new OOP transparency requirements under MPPP. CMS proposes to require plan sponsors to ensure that pharmacies:

[1] CMS, "Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments," July 16, 2024.

- Can easily access a Part D enrollee's OOP cost for the Medicare Prescription Payment Plan at the point-of-sale; and,
- Are prepared to provide OOP costs for the Medicare Prescription Payment Plan to a participant at the point-of-sale.

Humana Comment: Humana appreciates CMS's recognition that pharmacies must necessarily play a key role in educating enrollees about the MPPP. We believe it will be vital for pharmacies to work in tandem with Part D plan sponsors to assist the enrollee decision-making process and convey both the potential benefits and responsibilities associated with MPPP participation.

Humana requests that CMS provide additional clarity on the mechanism(s) that it envisions plan sponsors using for purposes of communicating member OOP costs to pharmacies at the point-of-sale, as this information will be available on current, NCPDP standard claim responses to the pharmacy. The pharmacy could utilize these existing NCPDP standard claims responses to include member OOP on the transaction receipt or as part of other existing information provided to the member at point-of-sale. Given the significant change in 2025 to existing pharmacy workflows, Humana suggests that pharmacies are granted flexibility in providing this information until we have at least one year of member experience, to understand what information participants may need at point-of-sale to avoid confusion about the MPPP.

II.C.2(k). Monitoring, Compliance, and Data Submission Requirements (§§ 423.504, 423.505, and 423.514)

CMS proposes to codify the monitoring and compliance requirements outlined in parts one and two of the final MPPP guidance.

Humana Comment: Humana supports CMS's efforts to ensure that MPPP processes are compliant with program guidance and the proposed regulations. In the final part two guidance on MPPP, CMS stated that it does not intend to conduct any audits of plans sponsors' MPPP programs in 2025. The proposed rule is silent on whether CMS will conduct audits of the programs beginning in 2026. While we recognize the need for CMS to conduct relevant oversight of the MPPP, we would encourage CMS to consider utilizing existing Audit Protocols and processes and also urge CMS to conduct any potential audits with the understanding that this novel program requires plan sponsors to undertake duties outside their traditional purview. The established Program Audit or CMS 1/3 Financial Audits could be updated to include MPPP processes as part of their protocols and testing. We ask that CMS use caution in adjudicating the good faith efforts of plan sponsors to implement the program and work collaboratively with plans to address any perceived deficiencies.

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

III.A. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program

III.A.2. Proposed Reinterpretation

CMS is proposing that AOMs when used for weight loss or chronic weight management for the treatment of obesity would no longer be excluded from Part D coverage.

Humana comment: Humana agrees with CMS on the need to address the increasing prevalence of obesity in the United States. **However, we are concerned about CMS's proposed expansion in access to AOMs.** Our concerns are four-fold: (1) CMS's proposed reinterpretation of the Part D statute nearly 20 years after the enactment of the law is arbitrary and capricious; (2) the high cost of newer AOMs necessitates financial considerations to ensure sustainability for the Medicare program; (3) the proposal does not contemplate coverage for or plan flexibility to support wrap-around services necessary for appropriate AOM utilization; and (4) there is a lack of up-to-date clinical guidelines to assist providers in prescribing and managing use of newer AOMs. Altogether, we have yet to see data that shows AOMs have found a sustainable place in therapy and the poor persistence data challenges the ability to achieve long-term health outcomes benefits when used for weight loss alone. Thus, prior to any coverage expansion for AOMs, we encourage CMS to take steps to address these concerns. Additionally, in order to build evidence on the use of AOMs for the treatment of obesity in the Medicare population, CMS could conduct a Centers for Medicare and Medicaid Innovation (CMMI) demonstration to develop the best approach to expand AOM access. We provide more details on our concerns and recommendations below.

CMS's proposed reinterpretation of the Part D statutory exclusion of "agents when used for . . . weight loss" is arbitrary and capricious and contrary to the unambiguous language of the statute. The statute explicitly excludes coverage for "agents *when used for* . . . weight loss." AOMs prescribed to treat obesity fall directly within the statutory exclusion for "agents when used for . . . weight loss." Whether or not obesity is a disease is irrelevant to the interpretation of the statutory exclusion, as the statute does not provide an exception for agents when used for weight loss related to treatment of diseases or treatment of obesity.

As recognized by the Centers for Disease Control and Prevention (CDC), obesity is simply defined by a certain level of excess weight and is not tied to the underlying physiological factors or conditions causing the excess weight.[2] Drugs that are prescribed *solely for the treatment of* obesity are, therefore, directly targeting a loss of weight and solely being *used for* weight loss. The fact that the statute includes an exclusion for drugs used for cosmetic purposes *and* an exclusion for drugs used for weight loss undermines the argument that AOMs are not subject to the statutory exclusion if used for *clinical* weight loss, i.e., where the level of excess weight is considered a disease.

CMS's proposed reinterpretation of the Part D statutory exclusion is an attempt to resolve a statutory ambiguity where none exists. The Part D statutory exclusion of weight loss agents has a single, best reading despite changes in how the medical community has come to regard obesity as a disease since the inception of the Part D Program. The meaning of the Part D statutory exclusion for weight loss agents was fixed at the time of enactment and does not include exceptions for weight loss agents used in the treatment of diseases, including obesity. As noted above, while Humana agrees with CMS on the need to address the increasing prevalence of obesity in the United States, it is our position that the inclusion of AOMs for the treatment of obesity in Part D coverage requires an amendment to the Part D statute and is a matter Congress should deliberate.

[2] "Obesity and Overweight," Centers for Disease Control and Prevention, U.S. Department of Health & Human Services, Dec. 16 2024, www.cdc.gov/disability-and-health/conditions/obesity.html.

The high cost of newer AOMs necessitates financial considerations to ensure sustainability for the Medicare program, and high abandonment rates in real world evidence challenge long-term outcomes benefits. The proposed rule's regulatory impact analysis indicates that CMS estimates expanded coverage of AOMs would increase federal costs over the next 10 years by $24.8 billion for Medicare Part D and $14.8 billion for Medicaid, but the CMS Office of the Actuary notes there is a high degree of uncertainty in the estimates. The Congressional Budget Office estimates that Medicare costs would increase by $35 billion for a similar proposal over the same time period.[3] Although the IRA's premium stabilization provisions will mitigate Part D base beneficiary premium impacts until 2031, this provision does not fully insulate beneficiaries from plan premium changes (as evidenced by the introduction of the Part D premium stabilization demonstration for CY 2025). Thus, the CMS proposal will have implications for Medicare's solvency and for beneficiary premiums.

Budgetary costs of this proposal are in part driven by the high prices charged by pharmaceutical manufacturers, with annual net costs in the thousands of dollars per user. Employers and other commercial market payers have struggled with the cost of covering these drugs and ways to appropriately manage their use.[4] CMS has announced that Wegovy will be a selected drug for the Medicare drug price negotiation program with a maximum fair price in effect for 2027.[5] However, AOMs in the pipeline will likely also launch with high list prices in the coming years.

If expanded access truly drove improved health outcomes, this proposal could be money well spent. However, CBO estimates that average offsetting federal savings from AOM expansion would only be about $50 per user in 2026, reaching $650 in 2034.[6] Real world evidence from one PBM indicates that costs rose 46 percent over 2 years for patients trying GLP-1 drugs for obesity in the commercial market, with no reduction in other medical costs.[7] CMS actuaries also do not include any offsetting savings from expanded AOM use in the proposed rule's regulatory impact analysis.

Equally concerning is the widespread abandonment of treatment among patients. Studies have shown poor treatment adherence for GLP-1s, including 14.8% persistence at 2 years post-initiation[8]; in the proposed rule, CMS actuaries estimate that 52.5% of patients will discontinue treatment after 2 months. Medicare costs aside, treatment discontinuation is not in the best interest of the enrollee or their provider. Humana's internal data reflects similar findings, with 15% of GLP-1 utilizers abandoning treatment after one fill. This is why we recommend that CMS take steps to ensure newer AOMs are used appropriately and adherently, including support for development of clinical guidelines and explicitly providing for plan flexibility that would allow for exercise or dietary programs to be part of the AOM regimen, per our comments below.

---

[3] How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget? | Congressional Budget Office; The CBO report reflects estimates of a policy that would expand AOM access to all beneficiaries with obesity as well as certain beneficiaries who are classified as overweight.

[4] See: Patients Lose Access to Weight-Loss Drugs as Employers Stop Coverage - WSJ; North Carolina ends coverage of new weight loss drugs for 750,000 state employees.

[5] Fact Sheet: Medicare Drug Price Negotiation Program 2027 IPAY

[6] How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget? | Congressional Budget Office

[7] Weight-loss drugs didn't curb health costs within two years | Reuters

[8] Gleason P, Marshall L, et al., Year-Two Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1) Obesity Treatment Adherence and Persistency. Available at: prime-mrx-glp-1-year-two-study-abstract-final-7-10

Lastly, given the popularity of newer AOMs, there may be incentives for fraud or abuse as some may seek to obtain prescriptions fraudulently and resell these high-cost products. CMS should take steps to mitigate this risk.

The proposed rule does not contemplate coverage for or plan flexibility to support wrap-around services necessary for appropriate AOM utilization. Newer AOMs are not silver bullets; they need to be used in conjunction with more traditional interventions – like diet and exercise – to result in successful treatment. Specifically, the FDA labels for Wegovy and Zepbound (GLP-1 and GIP/GLP-1 agonists approved for treatment of obesity, respectively) indicate that the drugs should be used in conjunction with reduced calorie diet and increased physical activity. This is why the Treat and Reduce Obesity Act (TROA) – the legislative proposal in Congress to allow Medicare to cover AOMs for treatment of obesity – provides for intensive behavioral therapy coverage for obesity under Medicare Part B along with drug coverage.[9] This type of complimentary support is lacking in the CMS proposal, but necessary to address real world persistency challenges.

Without CMS action, plan authority today is limited both in terms of requiring diet or exercise changes along with drug treatment or requiring a non-pharmacological step to initiate or maintain treatment. This lack of plan authority has meaningful impacts for the reach of CMS's proposed policy, as patients enrolled in nutritional and exercise programs are more likely to finish 12 weeks of therapy, which is recommended to achieve clinically meaningful weight loss.[10] Humana recommends that CMS explicitly provide for plan flexibility that would allow for exercise or dietary programs to be part of the AOM regimen, similar to the flexibility granted within VBID program design. Without these appropriate lifestyle modifications, Part D enrollees could be at risk for unintended sequelae (e.g. muscle loss, falls, sarcopenia).[11]

There is a lack of up-to-date clinical guidelines to assist providers in prescribing and managing use of newer AOMs. As stated in the preamble to the proposed rule, obesity is associated with increased risk of a host of serious and life-threatening health conditions[12] and researchers estimate that annual obesity-related medical care costs in the United States, in 2019 dollars, are nearly $173 billion[13] and annual nationwide productivity costs of obesity-related absenteeism range between $3 and $6 billion[14]. Clinical trial data supporting the approval of new AOMs indicates that these are promising treatments that show potential to significantly address

[9] H.R.4818 - 118th Congress (2023-2024): Treat and Reduce Obesity Act of 2023 | Congress.gov | Library of Congress

[10] Issue Brief May 2024: Real-world trends in GLP-1 treatment persistence and prescribing for weight management

[11] See: Novel Approach to Sarcopenia in Diabetic Patients Treated with GLP-1 Receptor Agonists (GLP-1RA) | Diabetes | American Diabetes Association; Muscle matters: the effects of medically induced weight loss on skeletal muscle - The Lancet Diabetes & Endocrinology

[12] Consequences of Obesity | Overweight & Obesity | CDC

[13] Ward ZJ, Bleich SN, Long MW, Gortmaker SL .(2021). Association of body mass index with health care expenditures in the United States by age and sex. PLoS ONE 16(3): e0247307. Available at: https://doi.org/10.1371/journal.pone.0247307

[14] Trogdon JG, Finkelstein EA, Hylands T, Dellea PS, Kamal-Bahl. Indirect costs of obesity: a review of the current literature. Obes Rev.2008;9(5):489–500.

morbidity and mortality associated with obesity, when used appropriately and adherently.[15] We believe increased access to AOMs could be part of a broader solution to address the obesity crisis, but additional research and tools for providers and plans to appropriately manage the use of these drugs are needed prior to such an expansion occurring.

Specifically, there is a lack of up-to-date clinical guidelines to assist providers in prescribing and managing use of newer AOMs. Lack of guidelines makes it challenging for prescribers to ensure AOMs are used appropriately, and treatment is managed properly. Although we concur with CMS's proposal to allow plans to define obesity for purposes of establishing AOM coverage, the existence of clinical guidelines would assist plans and providers in ensuring appropriate use of treatments and maximizing potential patient benefit. Lack of obesity specialists is a complicating factor, as is the use of newer AOMs in the Medicare population, since Part D enrollees frequently have more complicated health care needs. We anticipate that many Medicare enrollees will access these treatments via their primary care physicians, who may have limited clinical experience or expertise in managing obesity in a primarily older adult population. Clinical guidelines, particularly with an emphasis on the Medicare beneficiary demographics, would help promote equitable and consistent treatment and monitoring. Humana recommends that CMS ensure the presence of clinical guidelines for AOM use among Medicare beneficiaries from medical professional societies prior to any coverage expansion.

Lastly, in order to ensure that Part D plans receive appropriate payment for enrollees prescribed an AOM for treatment of obesity, CMS should update the RxHCC risk adjustment model to reflect an obesity diagnosis. We encourage CMS to consider further modifications to the RxHCC model to ensure plans receive appropriate payment for enrollees who might be on an AOM maintenance medicine, but are no longer obese.

