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RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair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 in 2026 and 2027

Dear Dr. Seshamani,

The Alliance for Aging Research ("Alliance") appreciates the opportunity to review and comment on the Medicare Drug Price Negotiation Program (MDPNP) Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity.

The Alliance appreciates CMS's willingness to revisit and solicit comment on several key areas, including the patient-focused engagement process and the grouping of qualifying single source drugs. We also strongly believe that CMS must, and has legal authority to, be more proactive in establishing expectations and guardrails to prevent inappropriate or excessive applications of utilization management.

30.1.1 Qualifying Single Source Drugs

CMS has chosen to combine all indications, dosage forms, and strengths of a medication together as one "drug" for the purpose of applying the MFP. The Alliance has concerns about the downstream impacts of this decision on areas of medical research. For example, the

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manufacturers of some glucagon-like peptide 1(GLP-1) agonists are currently in clinical trials for conditions that are very different from their originally approved indication of diabetes, such as Alzheimer's disease and slowing the progression of kidney disease. The difference in patient population and condition is significant, requiring separate clinical trials and substantial investment. However, if a drug in the future is subject to the current QSSD grouping guidelines, there will be greatly reduced incentives to perform these types of additional research, leaving potentially very meaningful treatments unexamined. Further, Medicare's negotiated price for a qualifying single source drug (QSSD) may or may not incorporate costs associated with additional research and development of a drug with an existing approved FDA indication.

While we have the greatest concern about the above potential application of the statute, there are also concerns about whether the QSSD structure excessively disincentivizes research into distinct formulations or routes of administration. CMS should assess whether these advances represent clinical improvements (based on better efficacy due to the method of action, or due to ease of administration that improves adherence, for example) that improve outcomes and/or quality of life.

The Alliance asks CMS to explore with the wider patient community and other subject matter experts the degree to which application of an MFP on a QSSD constitutes a deterrent for investment and research into novel indications. We hope manufacturers and pharmaceutical companies will continue investing significantly in novel areas regardless of CMS policy, but we are cognizant of real-world considerations and are concerned about the unnecessary risks the current formulation of the QSSD policy raises for the development of novel uses of therapeutics. Over time, this policy could impact patients in nearly every disease area, including areas with significant unmet need.

60.3 Issues Resulting from CMS' Lack of Transparency About Methodology and Potential Use of Discriminatory Metrics

Currently, there is little to no publicly available information on the process and methodology used by CMS as they negotiate prices. However, CMS is a public agency – not a private payer – and there is little need for a similar level of secrecy or guarding of "trade secrets" around methodology. There is material public interest in how CMS is establishing the MFP, given that millions of beneficiaries take the medicines subject to negotiation and there may be resultant impacts – positive or adverse – that result as negotiated prices take effect in 2026. We encourage CMS to change course and publicly release information on the methodology used to establish the MFP and price negotiation. Further, releasing this information will encourage drug manufacturers to collect relevant data, either during the clinical trial process or through real-

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world data collection, to provide a robust base of information on factors likely to be considered in Medicare negotiations in the future.

There is also interest in ensuring that metrics assessed as discriminatory are not used in price negotiation. While CMS has noted that they will not be using the quality adjusted life year (QALY) to set the MFP, there have been explicit mentions of other equally discriminatory metrics in guidance. In the June 2023 Revised Direct Negotiation Guidance, CMS noted that many commenters recommended metrics such as the equal-value of life years (evLY) gained – which was developed and is calculated in part by using the QALY¹- or the Health Years in Total metric and then responded, "CMS will review cost-effectiveness measures and studies that use such measures for initial price applicability year 2026 to determine if such measures are permitted under section 1194(e) of the Act."² The public is not able to know the degree to which this research was conducted or the implications it had on the initial prices the Agency proposed. This is especially notable given the finalization of the updated final rule on Section 504 of the Rehabilitation Act, which confirmed that agencies under the umbrella of the Department of Health and Human Services cannot use metrics that discount the value of life extension based on disability.³

Further, methods for the underlying data collection used to complete the QALY, evLY, and similar analyses are incomplete and immature. At present, these analyses rely solely on clinical trial data, which typically include exclusion criteria that disqualify individuals from participating in a trial based on comorbidities, age, and other factors. As a result, clinical trial data often reflects a population that differs significantly from real-world users, meaning that any calculations of evLY are not representative of a drug's entire intended user base. Negotiated drugs are not new to the market, and so CMS should not be relying primarily on preclinical data, but rather should incorporate analysis of real-world data and real-world evidence.

CMS must be transparent about data collection and analysis in calculating the MFP, as well as the role of the engagement sessions, so that stakeholders can have meaningful engagement, including around the methodology the agency chooses to deploy.