Conclusion and Recommendations. In summary, Humana agrees there is a need to address the increasing prevalence of obesity in the United States and that newer AOMs are a potential tool to address morbidity and mortality associated with obesity, when paired with lifestyle modifications, and used adherently. However, we disagree with the proposed reinterpretation of the Part D statutory exclusion of "agents when used for . . . weight loss". Congress must amend the Part D statute to allow for coverage of agents when used for weight loss and prescribed *s*olely for the treatment of obesity. Additionally, prior to any coverage expansion for AOMs, we encourage CMS to do the following:

[15] Rubino D, Abrahamsson N, Davies M, et al. Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults With Overweight or Obesity: The STEP 4 Randomized Clinical Trial. JAMA. 2021;325(14):1414–1425. doi:10.1001/jama.2021.3224; Garvey WT, Batterham RL, Bhatta M, Buscemi S, Christensen LN, Frias JP, Jódar E, Kandler K, Rigas G, Wadden TA, Wharton S; STEP 5 Study Group. Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial. Nat Med. 2022 Oct;28(10):2083-2091. doi: 10.1038/s41591-022-02026-4. Epub 2022 Oct 10. PMID: 36216945; PMCID: PMC9556320.; Wadden TA, Chao AM, Machineni S, Kushner R, Ard J, Srivastava G, Halpern B, Zhang S, Chen J, Bunck MC, Ahmad NN, Forrester T. Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial. Nat Med. 2023 Nov;29(11):2909-2918. doi: 10.1038/s41591-023-02597-w. Epub 2023 Oct 15. Erratum in: Nat Med. 2024 Jun;30(6):1784. doi: 10.1038/s41591-024-02883-1. PMID: 37840095; PMCID: PMC10667099.; Aronne LJ, Sattar N, Horn DB, Bays HE, Wharton S, Lin WY, Ahmad NN, Zhang S, Liao R, Bunck MC, Jouravskaya I, Murphy MA; SURMOUNT-4 Investigators. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial. JAMA. 2024 Jan 2;331(1):38-48. doi: 10.1001/jama.2023.24945. PMID: 38078870; PMCID: PMC10714284.

- Explicitly provide for plan flexibility that would allow for exercise or dietary programs to be part of the AOM regimen, similar to the flexibility granted within VBID program design.
- Ensure the presence of clinical guidelines for AOM use among Medicare beneficiaries from medical professional societies prior to any coverage expansion.
- Ensure the RxHCC risk adjustment model is updated to reflect an obesity diagnosis. We also encourage CMS to consider further modifications to the RxHCC model to ensure plans receive appropriate payment for enrollees who might be on an AOM maintenance medicine, but are no longer obese.

More research is needed on the best ways to expand access to obesity treatments while mitigating costs, using tools like: limited provider networks for prescribing AOMs; obesity management programs including access to nutritional counseling among other benefits; and healthy meal delivery or other interventions. We encourage CMS to support research and evidence development in this space, including potentially through a CMMI demonstration that could build evidence on AOM use in the Medicare population.

III.A.3. Impact on Medicaid Coverage

The CMS proposal to reinterpret the reference to "[a]gents when used for…weight loss" in section 1927(d)(2) of the Social Security Act to allow for Medicare Part D coverage of drugs used for the treatment of obesity would also apply to the Medicaid program.

Humana Comment: State Medicaid programs already have the option to extend coverage for GLP-1s to include treatment for obesity. This coverage decision should continue to remain with the states. With state budget shortfalls and challenges in determining actuarially sound rates following Medicaid unwinding, states cannot account for the significant costs of GLP-1s within the proposed timeframe. The earliest effective date that would account for state rate setting would fall in CY 2027. State Medicaid programs will also require additional time to develop clear clinical guidance and determine medical necessity for children, adolescents and adults. Clear guidance will be critical to ensure that managed care organizations take the same approach to coverage and to prevent provider abrasion in states where the pharmacy benefit is carved out of managed care.

III.A.4. Coverage Considerations

If finalized, state Medicaid programs that provide drug coverage would generally be required to provide coverage of AOMs for weight loss or chronic weight management for treating obesity in Medicaid-enrolled individuals as of the effective date of the final rule.

Humana Comment: As discussed above, Humana has concerns with the proposal to expand Medicare and Medicaid coverage of AOMs as drafted. If CMS decides to proceed with the policy, we recommend that the proposed reinterpretation not be applicable for Part D or Medicaid coverage until 2027. This delay would allow for time needed to address the lack of clinical guidelines for use of newer AOMs, per our comments above. Additionally, CMS recently announced that semaglutide will be a selected drug for the Medicare drug price negotiation program, with a maximum fair price effective in 2027, which could help mitigate costs for beneficiaries and the Medicare program. Lastly, newer AOMs have encountered supply

challenges[16], and the CMS proposal could impact access for patients stable on therapy if coverage is expanded in 2026. A delay until 2027 would allow more time for manufacturers to address shortages and ensure that appropriate levels of supply are available for all patients.

III.B. Network Transparency for Pharmacies (§ 423.505)

CMS proposes to require Part D sponsors to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year. CMS also proposes to require plan sponsors to provide pharmacies with such a list of in-network plans on request after October 1.

Humana Comment: Humana appreciates CMS's desire to ensure that pharmacies and their customers have adequate notice of Part D plan pharmacy networks ahead of the annual enrollment period. However, we have concerns around the burdensome nature of this proposed notification requirement, which will require additional communications to tens of thousands of pharmacies. If CMS is committed to moving forward with a notice requirement, in order to reduce burden on Part D sponsors, we recommend that CMS revise this proposal to allow pharmacies to make the request of Part D sponsors of network information by October 1 of the year prior to the plan year. This revised approach would balance the needs of pharmacies and their customers to understand Part D plan pharmacy networks ahead of the annual enrollment period, while minimizing undue burden on Part D sponsors.

III.C. Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d)(2))

CMS proposes to modify the existing core chronic disease identified as "Alzheimer's disease" to "Alzheimer's disease and dementia". This change would have the effect of including other dementias among the core conditions that must be targeted for MTM services.

Humana Comment: Humana is comfortable with the suggested modification of the existing core chronic disease identified as "Alzheimer's disease" to include "other dementias" as we see value in using a broad definition of this core condition for MTM purposes. Beyond MTM, Humana offers a suite of clinical programs that are designed to reduce the risk of adverse events, including drug to drug interactions, medication optimalization, and medication adherence programs. We have repeatedly supported approaches to MTM and related services that afford plan sponsors the flexibility to tailor those services to meet member needs.

In that vein, Humana maintains concerns about the expanded MTM requirements which took effect on January 1, 2025. CMS has now implemented MTM regulations that are much more prescriptive than past approaches, arresting the ability of plan sponsors to target those services to members who are most likely to benefit. We urge CMS to revisit this policy change to allow plan sponsors to focus on subsets of the core chronic conditions, rather than mandating the use of MTM for all core chronic conditions. Humana does not believe the MTM expansion will achieve CMS's intended policy goals but will instead increase costs and divert resources from those members with the greatest needs. We continue to hold that the most appropriate approach to MTM services is one in which a plan sponsor can use its accumulated experience to tailor those services to specific subsets of plan membership.

III.E. Modifying the Definition of "Service Area" § 422.2

[16] FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize | FDA

CMS is proposing to modify its definition of "service area" to align with their proposal to include a definition of county in § 422.116 that includes "county-equivalents" as recognized by the United States Census Bureau for economic census purposes.

> **Humana Comment:** Humana supports amending the regulatory definition of "service area" under 42 CFR 422.2 to align with the proposal to include a definition of "county" in § 422.116 that includes "county-equivalents". As CMS notes in the Proposed Rule, there are "county-equivalents" as recognized by the United States Census Bureau which are not included in the current definition of "service area" under 42 CFR 422.2. For example, the state of Connecticut has replaced counties with "county-equivalent" Planning Regions.
>
> To ensure plans can care for their membership in areas where a "county-equivalent" Planning Region may not fully overlap with the previously mapped county, Humana requests that CMS would allow a grace period for adequacy gap closure along with timely revised sub-regulatory and technical guidance for those impacted by this change.

III.F. Administration of Supplemental Benefits Coverage Through Debit Cards §§ 422.2, 422.102, 422.102, 422.111, and 422.2263

CMS is proposing requirements on the proper administration of supplemental benefits. Specifically, CMS is proposing to codify in regulation text the requirements and limitations discussed in the preamble of the 2022 final rule and later in the May 6, 2024, memo titled "Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation" regarding the administration of supplemental benefits, including the use of plan debit cards. CMS is proposing to expand on these requirements by adopting additional disclosure and access guardrails to increase transparency, protect access to plan-covered services for MA enrollees, and ensure that MA plans cover (that is, provide, furnish, and/or pay for) only those items and services that are permissible MA benefits. CMS also proposes that MA organizations be required to cover all benefits, including supplemental benefits, at in-network cost sharing when an in-network provider of benefit is unavailable or inadequate to meet an enrollee's medical needs.

> **Humana Comment:** We acknowledge and support CMS's commitment to ensuring that all beneficiaries have appropriate access to necessary services for all benefits, including mandatory supplemental benefits (MSBs) and special supplemental benefits for the chronically ill (SSBCIs). We offer the below specific comments on the various proposals in this section.

2. The Administration of Supplemental Benefits

CMS is proposing that MA organizations be required to cover all benefits, including supplemental benefits, at in-network cost sharing when an in-network provider of benefit is unavailable or inadequate to meet and enrollee's medical needs.

> **Humana Comment:** Humana appreciates and supports CMS's commitment to ensuring beneficiaries have access to their benefits. That is why we partner with vendors and providers that offer robust national networks, offering convenient benefit access to our members, in addition to permitting access under certain circumstances to online or telephonic options. In light of the variety of SSBCI and provider-types for those benefits, Humana appreciates the flexibility that existing regulations provide to MAOs to meet network adequacy and other requirements. This flexibility is critical to ensuring ongoing success of these benefit types; accordingly, Humana does not believe 42 C.F.R. § 422.102 requires any further modification.

3. New Guardrails for Plan Debit Cards

CMS proposes that MA organizations must provide debit cards that are electronically linked to plan covered benefits through a real-time identification mechanism to verify eligibility of plan covered benefits at the point-of-sale.

> **Humana Comment:** Humana is committed to ensuring that our members receive their benefits in the most efficient and compliant manner possible and is therefore generally aligned with the requirement to electronically link card purchases to covered items and services. However, Humana is concerned that certain provider types cannot administer CMS's proposed requirement for real-time, point-of-sale verification of eligibility of plan covered benefits. For example, Humana's spending cards may be used to reimburse certain qualifying expenses at dental or vision providers. Those providers may not have the systems or operational controls necessary to ensure coverage at point-of-sale. As a result, should CMS proceed with this proposed requirement, Humana would be forced to remove coverage of dental and vision services to ensure compliance, which would negatively impact the beneficiary. As with other covered items and services, Humana should have the flexibility to validate coverage through other oversight and monitoring processes, whether that includes the type of point-of-sale validation process CMS outlines in the proposed rule, or back-end audits of paid claims, etc.

CMS proposes that all card-based benefits must be limited to the specific plan year in which they are offered.

> **Humana Comment:** Humana supports CMS's recommendation that card-based benefits be limited to the current plan year. The means to enforce such a requirement are technologically feasible and readily available.

CMS proposes that MA organizations that use debit cards to administer a supplemental benefit provide instructions for debit card use and customer service support to enrollees to answer questions or help with issues related to the administration of the card.

> **Humana Comment:** Humana appreciates CMS's proposal that beneficiaries should be given relevant instructions on how to use any spending cards tied to their benefits and agrees that this is critical to ensuring beneficiaries fully understand their benefits. Humana currently includes detailed instructions to members on card usage, as well as eligible items/categories, in a printed document that is enclosed with the card itself.

Revision of § 422.102(a)(6) to Limit Reductions in Cost Sharing Processes

CMS proposes to revise § 422.102(a)(6) by removing "or other means" and adding "manual" before reimbursement to ensure that reductions in cost sharing as a supplemental benefit are clearly limited to either manual reimbursement or to a debit card. In addition, CMS is soliciting comment on whether other means would be unintentionally removed and the potential impact to "stored value cards."

> **Humana Comment:** Humana is aligned with CMS's efforts to ensure that cards are exclusively used for purchasing covered items and services. While we recognize the benefits of clarity in the proposed language change, we are concerned that limiting reductions in cost sharing strictly to "manual reimbursement" or "debit card" usage could potentially restrict future innovations in this area. The technological landscape, especially in restricted spend areas, is rapidly evolving. There may soon be new electronic or app-based solutions that do not rely on traditional debit

cards but could offer secure, compliant, and user-friendly alternatives for managing cost sharing reductions.

Therefore, **Humana recommends that CMS reconsider making this change to § 422.102(a)(6).** We suggest maintaining a degree of flexibility in the regulation that would allow for the incorporation of future technological advancements in administering cost sharing reductions.

4. Access

CMS proposes that plans must offer post-sale reimbursement mechanisms to allow enrollees to access their benefits if there is any situation in which the use of a debit card is unfeasible for the enrollee.

Humana Comment: Humana understands CMS's intent behind ensuring continued access to benefits during technical failures, vendor issues, or member caused issues. However, we have several concerns with the proposed requirement for an alternative receipt-based reimbursement process, as Humana believes this will create additional issues and complexities for members.

First, Humana believes the existing debit cards work well and provide members robust access to benefits with limited issues. In fact, many Humana plans include card-based benefits where more than 90% of members regularly use these benefits, indicating that they are not experiencing any significant difficulties accessing the network or utilizing the card.

Though there are limited circumstances where members may have issues using their card, it is important to note that they do not lose access to their benefit in these cases. If the card is not used to make a purchase, the funds remain on the card for the member to spend at a later date or time. While Humana's goal is to limit such occurrences as much as possible, these issues primarily delay the use of the benefit, as opposed to preventing use of the benefit altogether.

In addition, members often do not have the funds available to purchase items directly, meaning that a receipt reimbursement process does little to help them. Humana acknowledges that these instances are regrettable, which is why we've worked with our vendor to eliminate systematic issues, expand our network, and further educate our members on card usage. We believe this is the best way to make the benefit accessible, rather than creating a receipt reimbursement process which does not alleviate member issues and creates additional operational and compliance risks.

Further, the proposed manual reimbursement process introduces significant operational, administrative, and compliance challenges. These include:

- **Lack of standardization in receipts** – Receipts are not standardized across the retail industry, making it very difficult to effectively evaluate purchases and determine whether specific items are covered under the benefit. This is especially true for smaller "mom and pop" business where item descriptions or receipt itemization is lacking. The lack of standardization will increase the risks of reimbursement for non-covered items, as manual reviewers will have to guess coverage based on the limited receipt and item information. This is in direct contrast to CMS's proposed requirement that debit cards must be electronically linked to covered items and services.

- **Receipt Validation** – There is no way to validate that an enrollee actually made the purchases indicated on a given receipt. Items could have been subsequently returned, someone else may have made the purchase, or the receipt may otherwise be misrepresented. The proposed process would require an assumption that all submitted receipts were valid, even though that may not always be the case.
- **Issuing Checks** – Members may ultimately end up with similar issues cashing reimbursement checks, particularly if they do not have an active bank account. In addition, their card funds may be put on hold while a check is issued, making it more difficult for them to access their benefits, particularly if there are issues with the check mailing, delivery, or cashing process.
- **Administrative Burden of Reviewing Receipts** – The above listed complexities would make any receipt reimbursement process a manual and difficult process, increasing the administrative costs of managing card-based benefits.
- **Significant Fraud Risks** – All the nuances of implementing a receipt reimbursement process create an environment where it becomes extremely easy for enrollees to convert their card-based benefits into cash, with little to no controls for how members may spend that cash. This introduces new and significant risks for member fraud and payment for impermissible benefits.

Given these considerations, **we respectfully suggest that CMS reconsider the proposed requirement for an alternative reimbursement process and not finalize this proposal**. Maintaining the current debit card system, while encouraging plans to focus on member education and network expansion efforts, would be more beneficial and secure for both members and plan administrators.

CMS proposes that all PPOs be required to provide reimbursement for all covered services, regardless of whether the items are provided within the plan's network of providers.

Humana Comment: We acknowledge and support CMS's commitment to ensuring that all beneficiaries have appropriate access to necessary services for all benefits, including MSBs and SSBCIs. However, Humana has concerns regarding the proposed recommendation that plans provide reimbursement for out of network benefits on PPOs.

Humana believes that CMS's current guidance, where MSBs that are "nationally available to enrollees" satisfy any out-of-network requirements, has been effective in providing beneficiaries with convenient and appropriate access to supplemental benefits. This guidance was released in April 2020 through the MA benefits mailbox.

> 4. **Q. Does a PPO satisfy the requirement to provide a supplemental benefit both in-network and out-of-network when the service is nationally available to their enrollees?**
> **A.** A service that is nationally available to all enrollees does satisfy the PPO requirement of offering the supplemental benefit in-network andout-of-network.

The guidance currently in place allows MA organizations to contract with high quality providers and vendors to increase access and drive down costs. This allows Medicare Advantage Organizations to offer the best benefits to the largest number of beneficiaries possible.

In addition, providing an MSB or SSBCI through a select network of providers or vendors allows health plans to maintain a high degree of quality over the benefit. There often are not national standards for supplemental benefits as there are for medical providers and/or pharmacies, which makes it difficult to enforce any quality standards for non-network providers. For example, Humana works with our vendors to ensure that any given meal is clinically appropriate for a beneficiary's condition. Given the lack of standardized billing processes for meals, there would be no way to determine the nutritional impact or appropriateness of an out-of-network meal.

Furthermore, most MSB-type items and services do not have standardized billing mechanisms such as those in a medical setting, meaning that out of-network reimbursement would require burdensome manual review processes that would be subject to error. Similarly, all of the complexities noted previously regarding post-sale reimbursement mechanisms for card-based benefits would also apply here, making it easy for members to convert their benefits into cash.

Given these considerations, **Humana respectfully recommends that CMS leaves the current guidance in place and not require that nationally offered MSBs be required to reimburse for out-of-network benefits on PPOs when in-network providers are available to all plan members**.

CMS encourages that supplemental benefits, including card-based benefits, allow for Community-Based Organizations to be able to accept cards and fulfill the member's benefits, particularly for food and produce SSBCIs.

Humana Comment: Humana appreciates CMS's encouragement to include additional Community Based Organization (CBOs) as participants in card-based benefit networks and Humana has actively worked on adding additional CBOs to the network when possible.

However, from experience, Humana is aware that the CMS requirement requiring card-based benefits to be electronically linked to covered items and services could be burdensome for CBOs. It generally takes significant IT resources and infrastructure to integrate with real-time electronic item-level adjudication platforms, and this can be particularly challenging for small not-for-profit companies. It may be beneficial to exempt CBOs from electronically linking payments to covered items and services to encourage more participation.

5. Additional Disclosure Guardrails

CMS proposes to clarify that MAOs must disclose detail about supplemental benefits to enrollees, including eligible OTC items and, where supplemental benefits are administered through a debit card, specifying which benefits may be accessed using the debit card. CMS believes this disclosure will ensure transparency concerning enrollee's benefits.

Humana Comment: Humana is aligned with CMS's proposal to require plans to disclose the items and services covered by card-based benefits. Humana does this today by including a document with categories and examples of covered items and services in the card mailing, in the Summary of Benefits and Evidence of Coverage, and through online resources. In addition, our vendor provides an app available to members that allows them to scan approved food, over-the-counter, and other items in real time to know whether they are covered or not.

Though we agree with CMS's recommendation, it is important to note that this requirement should be considered met if plans provide covered item categories and/or covered item examples to members. Given the sometimes broad scope of items and services that are covered (for example, food), it would be impossible to include a list of every covered item, as the list could be composed of thousands, and potentially millions, of different items.

CMS proposed a non-exhaustive list of items that can and can't be included under Medicare Advantage Organization's OTC benefit.

Humana Comment: Humana appreciates the additional clarity provided by CMS's proposed non-exhaustive list of inclusions.

Marketing Supplemental Benefits

CMS proposes to prohibit MA organizations from marketing the dollar value of supplemental benefits or the method by which a supplemental benefit is administered, such as use of a debit card.

Humana Comment: Humana appreciates CMS's desire to ensure that advertisements accurately depict the benefits offered, and we support efforts to prevent misleading communications to beneficiaries. This is particularly true of any advertisements that might suggest beneficiaries have "free money" to spend on whatever they want. We believe that it is crucial that advertising provides clear details about the items and services covered to help set appropriate expectations for enrollees.

However, Humana is concerned that prohibiting the marketing of specific allowance amounts or the mechanisms of card usage will intentionally withhold vital information that beneficiaries rely on to make informed decisions. For example, if a dental MSB includes an allowance, not advertising the allowance amount could obscure the plan's value, limiting beneficiary understanding. **Humana suggests a revision of the proposed guidelines to prevent only the advertisements that falsely claim "free money," while still allowing for the clear and factual presentation of essential plan details.** This approach would maintain transparency and aid beneficiaries in their decision-making processes.

III.G. Non-Allowable Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

CMS proposes a non-exhaustive list of non-primarily health related items or services that do not meet the standard of having a reasonable expectation of improving or maintaining the health or overall function of the enrollee standard.

Humana Comment: Humana appreciates CMS's clarification on benefits that cannot be offered as an SSBCI and encourages CMS to finalize this proposed non-exhaustive list.

III.H. Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) and Technical Changes to the Definition of Chronically Ill Enrollee (§ 422.102)

CMS clarifies that having a medically complex chronic condition or comorbidity by itself is insufficient to satisfy the requirements for SSBCI eligibility. CMS proposes amending the definition of "chronically ill enrollee". CMS proposes that plans must demonstrate that an enrollee has met all three of the criteria set forth in this definition, through an objective process. CMS proposes to codify a provision prohibiting MA plans from using the presence of a chronic illness as the sole basis for determining eligibility for SSBCI. CMS also proposes that plans must publish on their public-facing website the objective criteria

developed and used by the MA plan to determine whether an enrollee is eligible to receive any, and which particular, SSBCI benefits the plan offers.

> **Humana Comment:** Humana appreciates CMS's effort to provide clarification on the eligibility criteria for SSBCI and recognizes that MAO's have different interpretations of the existing guidance. Humana supports CMS's goal of ensuring precise definitions so that all plans are following the same set of rules and maintaining flexibility around how plans determine the criteria under 42 C.F.R. 422.102(f)(1)(i)(A) are met. SSBCI continues to be a critical offering for our members, particularly with the decision to terminate the Value Based Insurance Design (VBID) program at the end of 2025.

CMS also proposes that plans must publish on their public-facing website the objective criteria developed and used by the MA to determine whether an enrollee is eligible to receive any, and which specific SSBCI benefits the plan offers.

> **Humana Comment:** Humana appreciates CMS's proposal to list the objective criteria for SSBCI eligibility on public facing websites and believes this will help ensure beneficiaries have access to information to understand how they may qualify for such benefits. **Humana believes that CMS should allow for clinical discretion in determining eligibility**, and plans should adequately explain this in any public facing website disclosures.

III.I. Risk Adjustment Data Updates

III.I.1. Update Hierarchical Condition Categories (HCC) Definition

CMS propose to remove the reference to a specific version of the ICD from the definition of HCC at § 422.2, while maintaining a reference to the ICD in general. CMS also proposes to substitute the terms "disease codes" with "diagnosis codes" and "disease groupings" with "diagnosis groupings" to be consistent with ICD terminology.

> **Humana Comment:** Humana is supportive of CMS's proposal to remove the reference to a specific version of the ICD from the definition of HCC at § 422.2, while maintaining a reference to the ICD in general. In addition, Humana is supportive of CMS substituting the terms "disease codes" with "diagnosis codes" and "disease groupings" to be consistent with ICD terminology.

III.J. Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence (§ 422.112)

CMS is proposing to revise § 422.112(a)(8), *Ensuring equitable access to Medicare Advantage (MA) Services*, by moving the examples listed in paragraphs (i) through (vii) under a new paragraph (i)(A) through (G), and creating a new paragraph (ii) that requires MA organizations to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems.

> **Humana Comment:** Humana is aligned with CMS's goal of ensuring equitable access to MA while maintaining appropriate Artificial Intelligence (AI) guardrails. However, we are concerned that the proposed language could potentially be misinterpreted as broader than what CMS intends and may unintentionally place undue burden on plans by extending beyond the scope of the Executive Orders and the CMS article referenced in the proposed rule.

It is also unclear how compliance would be measured if these proposed revisions were finalized. To that end, Humana recommends CMS clarify language around demonstrating compliance with the rules. In absence of this, compliance may be difficult for an MAO to measure and/or definitively prove.

CMS is proposing to define "automated system" as "any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both.

Humana Comment: Humana believes that the inclusion of the word "process" in the proposed automated system definition could be interpreted as expanding the application beyond technology solutions as most "processes" are manual tasks. To that end, we recommend that CMS update the definition to read "any system or software with embedded algorithms that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both."

CMS also proposes to define "Patient care decision support tool," consistent with the definition at 45 CFR 92.4, as any automated or non-automated tool, mechanism, method, technology, or combination thereof used by an MA organization to support clinical decision-making in its health programs or activities.

Humana Comment: Humana recommends that CMS update the proposed definition of "patient care decision support tools" as the proposed definition implies that UM processes are directing care for patients, which could potentially be framed in a manner that contributes to the mischaracterization of the procedures used by MAOs to carry out utilization management.

III.K. Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors

CMS proposes to add a definition for "direct furnishing entity" which means any individual or entity that delivers or furnishes covered benefits to an enrollee, for the purposes of inclusion in provider directories. CMS solicits feedback on the proposed definition for a direct furnishing entity. CMS proposes to add new language to clarify that plans must include all "direct furnishing entities" in their provider directories. CMS also proposes that plans must clearly identify all "direct furnishing entities" that provide in-home or at-home supplemental benefits or services or a hybrid of these benefits and services. CMS proposes to codify a definition of community-based organizations (CBOs) as "public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations."

Humana Comment: Humana agrees with the Agency's effort to promote greater transparency regarding who furnishes the care beneficiaries receive through our plans and understands this is particularly important in relation to services provided in-home. However, we have significant concerns that the proposed regulations surrounding "direct furnishing entity" are overly broad and would lead to inflated and confusing provider directories, while providing limited benefit to the beneficiary. We therefore oppose the proposed change.

More specifically, the proposed definition of "direct furnishing entities" to include "any individual…that delivers or furnishes covered benefits" could be broadly interpreted to require

listing every employee of an adult day care, hospital, transportation vendor, etc.—not just the entity itself. Aside from creating an unnecessarily lengthy provider directory, the overturn rate at hospitals and with other employers would make updates nearly impossible and create directory accuracy concerns, thereby compromising CMS's goal of transparency.

Requiring disclosure at the provider level as the current regulation requires—rather than every individual—still addresses CMS's primary goal of safety and transparency, as it enables the member to work directly at the entity level to schedule appointments and obtain any specific detail on employees delivering care. An example of the impact to providers and carriers if this language were to be implemented is with adult day service facilities. For these kinds of facilities, Humana follows the CMS model directory guidelines in displaying only the facility information and not specific providers who may perform covered services at the facility. Members would historically not need to see each employee at the facility listed, as they would only contact the center itself for an appointment. Requiring carriers to display each employee of the facility would not only place burden on these facilities to provide us with updated rosters at a frequent rate, but would raise questions around contracting, credentialing and printing demographic information for employees who may not be traditionally of the type of care provider we would display in member-facing material; some of whom may not want to be published in these directories and typically would not be.

Regarding identification of in-home services in provider directories, the proposed language aligns with our current policy and Humana agrees with the proposed definitions and requirements. Between the two proposals included in the preamble, Humana recommends a subset list rather than a separate accounting of these providers.

Humana further agrees that identifying community-based services is a benefit to enrollees and their communities. However, we would dispute that the burden placed on carriers to identify which entities among their network of contracted providers qualify as CBOs is "minimal." Humana recommends that CMS either collect and distribute a list of qualified CBOs or establish a more specific, targeted definition of CBO to which providers or facilities must adhere to qualify. Without a standardized process, carriers are left to leave the question to the entities themselves to answer – in the form of roster responses, for example – and it is unclear if this would produce the intended results. If carriers are meant to decide which of their contracted providers meets this definition, then a set of specialties, practice focuses, or other already-available data points by which we could sort and define our provider network would be preferable to the broader language found in the proposed regulation.

III.L. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

CMS is proposing to require that in-network cost sharing for certain behavioral health service categories be no greater than that of Traditional Medicare for MA and Cost Plans (including EGWPs). CMS also proposes to update the cost sharing standards for several categories of benefits, including behavioral health and non-behavioral health related benefit categories, for Cost Plans to match the standards for MA plans.

Humana Comment: Humana is aligned with CMS's goal of addressing access barriers to mental health and substance use disorder care. We support the Agency's proposal to implement the

proposed behavioral health cost-sharing standards and are supportive of CMS moving to implement these changes beginning in Contract Year 2026.

III.M. Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 422.137)

CMS is considering whether to include a provision to allow suppression of certain data points should disaggregation present an issue regarding enrollee privacy. CMS solicits feedback on whether cell suppression is necessary in order to ensure enrollee privacy is protected.

Humana Comment: Humana appreciates the consideration CMS is giving to protecting enrollee privacy, particularly in this area given the sensitive items and services affiliated with diagnosis. To that end, Humana supports aggregating sensitive items and services to protect privacy.

With specific regard to items and services with low utilization by enrollees (with or without Social Risk Factors), Humana recommends that the percentage be suppressed if the SRF or non-SRF number of requests is 30 requests or lower. Our plan-level analysis demonstrated that a SRF request with three cases and non-SRF requests with 75 cases, where the denial rate for SRF might be 33 percent (1 of 3 cases), compared to a denial rate for non-SRF of 7 percent (5 of 75 cases), where the disparate volume of cases, make the percentages non-comparable. In this example, the SRF percentage would be suppressed. Further, because only percentages are publicly posted, adverse actions by viewers seems likely, which Humana does not believe is the intent.

Humana suggests 30 as the case volume benchmark, as we understand that it is used in a similar manner for STARS reporting.

CMS solicits comment on alternative ways to group items and services for the purpose of reporting on these metrics while still allowing for meaningful disaggregation to increase transparency, identify trends, and address the impact of prior authorization on enrollees with specified social risk factors (SRFs).

Humana Comment: Humana understands and acknowledges the importance of analyzing prior authorization decision-making through the lens of Social Risk Factors. The current analysis demonstrates that the comparison of percentages is not a statistical model of comparison at the plan level. In a disaggregated data model, we believe the comparison of percentages will continue to not be a valid statistical model of comparison.

Additionally, Humana has concerns regarding potential variability in the definition of item and service as the definition of "services" under 42 CFR 400.202 is broad and Humana was unable to identify other protocols or CMS guidance to inform an approach for classification.

To ensure clarity, ensure comparability across plans, and facilitate equitable comparisons, Humana recommends that CMS provide additional clarity on the desired list of items and services.

CMS proposes to require that the results of the health equity analysis include an executive summary with specified elements. CMS solicits comments on additional requirements to be included in the executive summary.

Humana Comment: Humana appreciates the opportunity to provide feedback on how plans will utilize complex clinical information to develop enrollee-centric programs and services. However, we are concerned that distilling the complex and nuanced reality into a simplistic summary may drive actions that don't generate satisfaction.

When you consider the ways in which providers and facilities identify the need to secure a prior authorization, balanced against the framework of fraud, waste and abuse, as well as the safety of health care for our enrollees, in conjunction with CMS's established criteria, each item and service may have its own story. For example, at Humana SNF, IRF and LTAC decisions are made using fully established CMS criteria. An individual might make an adverse decision *not* to enroll in an MA plan if they see services have a denial rate of 5 percent, when in reality, the basis for the denial rate was against fully-established CMS criteria and whether medical records support the need for the service or not. Another example is a situation where bad actors are identified in a particular region where LCD criteria is applicable with a higher denial rate. The plan would still be administering CMS requirements for that locality; however, they could also potentially be adversely impacted in an enrollment decision.

Depending on the level of item and services detail CMS finalizes, the analysis could be extensive where plans likely would pull in additional data points to defend decision making performance, which, in our opinion would no longer make it comparable to other health plans or relevant to a lay person without clinical expertise.

Further, we recommend that CMS provide a sample format for the Executive Summary. The intent of this requirement to include an executive summary is to make the analyses less challenging for the public and enrollees to understand. Without a sample format, variability between payers' Executive Summaries may cause confusion and limit the value of the document.

CMS also solicits comments on adding "having a mental health or substance use disorder diagnosis" to the list of SRFs that MA plans must use to conduct the health equity analysis.

Humana Comment: Currently, Humana uses SRF indicators provided by CMS in Enrollment MMRR files. Should CMS decide to add behavioral health and substance use disorder indicators to the MMR files, doing so would ensure equitable applicability across health plans and consistency of Health Equity reporting in all forms across the spectrum of reporting for CMS. However, adding mental health or substance use disorder diagnosis, where diagnosis from a claim submission would move a member into the SRF population, would introduce inconsistency and latency to reporting.

Diagnosis is most reliably available at the time of a claims submission; a claims submission delay would create a steady stream of re-calculations. For example, in cases where a behavioral health or substance diagnosis is received *after* the end of the reporting period, plans would then have to continually look-back and update SRF indicators, based on date of service. Humana believes reporting criteria and cutoff times would need to be regulated to ensure consistency across health plans, should this approach be selected. Humana strongly encourages CMS to provide the designated SRF values, and apply to all health equity reporting, as appropriate.

III.N. Medicare Advantage Network Adequacy (§ 422.116)

CMS proposes to codify its policy of treating county equivalents the same as counties for network adequacy purposes by defining counties as "the primary political and administrative division of most States and includes functionally equivalent divisions called "county equivalents" as recognized by the United States Census Bureau (for economic census purposes)".

> **Humana Comment:** Humana is supportive of the language clarification around county equivalents for network adequacy purposes. Humana recommends that CMS and/or the Census Bureau continue to publish the county and county-equivalent definitions. Humana also urges that where there are any changes to geographic boundaries for counties or county-equivalents, CMS allow a grace period for adequacy gap closure if one were to open based on the change.

CMS proposes to codify its longstanding network adequacy exception request rationales except to eliminate the rationale that the "provider does not contract with any organization or contracts exclusively with another organization" as a basis for an exception.

> **Humana Comment:** Humana opposes these proposed changes. Humana shares CMS goal to ensure consistent and equitable access to healthcare services; however, these proposed changes will not further that goal.
>
> The proposal to eliminate the rationale that the "provider does not contract with any organization or contracts exclusively with another organization" (meaning MA organization) will increase provider leverage, decrease competition, supports monopolies and will decrease member choice and access for the following reasons:
>
> - There are providers in many counties that are necessary to meet network adequacy requirements. When these providers do not work with any MA plan, health plans request an exception to the requirements. If plans cannot request an exception, ALL plans are faced with the choice of leaving the community and its members or being non-compliant. This proposal could allow a provider to make the decision on the availability of MA health plans to all beneficiaries in the community.
> - If a health plan cannot request an exception with a provider that contracts exclusively with another organization, monopolistic practices will be encouraged. If one organization reaches an exclusive arrangement with a necessary provider group, they will make all competitors non-compliant. This would cause competitors to risk actions from CMS or leave the market.
> - These impacts will be felt most in rural areas. There are many providers that are required to meet adequacy standards in rural areas. Beneficiaries in those communities could lose options for their healthcare based on the decision of one provider.
>
> In addition, the proposal to eliminate the rationale that the "other" has the potential to cause beneficiary harm. Currently, the "other" rationale is used to cover special circumstances that do not fit within CMS's published list. CMS justifies the removal of "other – provider has the potential to cause beneficiary harm" because this exception rationale is already covered under CMS's evaluation of any exception. Humana agrees with this proposal conceptually but in practical terms, there will be no way for a plan to submit an exception request when a non-contracted provider meets all of CMS's published requirements *except* for the potential to cause beneficiary harm. If a plan has no other rationale for requesting the exception related to that

provider, under this proposal, there will be no exception request for CMS to review. We urge CMS to keep the "other – provider has the potential to cause beneficiary harm" rationale for these cases.

CMS solicits comment on a potential change to review network adequacy at the plan benefit package level (as opposed to the contract level). CMS is considering whether conducting network adequacy reviews at the MA plan benefit package level would provide greater assurances regarding the adequacy of an MA organization's network at the more discrete, plan level service area.

Humana Comment: Humana shares CMS's goal of ensuring consistent and equitable access to healthcare services but believes that this proposed change would not further that goal. We believe this proposal would place a significantly higher burden on CMS and on health plans and would provide little improvement to adequacy evaluation.

Plan Benefit Packages under a contract generally have the same network. The differences between the PBPs are in the offered benefits and plan service area. Therefore, if network adequacy were reviewed at a PBP level, the exact same information would be created, stored and transmitted twice. In some cases, PBPs will have a different network than the other PBPs of a contract, such as with provider specific plans. However, these types of plans make up a miniscule number of Humana's contracts, they are evaluated on the same cadence as other networks, and network adequacy is attested to annually. Making a significant change such as network adequacy review at the PBP level for such a small number of plans provides little benefit to CMS, enrollees, and plans.

Further, CMS's network submission portal is not currently set up to receive information in this way and it would have to be reworked and tested by plans before it could be used. Plans will need significant lead time to comply with this standard should it move forward, and data procedures will need to be completely rewritten to create files in this format. CMS and plans will need to work with their network adequacy software vendors to assess this much information at the PBP level and it may be unlikely that the shared vendor can absorb an increase in volume of this magnitude without significant lead time.

III.O. Promoting Informed Choice– Expand Agent and Broker Requirements regarding Medicare Savings Programs, Extra Help, and Medigap (§§ 422.2274 and 423.2274)

III.O.1. Low-Income Subsidy

CMS proposes to include LIS eligibility criteria as an additional topic that agents and brokers must address before enrolling a beneficiary in an MA, MA-PD or Part D plan.

Humana Comment: Humana is aligned with this proposed change and believes providing potential enrollees with this information will help them make more informed decisions.

III.O.2. Medicare Supplemental Insurance

CMS proposes to require than an agent or broker convey information regarding Medigap Federal Guaranteed Issue (GI) rights to beneficiaries who are enrolling into an MA plan when first eligible for Medicare, or those who are dropping a Medigap plan to enroll into an MA plan for the first time.

Humana Comment: Humana is aligned with this proposed change and believes providing potential enrollees with this information will help them make more informed decisions.

III.O.3. Pausing for Additional Questions

CMS proposes to add a requirement that agents and brokers pause to ask the beneficiary, prior to finalizing the enrollment, whether the beneficiary has any remaining questions related to the beneficiary's enrollment in a plan.

Humana Comment: Humana is aligned with this proposed change and supports adding a dedicated pause to allow a potential enrollee to ask any questions they may have.

III.P. Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (§§ 422.111 and 422.2265)

CMS proposes to make changes that will allow MA provider directories to be viewable on MPF for the 2026 AEP. In addition, CMS proposes to require MA organizations to attest to the accuracy of the provider directory data being submitted.

Humana Comment: Humana has taken steps to meet all requirements surrounding data sharing and provider directory API as per the Interoperability and Patient Access Final Rule. We would note, as does the proposed language, that the most recent revisions to the technical standards of the provider directory API were made effective only on February 8, 2024. While development on this API is ongoing, it is also a recent addition, and the technical burden of this proposal for integration into the CMS MPF would be substantial. If this proposal is finalized, carriers will need significant technical details in order to begin this work and it will require a substantial financial and resource investment. Humana strongly recommends that, should CMS finalize this proposal, the implementation date be delayed until the 2027 Annual Election Period, at the earliest.

Humana is fully committed to providing beneficiaries with accurate and updated provider data. Meeting this goal is a core pillar of not only our provider network operations organization, but of our company. Humana conducts quarterly secret shopper audits that mirror the audits performed by CMS to gauge the accuracy of our provider network. Additionally, we perform a monthly multi-faceted data validation of our full directory utilizing multiple vendor partners, claims data, member reported data, and provider self-reported data to maintain our directory accuracy. However, even with these substantial efforts, with such a vast and ever-changing network of contracted providers, maintaining complete directory accuracy is a constant challenge. Because of this, Humana has serious concerns that CMS does not propose a clear definition of accuracy or parameters for how accuracy will be defined. Having an aligned standardized definition of accuracy between CMS and the MA organizations will strengthen CMS's goal of simplifying and streamlining the provider directory experience for the MA beneficiaries. Additionally, it will allow MA organizations to streamline and strengthen their provider data governance practices. It is critical that CMS and MA organizations collaborate on defining the key directory data elements being attested to and align on what qualifies as a change, and we urge CMS to begin these stakeholder discussions as soon as possible.

Finally, Humana appreciates CMS's awareness of the impracticality of requiring an MA organization to attest with each change in their network as this practice would be an administrative burden on the organizations because of the volume and frequency of changes in the provider landscape that occur in a given timeframe. Humana is aligned with partnering with

CMS and other MA organizations on establishing an attestation cadence that is conducive to our business.

III.Q. Promoting Informed Choice– Enhancing Review of Marketing & Communications (§§422.2260 and 423.2260)

CMS proposes to eliminate the content standard of the current marketing definition (at §§ 422.2260(2) and 423.2260(2)) so that all communications materials and activities that meet the existing intent standard are considered marketing for the purposes of CMS's MA and Part D marketing and communications regulations.

Humana Comment: Humana is supportive of this proposal and believes that some entities have used the current definition of 'communications' to avoid submission of materials to CMS. Humana branded acquisition materials are all considered marketing and as such, we already adhere to the existing filing rules. We believe aligning the definition so that plan-branded materials and those produced by TPMOs are treated the same for submission and review purposes will ensure that enrollees are provided with accurate information.

As CMS notes in the preamble, this proposed change – if finalized – will lead to a significant increase in the amount of marketing materials submitted for review by the agency. Humana has concerns that the proposed timeline for implementation of this potential change may present challenges to CMS's ability to handle all submissions and reviews within the specified timeframes for review. For example, for TV ads subject to the 45-day file and approve timeline, some plans, such as Humana, wait for CMS approval before producing the submitted advertisement. If CMS is unable to handle the increase in reviews and provide plans with approvals, plans will be delayed in producing their marketing materials, which will have an adverse impact during the Annual Election Period. We urge CMS to delay the implementation of this proposed change in order to test and ensure that their systems are ready for the increase in submissions and reviews.

Additionally, CMS frequently references the Medicare Communications and Marketing Guidelines (MCMG) in the preamble language for this proposal. The MCMG has not been updated since February 9, 2022;[17] however, CMS has made numerous significant updates to marketing requirements since this date. Humana recommends that CMS publish an updated MCMG document to collate all of the recent changes to the marketing requirements in one document.

III.R. Timely Submission Requirements for Prescription Drug Event (PDE) Records (§423.325)

III.R.3. Requirements – General PDE Submission Timeliness

CMS proposes to codify the existing 30-day and 90-day general PDE submission timeframes, with two slight modifications:

- CMS proposes to specify that the 30-day and 90-day requirements refer to calendar days, as opposed to business days; and,

[17] https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf

- CMS proposes to clarify that initial PDE records must be submitted within 30 calendar days of when the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

Humana Comment: Humana supports CMS's proposal to codify the existing timelines for submission and adjustment of PDE records. We have no objections to the modest changes proposed to the general timelines.

III.R.4. Requirement – Selected Drugs PDE Submission Timeliness

CMS proposes a selected drugs PDE submission timeliness requirement, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

Humana Comment: Humana submitted comments to CMS in July 2024 in response to the draft guidance entitled "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027". We believe the concerns we expressed in those comments are still valid. We recognize CMS's interest in using Prescription Drug Event (PDE) files for purposes of the MTF data functionality. However, we disagree with the use of the PDE to validate claims for a number of reasons. First, some PDEs are never accepted, such as when there is a retroactive eligibility change. In these cases, the pharmacy may not receive a refund from the manufacturer for a drug dispensed to an individual who the pharmacy and plan believed was MFP-eligible at the time. It is unclear how these situations will be addressed under the CMS proposal.

Conceptually, Humana is concerned about the establishment of a bifurcated standard for submission of the PDE files. As noted above, CMS has used a single set of PDE submission timelines for the Part D program since 2011. We are concerned that establishment of a second PDE submission standard for selected drugs would necessitate significant changes to existing workflows and the manner in which PDE files are prepared and submitted to CMS for validation.

Additionally, as CMS recognizes in the proposed rule, there is currently a 30-day window for initial submission of PDE data. Although we appreciate CMS' desire to ensure that pharmacies are refunded for the difference between their acquisition costs and the MFP in a timely manner, we are concerned that shortening the allowed timeline to 7 days following adjudication for selected drugs is too restrictive and will result in the use of inaccurate data for purposes of MFP refunds. It often takes pharmacies up to 14 days to reverse a claim when a member doesn't pick up their prescription. With a shortened PDE submission window, CMS will need to ensure that manufacturers are notified of any changes in the status or number of claims that affect their MFP obligations. In the Medicare Drug Price Negotiation Program Final Guidance for 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, CMS provides limited detail on how it will track and communicate claim adjustments and reversals to manufacturers and pharmacies, and how it will resolve any disputes or discrepancies that may arise.

Additionally, CMS notes that the PDE data is validated by both the Part D sponsor and by CMS itself and therefore is appropriate for use by the MTF; shortening the data submission window introduces more errors into this data and therefore runs counter to CMS' intent. In its final guidance on the MTF, CMS states that its analysis of PDE record submissions shows that over

80% of PDE records are currently submitted within 7 days of receipt from Part D plans.[18] However, this analysis doesn't appear to reflect how often PDEs are reversed, as Part D enrollees often have at least 7 days to pick up their prescription from the pharmacy once it is ready; prescriptions that are never picked up result in a PDE reversal. According to Humana data, of the claims that get reversed (for example, because a prescription is no longer needed or abandoned), only 1/3 of them are reversed within 7 days. Assuming data for selected drugs will track similarly to overall data, that would mean a substantial number of PDE reversals would occur outside the proposed 7-day submission window. Humana recommends that CMS finalize a 14-day window, as a more significant number of reversals occur within 14 days. We believe extending the window to 14 days would result in much more accurate data for use in MFP reimbursement.

Although CMS's goal under this policy is to ensure pharmacies are reimbursed more quickly, it will likely be at the sacrifice of accuracy – requiring pharmacies to spend more time and resources tracking claim reversals and adjustments. This trade-off could be to the detriment of pharmacies' overall bottom line. Contrary to CMS's goals in shortening the PDE submission window, we suspect that pharmacies may actually incur additional financial strain as they may be required to return payments they received incorrectly due to increased errors in the PDE submissions.

If CMS is fully intent on abbreviating the PDE submission timeline for selected drugs, we urge CMS not to shorten the submission window to a period of less than 14 days following claim adjudication. We believe 14 days strikes the right balance between data accuracy and timely reimbursement for pharmacies. Otherwise, manufacturers may be forced to provide remuneration to pharmacies for many claims that will ultimately be reversed. Part D plan sponsors and pharmacies themselves could also incur additional administrative costs in order to facilitate the abbreviated PDE timeline.

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

III.T.7. Proposal to Exclude Medicare Prescription Payment Plan Unsettled Balances from the MLR

In this proposed rule, with respect to the treatment of unsettled balances from the Medicare Prescription Payment Plan, CMS proposes to exclude unsettled balances from the Medicare Prescription Payment Plan from the MLR numerator.

Humana Comment: MA Organizations are currently prohibited from attempting to collect the money from unsettled balances. As a result, Humana believes CMS's proposal to remove this as an expense from the MLR calculation unfairly penalizes the MAO given that this is largely out of the MA Organization's control. For this reason, Humana believes it should remain unchanged.

III.T.8. Request for Information on MLR and Vertical Integration

CMS is issuing a request for information on whether CMS could and should adopt policies, and if so, what potential policies it could or should adopt, regarding how the MA and Part D MLRs are calculated

[18] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, see page 51.

to help enable policymakers to address concerns surrounding vertical integration in MA and Part D. Based on responses to this RFI, CMS will consider additional rulemaking or guidance for future contract year rulemaking.

> **Humana Comment:** Humana understands the importance of ensuring claims dollars are properly included in the MLR calculation. However, for the purpose of monitoring and oversight, Humana believes it would be sufficient for the MAOs to provide information upon request without the additional burden of a specific reporting requirement.

III.T.10. Proposal to Add Provider Payment Arrangement Reporting in the Medicare MLR Reporting Regulations

CMS proposes to amend § 422.2460(a) so the regulation text explicitly provides that the MLR report submitted to CMS includes aggregate expenditures by provider payment arrangement type in MA.

> **Humana Comment:** Humana uses many different types of payment arrangements. There is concern in the case where CMS defines numerous buckets they would not truly reflect of the complex nature of these arrangements, and thus could in some cases negate the value of the data collection effort. For these reasons Humana believes the number of buckets should remain small and be well defined.
>
> If this proposal were finalized, Humana would encourage CMS to work with MAOs to categorize various payment arrangements in order to create a thorough, but static, list that supports CMS's MLR accuracy goals while reducing the administrative burden on the MAO.
>
> Humana appreciates CMS's acknowledgement of the sensitivity of provider payment arrangement data. Humana considers it a proprietary business issue and as such, we would strongly oppose any of this information being made public.

III.U. Enhancing Rules on Internal Coverage Criteria § 422.101

CMS is proposing to build on the regulations from the April 2023 final rule by defining the phrase "internal coverage criteria," establishing policy guardrails to preserve access to basic benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

III.U.1. Using Internal Coverage Criteria to Interpret or Supplement General Provisions

CMS proposes to replace the existing language related to when a MAO is permitted to adopt internal coverage criteria with the phrase "Additional, unspecified criteria are needed to interpret or supplement the plain language of applicable Medicare coverage and benefit criteria in order to determine medical necessity consistently."

> **Humana Comment:** Humana opposes the addition of a qualifier that suggests internal coverage policies can only ever interpret or supplement the "plain language" of Medicare criteria. The term "plain language" is frequently used in the Code of Federal Regulations to describe language easily understood by lay persons. For example, one regulation describes plain language as text that is "easy to read and uses a question-and-answer format directed at the reader, active voice, shorter sentences, and, where appropriate, personal pronouns."[19] Using the term "plain

[19] 41 C.F.R. § 102–2.140.

language" in this context, to limit the circumstances in which a MAO may adopt internal coverage criteria, inappropriately suggests that the need for clarification must readily be apparent on the face of the NCD or LCD to a lay person. However, Medicare clinical criteria are generally drafted using technical language by and for the use of medical doctors and other practitioners. A gap not suggested by the "plain language" of an NCD or LCD may be readily apparent to a trained practitioner.

If CMS wishes to constrain MAOs from adopting "new, unrelated (that is, without supplementary or interpretive value) coverage criteria," it should say so in regulations specifically and provide a definition of supplementary value. Adding the term "plain language" to the regulation further confuses CMS's intent.

CMS also proposes to eliminate the requirement that MAOs demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms.

Humana Comment: Humana supports this proposal. Our experience has shown that demonstrating a policy is "highly likely" to have a specific impact is, as CMS notes, "difficult to definitively prove through evidence." This limitation therefore serves little practical value. Instead, CMS and MAOs should focus on creating policies that are supported by reliable evidence as required by other provisions of this regulation.

III.U.2. Definition of Internal Coverage Criteria

CMS proposes to define "internal coverage criteria," which is a term not previously defined in the April 2023 final rule. The proposed definition states, in part, that these criteria are "policies, measures, tools, or guidelines, whether developed by an MA organization or a third party . . . adopted or relied upon by an MA organization for purposes of making a medical necessity determination."

Humana Comment: Humana does not support this proposed definition and urges CMS not to finalize this proposal. The term "adopted or relied upon" is exceptionally broad and potentially encompasses a universe of materials that were never intended by CMS to be subject to the rule.

MAOs could rely upon a myriad different documents in the course of their utilization management operations. Some of these are recognizable as policies or criteria in the normal sense: they are documents containing specific clinical circumstances that must be part of an enrollee's clinical presentation in order for an item or service to be covered. For these, the complex CMS rules governing the content of criteria, the adoption of criteria by Utilization Management Committees, and public access to criteria are more understandable.

Other documents fall outside this range, and applying the current CMS regulatory framework to these materials is overly burdensome, can interfere with necessary plan operations, and, in many cases, is nonsensical. For example, internal documents such as training materials or communication templates are "developed" by an MAO and strictly speaking are "relied upon" when making a determination. But these documents do not seem to be those CMS contemplated when adopting the April 2023 rule. Nor would it be logical for an MAO to post these online or for these documents to be subject to the many limitations CMS has imposed on MAO "criteria."

Much the same way, there are third-party materials that are "relied upon" in a UM process but that have no binding effect. For example, in the absence of an established policy, a medical

director might consult a medical journal article or treatise to better inform their clinical judgment when making an individualized determination about whether a service is reasonable and necessary for a specific beneficiary. Further, a plan might use third-party criteria as a screening tool, just as CMS contractors do, to determine which cases need heightened review but not as a determinative of the result in any case. Journal articles, treatises and screening tools are not plan policies of the type that a MAO would ordinarily consider subject to a UM committee's approval or publication on a website.

To resolve this tension, we suggest that CMS focus on the binding nature of a plan document and whether it specifies the clinical presentation that must be present for coverage of an item or service to determine whether a document constitutes "internal coverage criteria." If a document forms a rule regarding requisite clinical presentations that would bind the plan staff's decision making in a particular instance, that document should be considered "internal coverage criteria" subject to the April 2023 rule's limitations. This could apply whether the document is created by the MAO or created by a third party but adopted by the MAO as its own. However, in a case where a document is procedural or advisory in nature, with the ultimate determination of reasonableness and necessity within the discretion of the health care professional reviewing the case (as in a case-by-case determination in traditional Medicare made in the absence of an NCD or LCD), that document should not be considered "criteria" under CMS's regulations.

We believe this is also consistent with CMS's comment that the documents it considers to be criteria are those that "restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care." While a binding policy clearly restricts access, a process, a reference document, or screening tool that aids but does not control the judgment in terms of the appropriate clinical presentation for coverage does not.

CMS should also explicitly confirm that denials based on the experimental or investigational nature of requested items or services are not denials based on internal coverage criteria. An item or service is not reasonable and necessary if it is experimental or investigational.[20] Longstanding Medicare guidance supports that experimental or investigational means the item or service has not been proven safe and effective based on authoritative evidence, or alternatively, generally accepted in the medical community as safe and effective for the condition which it used.[21] Any definition of internal coverage criteria which implicates determinations that a service is experimental or investigational is non-sensical in the context of CMS's regulatory requirements. Prior CMS sub-regulatory guidance has stated that "if the standards in § 422.101(b)(6) and 422.101(b)(6)(i)(A) cannot be met because there are no widely used treatment guidelines or high-quality clinical literature to suggest that the clinical benefit of the internal coverage criteria is highly likely to outweigh the clinical harm, the MA organization is not permitted to adopt that internal coverage criteria even if the Traditional Medicare coverage criteria are not fully established."[22] The crux of the issue with an experimental or investigational item or service is that the item or service lacks sufficient clinical support and/or acceptance in the medical community, thus requiring an MA organization to support determinations that a service is experimental or

[20] *See* Medicare Program Integrity Manual, Ch. 3, § 3.6.2.2; Medicare Program Integrity Manual, Ch. 13, § 13.5.4.
[21] *See* 54 Fed. Reg. 4302, 4304 (Jan. 30, 1989).
[22] CMS, *HPMS Memo - Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule* (CMS-4201-F) (Feb. 6, 2024).

investigational when "current evidence in widely used treatment guidelines or clinical literature" is illogical.

III.U.3. Prohibitions

CMS proposes a "guardrail" on the use of internal coverage criteria that prohibits the adoptions of a "criterion [that] does not have any clinical benefit."

Humana Comment: Humana opposes this criterion and urges CMS not to finalize it. Humana agrees with CMS that the contents of internal coverage criteria should contribute to a determination of whether the item or service is reasonable and necessary under the statute. However, requiring a "clinical benefit" is a broader and more encompassing requirement than this specific goal articulated by CMS. We suggest CMS simply state that the criteria of a UM policy must be designed to determine whether the requested item or service is reasonable and necessary for an enrollee.

We further request that CMS clarify its statements that UM processes should not be "managing care to reduce utilization of an item or service to a less costly alternative," or any implication that such processes have no value to enrollees. As CMS stated in the April 2023 rule, members of MA plans are generally entitled to coverage of items and services at the same types of care sites and levels of care for which they could obtain those items and services in the traditional Medicare program. But if that care can be obtained more cost effectively (and potentially at lower out-of-pocket cost to the enrollee) in one site of care versus another, or a more cost-effective treatment exists, MAOs should be permitted to encourage or incentivize the use of the lower-cost site of care or service. So long as UM processes do not result in an outright denial of otherwise covered care, CMS should clarify that these processes may encourage or incentivize more cost-efficient care.

A second guardrail proposed by CMS is a requirement that a criterion not be "used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination."

Humana Comment: Humana opposes this proposal as it is duplicative of existing requirements and is framed in a manner that could contribute to the mischaracterization of the procedures used by MAOs to carry out utilization management.

Under current regulations, each MAO is required to make utilization management decisions based on "[t]he enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes."[23] After reviewing those sources, a clinical professional "with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria"[24] may issue a full or partial denial on medical necessity grounds if the patient's medical condition does not meet Medicare coverage requirements, or plan coverage requirements duly adopted under CMS's regulations.[25] Clinical criteria are intended to help provide clarity to both providers and members about coverage and to assist MAOs in fairly and efficiently adjudicating medical

[23] 42 C.F.R. 422.101(c)(1)(i)(C).
[24] 42 C.F.R. 422.566(d).
[25] 42 C.F.R. 422.101(c)(1)(i)(A).

necessity decisions in a way that quickly yields answers for members and that treats similar cases the same.

III.U.4. Public Availability

CMS proposes certain changes regarding the structure and detail required with respect to public accessibility of internal coverage criteria.

Humana Comment: Humana appreciates CMS's focus on UM transparency and is aligned with the intent of this proposal. However, the proposed approach is not likely to achieve the agency's goal of ensuring "MA organizations are making this information available in a manner that is routinized and easy to follow." We offer the following specific comments on the full proposal.

The proposed requirement that MA plans publish criteria in a manner that is a "machine-readable format with the data contained within that file being digitally searchable and downloadable, and include a text file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access" goes above and beyond what is published for Original Medicare, as NCDs and LCDs are not currently published in a list in a machine-readable text file. We believe the transparency requirements for Original Medicare and MA should be consistent and that CMS should not finalize this proposal.

Additionally, 42 CFR 400.202 defines "service" broadly and Humana was unable to identify other protocols or CMS guidance to inform how this list might be populated. Specifically, Humana is unable to assess whether existing internal documentation is aligned with CMS's intention for the list of items and services. Humana maintains information in alignment with how Humana groups services for purposes of developing our internal coverage policies. If services are categorized differently by other MAOs the resulting output would not be consistent and may create more confusion. For example, Humana internal coverage policy 1007, Airway Clearance Devices, addresses a variety of medical treatments, diagnoses, supplies, devices, and equipment. Humana maintains the information for each of these "services" at the level of the policy. Further, Humana notes that under the proposed Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request (CMS-10913), CMS has proposed other versions of internal coverage criteria lists. While each list (the UMAS, the UM Audit universe, and this proposed list) has unique aspects, there are overlaps and some differences in what CMS is asking to have tracked and reported.

If CMS is to proceed with this proposal, additional context and discussions with stakeholders are needed as well as a standard list of services CMS expects to be included. A library of examples based on NCDs and LCDs would also facilitate understanding and set a strong foundation.

III.V.1. Clarifying When a Determination Results in No Further Liability for the Enrollee (§ 422.562)

CMS proposes to modify the language in 42 C.F.R. § 422.562(c)(2) by adding the phrase "[b]ased on an MA organization's determination on a request for payment." Accordingly, if finalized, 42 C.F.R. § 422.562(c)(2) would state: "Based on an MA organization's determination on a request for payment, if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal."

Humana Comment: Humana appreciates CMS's reiteration of the distinctions between the Medicare administrative appeals process, which is designed to protect enrollee interests, and payment dispute processes for participating providers. However, Humana opposes CMS's proposed change because the proposed regulation and CMS's preamble commentary introduces additional confusion and is potentially inconsistent with other statutory and regulatory requirements. If CMS's intent is to curb specific MA plan practices regarding inpatient acute care hospital admissions, CMS should more narrowly tailor its proposed changes in order to avoid unintended impacts on other types of organization determinations and appeals.

Appropriate delineation between the Medicare administrative appeals process and payment dispute processes for participating providers is important to ensure the administrative appeals process functions as Congress intended and appropriately focuses on enrollee interests. CMS's proposal implicates four important principles, only some of which CMS discusses in its preamble commentary.

- First, per 42 U.S.C. § 1395w-22(g)(5), the administrative appeals process is limited to circumstances where an enrollee "is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay."[26] Thus, any appeal must, throughout all phases of the administrative appeal process, have a live dispute as to either: (1) the enrollee's entitlement to receive services on an ongoing basis or in the future or (2) a charge incurred by an enrollee that is greater than what the enrollee believes they should be required to pay.
- Second, as recognized by CMS, "once a service has been fully furnished, the only matter for an MA organization to decide is whether to make payment and any resulting financial liability or cost sharing."[27]
- Third, as also recognized by CMS, "plan-directed care" beneficiary protections mandate that an enrollee be held harmless when the enrollee receives a service from a plan provider without prior notice that the service would not be covered.[28]
- Fourth, principles of non-interference prohibit CMS from interfering with the contractually bargained for dispute processes in MA organization participating provider agreements. CMS has made clear that "[c]ontract provider disputes involving plan payment denials are governed by the applicable/dispute resolution provisions in the contract between the provider and the plan."[29]

CMS's proposed rule fails to connect these principles, making it difficult for MA organizations and other appeal adjudicators to operationalize and consistently interpret these requirements. Specifically, CMS's proposed language fails to provide clear guidance on how to address status changes during the appeals process. In some instances, an MA plan may make an initial coverage decision before or during the provision of services, but the services are completed at some point during the appeal process. Merely because an organization determination was initially made on a pre-service or concurrent basis does not "lock in" its appeal status as a coverage dispute throughout the pendency of an appeal. This is mandated by the statutory

[26] 42 U.S.C. § 1395w-22(g)(5).
[27] 89 Fed. Reg. at 99466, n. 258.
[28] 42 C.F.R. § 422.105(a); Medicare Managed Care Manual, Ch. 4, § 160.
[29] Medicare Managed Care Manual, Ch. 13, Sec. 50.1.

definition of "appeal" in 42 U.S.C. § 1395w-22(g)(5), which, as noted, limits appeal rights to circumstances where an enrollee "is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay."

CMS's proposed regulation could create confusion in terms of the treatment of appeals after the completion of services as to whether appeal requests are themselves requests for payment and, if so, how those should be adjudicated in the absence of a claim. Further, absent additional clarification in CMS's regulatory text, participating providers could inappropriately seek to manipulate the enrollee appeal process to advance their own interests, to the detriment of the enrollee's interest and in violation of 42 U.S.C. § 1395w-22(g)(5). For example, upon admission, a participating provider could obtain an Appointment of Representative (AOR) from the enrollee, and then, attempt to pursue an appeal after the services are fully furnished—thereby classified according to the aforementioned proposal as a payment appeal—but prior to the submission of the claim. This type of misguided attempt to exploit the process could sow confusion as to whether there has been a "request for payment."

CMS should also clarify that "no further liability to pay" refers only to circumstances where an appeal overturn results in ***less*** enrollee financial responsibility. As discussed above, by statute, 42 U.S.C. § 1395w-22(g)(5), the administrative appeals process is limited to circumstances where either an enrollee believes they are entitled to receive services they have not received or believes they have been subject to a "***greater charge*** than the enrollee believes the enrollee is required to pay." Any attempt at expanding the administrative appeals process to encompass any impact (positive or negative) to enrollee financial responsibility is agency overreach and contrary to CMS's statutory authority.

Some of CMS's preamble commentary in the Proposed Rule is inconsistent and potentially contradictory regarding this issue. For example, in one place CMS appropriately states: "This means that neither the enrollee nor any other party may appeal an adverse payment decision under subpart M after an MA organization determines the enrollee is not financially liable ***for more than the applicable cost-sharing of the services for which payment was requested***."[30] However, CMS later introduces confusion in a failed attempt to "eliminate potential confusion" by stating "The reference to 'no further liability to pay' in 422.562(c)(2) means the enrollee's financial liability ***will not be affected*** by whether the payment determination is upheld or overturned."[31] Any appeal pursued purportedly on the enrollee's "behalf" where the outcome sought is additional financial liability for that enrollee is inappropriate and contrary to the statutory authority for the appeals process at 42 U.S.C. § 1395w-22(g)(5) as well as being contrary to existing statutory and regulatory non-interference requirements.[32]

<u>Proposed Revisions to Reopening Rules Related to Approved Hospital Inpatient Admissions</u>

CMS proposes to amend 42 C.F.R. § 422.616 to add a new paragraph (e) to place a limitation on reopening determinations related to favorable inpatient admissions. Specifically, proposed 42 C.F.R. § 422.616(E) would state that if an MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) or (3), any additional clinical information obtained after the initial organization

[30] 89 Fed. Reg. at 99462.
[31] 89 Fed. Reg. at 99462.
[32] *See* 42 U.S.C. § 1395w-24(a)(6)(B)(iii); 42 C.F.R. § 422.256(a)(2).

determination cannot be used as new and material evidence to establish good cause for reopening the determination.

> **Humana Comment:** Humana opposes the proposed amendment, which attempts to remove the ability of an MAO to reopen approved inpatient hospital admissions based on new and material evidence that was not available or known at the time of the determination. In support, CMS reminds MAOs that the plan's determination must be made based on what was known by the physician and documented in the medical record at the time of admission.[33] But CMS does not consider or address the scenario where the requesting provider failed to provide an accurate and/or complete medical record or other pertinent information to the health plan in the first place. Aside from providing complete medical records, plans may require that the requestor provide certain information through prompts in an electronic authorization portal. In some cases, that information may not be accurate or complete. Under these circumstances, pertinent information may not have been "available or known" at the time the MAO made its decision. If the proposal is finalized, the MAO would be left with trying to either (1) establish fraud or similar fault[34], or (2) the remaining "good cause" exception that "the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision."[35] Failing to provide an accurate or complete medical record may not rise to the level of fraud, or indicate an "obvious error" made at the time of the determination.
>
> Additionally, the proposal inappropriately inserts CMS into MAO and participating provider contractual relationships and could hamper an MAO's ability to fulfill its obligations to prevent, detect, and correct fraud, waste, and abuse.[36] Accordingly, Humana recommends that CMS maintain the plan's ability to reopen for "new and material evidence" in inpatient admission decisions. Doing so will help ensure the plan has the ability to reevaluate its initial decision and reopen to ensure accurate coverage decisions that meet the requisite criteria under 42 C.F.R. § 412.3.

III.W. Formulary Inclusion and Placement of Generics and Biosimilars (§ 423.153(b))

CMS proposes to holistically review whether a plan's formulary and UM practices with respect to generics, biosimilars, and other low-cost drugs constitutes a drug UM program that is "cost-effective," "reasonable and appropriate," and inclusive of "incentives to reduce costs."

> **Humana Comment:** Humana believes increasing generic and biosimilar use is an important tool in bringing down total drug costs and increasing competition in the prescription drug market. Humana concurs with CMS in this regard and has developed formularies that offer broad coverage of generics and biosimilars as they drive affordability for our members.
>
> In the preamble to the proposed rule, CMS indicates it now plans to holistically review whether a plan's formulary and UM practices with respect to generics, biosimilars, and other low-cost drugs constitutes a drug UM program that is "cost-effective," "reasonable and appropriate," and inclusive of "incentives to reduce costs." Humana does not oppose this approach, but does

[33] 89 Fed. Reg. 99340, 99469.
[34] 42 C.F.R. § 405.980(b).
[35] 42 C.F.R. § 405.986(a)(2).
[36] 42 C.F.R. § 422.503(b)(4)(vi); Medicare Managed Care Manual, Ch. 21.

support continued flexibility for plan sponsors to develop formularies that drive the lowest net costs to the plan, the Medicare program, and Medicare beneficiaries. This includes the potential to cover an innovator product in lieu of a generic or biosimilar if such formulary treatment reduces total costs for the Part D program and beneficiaries, including in the form of reduced premiums and additional enhanced benefits.

Although the generic marketplace is well-established, Plan Year 2024 represented the first full year where biosimilars were available in Medicare Part D. Despite challenges in adoption among prescribers, competition between biosimilars and innovator products has already been successful in lowering costs, with researchers estimating that in the first year of competition, adalimumab net spending and prices declined nearly 50 percent.[37]

Humana opposes any new formulary controls in Medicare Part D that mandate coverage of certain products and therefore might limit competition and unintentionally raise costs. However, Humana does agree that policy solutions may be needed to improve uptake of biosimilars and ensure stability of the biosimilar pipeline. We appreciate the additional flexibility CMS provided Part D plan sponsors as part of last year's rulemaking to classify midyear formulary substitutions of biosimilars for reference products as "maintenance changes". We are supportive of FDA's continued work reducing barriers to the development of interchangeable biosimilars, which could improve biosimilar availability and affordability. Additionally, we believe HHS could do more to support a holistic effort to educate prescribers about biosimilars and their safety and efficacy coupled with potential for lower patient out-of-pocket costs in some circumstances.

CMS seeks comment on whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generics, biosimilars, and other lower cost drugs. We are concerned that formulary requirements for selected drugs in the Medicare Drug Price Negotiation Program could have unintended consequences for the Medicare program and beneficiaries. Specifically, under current program guidance, CMS indicates that – although they are not implementing explicit tier placement or UM requirements for selected drugs – CMS will use its formulary review process to assess instances where a selected drug is subject to higher tier placement or more restrictive UM compared non-selected drugs in the same class. Under such requirements, it is unclear if Part D plan sponsors will be able to develop formularies with the option to provide for preferential access for biosimilar entrants (in the case of Stelara) and generic entrants (in the case of Entresto and Farxiga). CMS should clarify that, even in the case of selected drugs, Part D plan sponsors have the option to use formulary tools to encourage uptake of generics and biosimilars if those formulary design decisions help facilitate lower net costs, consistent with current guidance for non-selected drugs. This includes the flexibility to cover or not cover a selected drug when an equivalent drug is on the market, consistent with Congressional intent for the Medicare drug price negotiation program to focus on drugs without competition. CMS clarification will ensure a viable generic and biosimilar market for all prescription drugs, improve accuracy and experience for Medicare beneficiaries for plan selection, and lower costs for the Medicare program and beneficiaries.

[37] Use, Spending, and Prices of Adalimumab Following Biosimilar Competition | Health Policy | JAMA Health Forum | JAMA Network

IV. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

IV.A Introduction (§§ 422.166 and 423.186)
CMS is proposing to finalize the removal of guardrails when determining measure-specific thresholds for non-CAHPS measures, to apply beginning with the 2026 measurement year and 2028 Star Ratings.

> **Humana Comment:** Humana does not support the removal of guardrails in the absence of other means to smooth changes in measure cut points. **To increase cut point validity and support sustained quality improvement, Humana urges CMS to adopt a threshold calculation approach leveraging multiple years of data, with the greatest weight given to the most recent year** (e.g., 2024 – 40%, 2023 – 20%, 2022 – 20%, and 2021 – 20%). Such an approach could be leveraged for most measures while excluding new measures or those with recent methodological or reporting method changes. Humana also continues to recommend that CMS return to cut points established before the measurement period to enhance program predictability and clarify goals for plans and network providers.
>
> Notably, Humana continues to firmly oppose the implementation of the Tukey outlier deletion methodology, as mentioned in prior comment letters. The anticipated effects to decrease Star Ratings, not increasing cut point stability in any meaningful way, and negative impact on beneficiaries' access to benefits associated with high quality plans has now been observed in the originally released 2024 Star Ratings and the 2025 official Star Ratings. As such, Humana urges CMS to retract the Tukey outlier deletion methodology.

IV.B. Adding, Updating, and Removing Measures

IV.B.1.a. Initiation and Engagement of Substance Use Disorder Treatment (IET) (Part C)
CMS proposes to add the Initiation and Engagement Substance Use Disorder Treatment (IET) measure beginning with the 2028 Star Ratings covering the 2026 measurement year. CMS is proposing to average the initiation and engagement rates into one measure for reporting in the Stars Ratings program.

> **Humana Comments**: Humana acknowledges the importance of substance use disorder treatment and is supportive of the Initiation and Engagement Substance Use Disorder Treatment (IET) measure as an effort to increase access to treatment; however, the main drivers on this measure are still unknown, and as such, Humana remains **opposed** to the addition of the measure to 2028 Part C Star Ratings. This disorder presents exceptional challenges, as many people who suffer from substance abuse do not acknowledge their need for assistance; therefore, are likely to be more resistant to health care provider and health plan initiatives. Other external factors such as stigma, social determinants of health, and limited access to specialized treatment providers are often beyond the direct control of a health plan but can significantly impact performance on the measure. Health plans also face barriers in accessing comprehensive behavioral health data due to inconsistent coding practice and privacy concerns with varying state laws (e.g., 42 CFR Part 2) specific to substance use treatment data, which may inhibit accurate quality measurement. These issues would collectively undermine the validity and reliability of the measure and introducing it in the short-term can penalize health plans unfairly, especially those that serve high-risk and disadvantaged populations.

A 2019 study examining IET performance across seven health systems and ~87K patients found several factors associated with IET over which health plans have limited control (e.g., age, race/ethnicity, and co-occurring conditions)[38]. In addition, race/ethnicity and many co-occurring conditions are not adjusted for in the HEI or CAI, and therefore some MA plans would be inherently disadvantaged. Consequently, Humana recommends CMS allow additional time for health plans to research and define an effective strategy to best impact this measure and access to care.

IV.B.1.b. Initial Opioid Prescribing for Long Duration (IOP-LD) (Part D)

CMS proposes to add the IOP-LD measure for the 2028 Star Ratings (2026 measurement year).

Humana Comment: Humana continues to oppose the addition of IOP-LD and any other measure with a lower-is-better rate, as the industry response is primarily focused on point-of-sale edits, which are likely to generate both beneficiary and provider abrasion. Additionally, given alternative means to access medications outside of Part D benefit such as discount cards and cash payments, Humana does not believe the measure will lead to the expected improvement outcomes (e.g., reduction in hospitalizations or overdoses).

IV.B.2.a. Breast Cancer Screening (Part C)

CMS is proposing a substantive update to the existing Breast Cancer Screening measure by expanding the age range for the Breast Cancer Screening measure to women aged 40-49, for an updated range of 40-74, for the 2027 and subsequent measurement years.

Humana Comment: Humana supports the update to the Breast Cancer Screening measure to align with the updates made to this measure by NCQA as a result of changes in the applicable clinical guidance to expand the age range to 40-74 years old.

IV.B.2.b. Plans Make Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C)

CMS is proposing updates to the Plan Makes Timely Decisions about Appeals (Part C) measure.

Humana Comment: The proposed substantive change eliminates the current 5-day buffer time, placing significant cost and administrative burden on health plans to meet the required appeal submission timeframe to the IRE. Considering the necessity for health plans to achieve almost flawless performance within these measures, Humana opposes the decision to update the measures without allowing plans sufficient time to assess the data from the first year the measure is on display. CMS does not provide industry data for display measures until January of the year after the measurement year's close – a full year after. Specifically, the results of the 2024 measurement year would not be available until January 2026 leaving payers without sufficient time to assess whether adjustments are needed to keep pace with the industry for the 2026 measurement year.

Additionally, Humana recommends that a case should be considered timely if, when a case is due outside of IRE business hours, it is submitted to the IRE by the health plan prior to the start of business the following business day.

[38] Amy M. Loree, PhD, Center for Health Policy & Health Services Research, Henry Ford System. HHS Public Access. *Psychiatric comorbidity and HEDIS measures of alcohol and other drug treatment initiation and engagement across seven health systems.* Available in PMC 2020 January 25.

IV.C. Health Equity Index Reward (HEI) (§§ 422.166(f)(3) and 423.186(f)(3))

Beginning with the 2027 Star Ratings, for the second year following a consolidation, CMS is proposing to clarify that the combined enrollment from the consumed and surviving contracts from the most recent year of data used in calculating the HEI will be used to assess whether the surviving contract meets one of the enrollment thresholds. CMS is proposing to modify the way eligibility for an HEI reward and the size of the HEI reward are determined for legacy MA contracts that no longer meet either of the percentage SRF enrollment thresholds due to state contracting requirements. CMS is proposing a series of rules that would be applied in order to determine whether the legacy MA contract would qualify for an HEI reward and the size of the reward if applicable.

> **Humana Comment:** Humana has serious concerns about the current implementation of the HEI, which we describe in more detail below in Section IV.D. of our comment letter. We believe that CMS has unnecessarily rushed HEI implementation and failed to give plans critically important information to evaluate and confirm performance data. We strongly encourage the Trump Administration to pause implementation of the HEI for 2027 Star Ratings to better understand its impact on plans and beneficiaries and to determine whether the HEI, as currently constructed, is consistent with the new Administration's policy objectives.
>
> If CMS elects to move forward despite our significant concerns, Humana supports the proposed approach for handling consolidations. For instances in which a contract's HEI reward is calculated differently due to consolidations, Humana recommends supporting data points from consumed and surviving contracts be provided to plans to enable proper validation.
>
> Additionally, Humana supports the proposed approach to modifying the way the HEI reward is calculated for MA contracts that are required to shift D-SNP enrollment to a D-SNP-only contract, but requests additional clarity on: (1) the anticipated duration of the temporary adjustment period that has been proposed; and (2) the new SRFs whose addition to the HEI will bring about the end of this temporary adjustment period. The proposed rule states that the adjustment to the way legacy contracts' HEI reward eligibility is determined will be temporary, continuing only until the Star Ratings year when additional social risk factors (SRFs) are added to the HEI reward. However, the proposed rule does not provide clarity on the duration of this temporary adjustment period, nor does it state which additional SRFs will be added to the HEI reward.
>
> Due to the complexity of the criteria for determining legacy contract HEI reward eligibility and amount, Humana requests that CMS provide both advanced written communication to affected health plans outlining the legacy contracts that will undergo this adjustment, as well as supporting data on the legacy contract and D-SNP-only contract enrollment and performance.
>
> Finally, Humana supports the proposal and recommends that CMS consider whether performance disparities between I-SNP-only contracts and non-I-SNP contracts merits consideration of different cut points for I-SNP-only contracts.

IV.D. Applying the Improvement Measure Scores (§§ 422.166(g) and 423.186(g))

CMS proposes to clarify that the improvement measure hold harmless for the highest rating is determined based on the rounded rating before the addition of the HEI reward, if applicable.

Humana Comment: Humana thanks CMS for this clarification; however, disagrees with the approach of adding the HEI reward *after* applying improvement measure hold harmless rules. In contrast, the legacy Reward Factor is currently added before applying improvement measure hold harmless rules, and Humana believes that maintaining this order of operations will more accurately reflect health plan quality. Humana urges CMS to reconsider the approach to add HEI after hold harmless and requests that it provide additional rationale for the change to the order in which rewards are added.

Since CMS initially conceptualized the HEI in February 2022, it has been on a fast track to implementation with a lack of transparency to the data and methodology that plans need to prepare for such a substantial change, particularly in light of other significant methodology changes in recent years, including the weighting changes for Patient Experience and Complaints and Access measures and the implementation of the Tukey Outlier Deletion methodology. Given that one of the foundational principles of the Star Ratings is "to provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program",[39] it is imperative that the ratings are an accurate and reliable reflection of plan quality so as not to further confuse beneficiaries in their decision-making process or discredit the CMS quality rating system.

When CMS shared they were developing a HEI through the *Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* in February 2022, Humana provided comments in encouraging CMS to move deliberately and cautiously because a meaningful, accurate, and reliable measure is critical to understanding progress over time. Humana strongly recommended making data transparent and publicly available, which CMS has not done, and where they have, it has not been timely. In CMS's April 2022 response in the *Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, the agency noted: "To provide Part C and D sponsors with information about how their contracts perform on the health equity index, we plan to make contract-specific index information available in HPMS later this year." However, this information was not made available in 2022; in fact, it was not made available until 20 months later on December 20, 2023, just 12 days before the start of the initial measurement period for the inclusion of the HEI in the 2027 Star Ratings.

Less than a year after initially sharing the Health Equity Index concept, CMS proposed its inclusion beginning with the 2027 Star Ratings in the proposed rule for the *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*. Because the HEI was to use two years of data, this meant measurement for it would begin January 1, 2024. CMS described the calculation for the two years of data as being "calculated using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data *to reflect performance in the second of the 2 years of data used*." [Emphasis added] Given that it was unclear how the data would be combined across the two years, Humana's comments submitted in February 2023 inquired about the methodology to

[39] 42 CFR 422.160(b)(1)

calculate the reliability, as well as requesting other data points be made public prior to implementation and strongly opposing the abrupt replacement of the reward factor before the impact of the HEI was understood. Humana also expressed concern that the proposal would have a disproportionately negative impact on rural beneficiaries, given that members with social risk factors (SRFs) in rural communities will likely perform lower than similar members in non-rural locations due to the general disparities in provider density, transportation availability, and data collection. Humana urged CMS to delay the implementation at least two years and provide the data requested in order for plans to have the ability to understand and evaluate the impact of the proposed methodology on the Star Ratings program. Despite concerns raised by commenters that the lack of available data prevented plans from being able to meaningfully comment during the notice and comment period, CMS finalized their proposal in April 2023 through a final rule, stating they would "calculate the HEI reward beginning with the 2024 Star Ratings and will share the results in confidential contract-level reports in HPMS. *Contracts will have these data for 3 years prior to the HEI being implemented* as part of the 2027 Star Ratings." [Emphasis added] "CMS will also share summary-level results by type of contract for informational purposes."

CMS subsequently shared confidential contract-level data in HPMS for 2024 Star Ratings on December 20, 2023, just 12 days before the measurement for the first year of implementation began on January 1, 2024, as noted above. In addition to its untimely release, the December 2023 HPMS memo had two other deficiencies. First, the description of how the two years of data would be calculated together into one score was general in nature, lacking detail of the calculation and necessary coefficients and averages. Second, the only industry data made available was the cut points of the performance distribution in bottom, middle, and top thirds for each measure. There were no industry averages for the population with one or more social risk factors and no plan-specific data other than the payer's own. While CMS stated in the December 2023 HPMS memo that it planned to release additional information with aggregated results from these calculations early in 2024, concerningly, this has yet to occur.

On December 20, 2024 and again just 12 days before the beginning of the second year of measurement for the 2027 Star Ratings, CMS shared confidential contract-level data in HPMS for 2025 Star Ratings. This HPMS memo included no reference to plans to share aggregated results, which have still not been shared from the year prior. The notes contain three new pages of detail on the rate calculation with clarity of how the two years of data will be calculated, which reveals the performance is not actually reflective of the plan's Year 2 performance, but rather an adjusted average of the two years then adjusted for the *industry* performance improvement or decline. There are also an additional 15 pages of measure-level means and coefficients required to validate the calculations and estimate future performance.

At this point, Humana firmly believes CMS has not adequately shared the data required to understand performance on the HEI for three years ahead of implementation as they stated would occur, given that only one year was shared mere days before the measurement began and there have been no indicators of industry performance other than the performance distribution one-third cut points. CMS is also already discussing adding new social risk factors to the scope of the HEI, when no one other than CMS has yet seen industry performance as it stands with the original social risk factors. Without such transparency, it is impossible to evaluate whether the proposed methodology and potential changes to the calculations and in-

scope social risk factors will produce an accurate reflection of plan quality to help Medicare beneficiaries compare their plan options.

Humana firmly urges CMS to retract the implementation of the HEI and maintain the current Reward Factor for 2027 Star Ratings, and delay HEI implementation until at least two years of plan-level data for the industry are made publicly available prior to measurement beginning and plans are afforded a meaningful opportunity to provide comments. For example, if the HEI methodology remains as-is, industry data for the past two years could be shared publicly no later than June 1, 2025 and Health Equity Index data for the 2026 Star Ratings could be shared by October 31, 2025, with measurement beginning on January 1, 2026 for Year 1 of the 2029 Star Ratings as a new implementation date.

V. Improving Experiences for Dually Eligible Enrollees

V.A. Member ID Cards, Health Risk Assessments, and Individualized Care Plans (§§ 422.101, 422.107, 422.2267, 423.2267)

V.A.a. Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D-SNPs

CMS proposes a federal requirement for applicable integrated plans to provide enrollees one integrated member ID card that serves as the ID card for both the Medicare and Medicaid plan in which they are enrolled. This proposal is applicable for contract year 2027, beginning October 1, 2026. CMS solicits comment on whether the final rule should provide that any requirement for integrated ID cards should apply to AIPs and all HIDE SNPs, including those that do not also qualify as AIPs.

Humana Comment: Humana supports an integrated member ID card for applicable integrated plans (AIP) to serve as the ID card for members enrolled in both the Medicare and Medicaid plans. Humana agrees that requiring an integrated member ID card for AIPs would reduce confusion for both providers and enrollees. Additionally, as CMS noted in the Proposed Rule, many states already have integrated ID card requirements for MMPs and AIPs.

CMS indicated there are no proposed substantive changes to the Medicare or Medicaid requirements for the content of the ID cards; however, we believe a model integrated ID card would reduce administrative burden for states and participating plans and ensure all requirements from both Medicare Advantage and Medicaid are accounted for within the card. CMS is already collaborating with states to develop integrated model materials, including Summary of Benefits and Formulary. We would encourage a similar model for integrated ID cards which incorporates Medicare Advantage and Medicaid requirements.

Lastly, while Humana agrees that integrated cards would be useful for AIPs, we are concerned that integrated ID cards for highly integrated dual special needs plans (HIDE SNPs) would be confusing if the member does not use the same Medicare Advantage Organization (MAO) and aligned Medicaid fee-for-service or Managed Care Organization (MCO) coverage. Although HIDE SNPs can be AIPs, many do not have exclusively aligned enrollment and therefore can have some D-SNP enrollees with aligned enrollment, and others enrolled in a Medicaid plan operated by a different organization or fee-for-service Medicaid. An integrated ID card requirement would often result in only some members receiving the integrated ID card, while others would still have two ID cards – one for the HIDE SNP and one for the Medicaid plan. Even if CMS were to require an integrated ID card across different organizations and fee-for-service Medicaid,

there are potential branding concerns and logistical challenges with ensuring the ID card is issued timely and accurately. For these reasons, we believe that an integrated ID card for HIDE SNPs would increase confusion and administrative burden on both members and providers.

V.A.c. Promoting Person-Centeredness in SNP ICPs and Timeliness of HRAs and ICPs

CMS proposes to specify that SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees.

Humana Comment: Humana supports CMS's proposal to codify the timing requirements for health risk assessment (HRA) completion in § 422.112(b)(4)(i). Engaging enrollees to actively participate in care management continues to challenge health plans. Through the quality and performance improvement process, Humana continues to identify and implement strategies to increase enrollee engagement. We understand the population continues to evolve, including how enrollees prefer to interact with their care team. The digital literacy and adoption of digital technologies as primary communication methods continue to increase with the SNP population. We encourage CMS to provide flexibility for plans to tailor HRA outreach with how and when to conduct outreach based on the population's preferences and needs. Text messaging along with other digital efforts should be considered valid attempts towards HRA outreach and Part C measures. Humana believes this would increase enrollee engagement, provide for a better enrollee experience, and target coordinated care to enrollees who otherwise would not participate.

CMS proposes to require that SNPs within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later, develop and implement a comprehensive ICP.

Humana Comment: Humana acknowledges CMS's efforts to mandate completion timeframes for care plan creation and shifting care plans from a medical model to a person-centered model for all SNP enrollees. However, we oppose restricting enrollee care plan development to a limited timeframe (i.e., within 30 days of conducting a health risk assessment (HRA) or 30 days after the effective date of enrollment). The SNP population typically sees a higher rate of enrollees who cannot be reached and enrollees declining to participate in active care coordination, which requires sufficient time to reach this population with the goal of engagement and meaningful care plan development. Additionally, health plans may utilize various sources and modalities in obtaining a completed HRA (e.g., vendor, providers, support staff). In this circumstance, the care manager must review and analyze the HRA with the enrollee/caregiver to develop the care plan. Often 30 days is not sufficient to reach all enrollees. Limiting the completion time may result in an increase in the number of basic care plans vs comprehensive, individualized care plans. This would reduce the positive impact on enrollees' health outcomes and increase negative enrollee experience. Another example, an enrollee may be experiencing a transition of care after enrollment or the completion of a HRA, which may require additional time beyond 30 days to reach the enrollee and create a comprehensive, tailored care plan.

Humana encourages CMS to allow plans to create care plans based on enrollee needs and preferences. We recognize person-centered care plans are appropriate for certain populations (i.e, D-SNPs, well controlled chronic conditions). However, the nature of the needs of the ISNP and CSNP populations, a medical focused care plan, is often more appropriate in most cases. For complex conditions, it may be more suitable to use a medical model. Education on medication

and treatment adherence and the importance of provider appointments is a vital part of managing chronic conditions and should be a component of the overall care plan when applicable.

V.A.b. Integrated Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D-SNPs

CMS proposes a requirement that D-SNPs that are applicable integrated plans conduct a comprehensive HRA that meets all requirements at § 422.101(f)(1)(i) through (v) as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees in the AIP complete a single integrated HRA for Medicare and Medicaid. CMS states that this proposal encompasses all FIDE SNPs; CMS solicits comments on whether the agency should apply this new requirement to all HIDE SNPs or all D-SNPs, even those without exclusively aligned enrollment.

Humana Comment: Humana acknowledges and agrees with CMS to only require D-SNPs that are AIPs to complete a single integrated HRA for Medicare and Medicaid because it is most feasible for D-SNPs whose enrollees are exclusively aligned with an affiliated Medicaid MCO to implement a fully integrated HRA. Humana supports CMS's approach to a single integrated HRA:

1. To address the reduction in the duplication of assessments, Humana supports an integrated HRA which may foster marginal increases in enrollee engagement. However, Humana encourages states to consider the length of the tool to ensure D-SNPs remain agile in the types of modalities that are used to complete the tool with enrollees and consider staff credentials that can complete the tool with an enrollee. Longer assessment tools become taxing for enrollees to complete leading to poor enrollee experience.
2. Humana requests that CMS encourage states to align HRA requirements to Medicare requirements, ensuring Model of Care domains are met (assess the medical, functional, cognitive, psychosocial, and mental health needs of each SNP enrollee). Humana does support CMS language within the proposed rule to allow for modular HRA tools to allow D-SNPs to target assessment questions beyond Medicare requirements such as NCQA and health equity requirements.

However, Humana is concerned that future consideration of expanding the integrated HRA for Medicare and Medicaid requirement to **all** D-SNPs including non-AIPs, HIDEs, and coordination only plans would be challenging for the following reasons:

1. Integrated HRAs may cause confusion with states that are non-AIP and these states may not have the bandwidth to procure an integrated HRA. In addition, MCOs do not always abide by Medicare HRA domain requirements and would not allow D-SNPs to develop an HRA that is specific to their targeted population needs.
2. Administrative burden and cost implications on D-SNPs to maintain multiple versions of HRAs with numerous MCOs within the same state. Multiple versions of HRAs within each state would increase administrative expense on the entire system for D-SNPs.
3. Lack of transparency by MCOs with D-SNPs related to assessment tools, including when MCOs change tools, pose challenges for D-SNPs to maintain compliance with an integrated HRA. D-SNPs would be dependent on the MCO to notify each plan of HRA revisions.
4. To reduce duplicative HRAs completed by MCOs and D-SNPs and improve enrollee experience, implement universal processes for MCOs to share enrollee responses to HRAs and HRA completion dates with D-SNPs. In addition, standardization of HRA timing including

when reassessments are conducted due to a significant change in condition would need to align between MCOs and D-SNPs.

5. Timing of state Medicaid agency contracts and MOC submission to CMS for approvals would need to align to ensure adequate runway to implement HRA tool requirements for both D-SNPs and MCOs. In addition, more specific state contract requirements add complexity to maintaining an aligned MOC by D-SNPs to MCO processes when MCOs lack transparency with D-SNPs.

Humana suggests rather than expanding integrated HRAs to non-AIPs, HIDEs, and coordination only plans to consider further standardization of HRAs by leveraging the approach like SDOH questions by allowing D-SNPs to select questions from preapproved set of tools based on the D-SNPs target population. Allowing D-SNPs to select a standardized tool for all enrollees at the contract level and SNP subtype would ensure the D-SNP's HRA is comprehensive and optimizes care of the member and ensures D-SNP adherence to CMS Part C – Medicare Advantage and 1876 Cost Plan Expansion Application, 5.8 Health Risk Assessment Attestation.

V.A.e. Assuring Enrollee Advisory Committee Input on MOC Updates

CMS proposes to add language to the D-SNP EAC requirements to include updates to the Model of Care (MOC) among the minimum required EAC discussion topics. CMS is not requiring that EACs review or approve the MOC but instead to provide perspectives to inform MOC updates over time.

Humana Comment: Humana acknowledges and maintains a neutral position related to soliciting feedback from enrollees on the Model of Care (MOC) via enrollee advisory committees (EACs). Humana appreciates the ongoing collaboration with CMS to expand EAC topics within § 422.107(f). Humana currently solicits feedback from enrollees on care coordination services by seeking input from enrollees on their awareness of benefits and enrollees' interest in learning more about care coordination. Enrollee opinions have varied, with some voicing interest in learning more about the benefits available and others showing little to no interest.

Humana encourages CMS to draft language that is broad in nature for inclusion in § 422.107(f) D-SNP EAC requirements related to the Model of Care. Thus, allowing plans the flexibility to raise awareness and understanding specific to the benefits the MOC offers, seeking feedback from enrollees on ways to encourage participation within the care management program and reducing the number of enrollees who choose not to participate in the program. Expanding the scope of what feedback is solicited from enrollees beyond HRAs and ICPs to encompass other care coordination benefits such as assisting members through transitions of care, enrollee participation in interdisciplinary care teams, and the benefits of having a single point of contact to coordinate their care would optimize enrollee experiences with the plans MOC.

In addition, allowing plans the flexibility to formulate questions related to the MOC would create opportunities for the plan to gather general themes from enrollees within each state that may encompass multiple contracts as MOCs are submitted at the contract level to CMS. Gathering general themes would promote building future updates into the MOC over time that are viable to and not contradictory to regulatory requirements CMS has implemented related to HRA tools and ICPs.

V.A.f. Comment Solicitation – Making State Medicaid Agency Contracts Public

CMS solicits comments on whether and how CMS should post State Medicaid Agency Contracts (SMACs) online.

> **Humana Comment:** Humana supports posting D-SNP SMACs on a CMS website, with the condition that CMS obtain SMACs directly from States rather than from individual D-SNPs and that any financial or plan identifiable content be omitted. We agree that making SMACs publicly available would make research easier and promote information sharing. However, we do not believe it would be appropriate to share payer-specific contracts. Rather, posting SMAC templates provided by States would satisfy the purpose of making access easier without compromising confidentiality.