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¹ O'Day, Ken and Dylan J. Mezzio. "Demystifying ICER's Equal Value of Life Years Gained Metric." Value & Outcomes Spotlight. <a href="https://www.ispor.org/publications/journals/value-outcomes-spotlight/vos-archives/issue/view/overcoming-vaccine-hesitancy-injecting-trust-in-the-community/demystifying-icer-s-equal-value-of-life-years-gained-metric

² Centers for Medicare and Medicaid Services. "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." 30 Jun 2023. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf

³ Department of Health and Human Services. "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance." Federal Register Vol. 89, No. 91. https://www.govinfo.gov/content/pkg/FR-2024-05-

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60.4 Negotiation Process (and Improvements to the Patient-focused Engagement Process)

The Alliance appreciates and acknowledges the proposed effort that CMS is making to improve the format of the listening sessions and the overall patient engagement process. In the first round of negotiation, the listening sessions and patient engagement processes fell short of expectations for participants and, we suspect, did not produce highly useful information for CMS. There are three overarching reasons for this: 1) The format of the listening sessions and requested written comments from beneficiaries, physicians, and manufacturers were intimidating and unapproachable for broad audiences; 2) CMS did not clearly communicate the purpose or importance of participating in the listening sessions, including what the agency hoped to learn during the sessions; and 3) the listening sessions were a one-way conversation that did not allow for discussion, or any acknowledgement by participating CMS staff that they were "listening." Below, we outline broad principles for improving this process. The Alliance also recommends that CMS consider the National Health Council's report, "Amplifying the Patient Voice: Roundtable Recommendations on CMS Patient Engagement"4 and the Innovation and Value Initiative's report, "Ensuring Equity in Implementation of IRA Drug Price Negotiations"⁵ that outline recommendations, including contributions from the Alliance and the wider patient advocacy community.

1. Clear Communication of Purpose and Meaningful Incorporation of Findings: There are significant opportunities for CMS to improve communications regarding the purpose and the importance of patient participation in these sessions. CMS should explicitly articulate the goals of the sessions and what the Agency hopes to gain from them, as well as what type of data or information on the patient experience might be useful. For example, CMS may note that the goal of the sessions to understand which endpoints are most significant to patients and how these could influence pricing methodology.

It is crucial to avoid assuming that beneficiaries inherently understand the value or purpose of their participation. CMS should provide comprehensive information on what is expected from participants, the type of information sought, and how the data coming out of that will be used in the negotiation process. Clear, detailed explanations will encourage more informed and willing participation.

⁴ National Health Council. "Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement. March 2024. https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

⁵ Innovation and Value Initiative. Policy Symposium: Ensuring Equity in Implementation of IRA Drug Price Negotiations. Dec 2023. https://thevalueinitiative.org/wp-content/uploads/2024/04/2023-IRA-Policy-Symposium-Proceedings-Report_FINAL.pdf

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CMS should use the data (both empirical and anecdotal) collected from the listening sessions into the setting of the MFP, and there should be greater transparency into how patient perspectives are being assessed. In addition to clinical factors, a drug's value should reflect the broad array of benefits important to patients, caregivers, and society. This means not only soliciting patient and provider input in a systematic way, but also establishing a process for this input to be quantified when setting an MFP.

- 2. Inclusivity and Representation: CMS should ensure diverse representation of patients during patient engagement sessions. It is essential to identify and reach out to groups that were underrepresented or absent in initial sessions. Specifically, CMS should coordinate with the Office of Minority Health, as well as organizations involved in outreach to underserved communities of color and rural communities to enhance participation from these demographics.
- 3. Adequate and Transparent Time Allocation: The current format, which allots only three minutes per speaker, is insufficient for patients and advocates to thoroughly discuss important outcomes and provide supporting data. Extending the time allocated for each participant will allow for more meaningful contributions. If CMS carries forward last year's format, CMS should consider adopting a visible countdown timer during sessions, similar to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices public meetings. This transparency would allow both speakers and listeners to monitor their progress.
- 4. **Accommodation for Disabilities:** During the sessions, CMS must ensure appropriate accommodations for individuals with disabilities. Participants should have the support they need to ensure they can participate meaningfully in the process, including additional speaking time for those who have disabilities that impact their ability to communicate. CMS must adhere to basic principles of patient engagement by providing necessary accommodations for all participants.
- 5. **Improved Notification and Timing:** The timing and method of notifying selected speakers also need improvement. Last year, the agency extended the deadline for sign up, but began selecting and notifying (on October 13th, 2023) participants before the extended deadline had lapsed (on October 15th, 2023). Further, selected participants were emailed on October 13th and told they needed to complete all relevant forms and submit to CMS by October 17th only four days, inclusive of weekend days, following receipt of the notification message.

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CMS should include a more generous notification and response period to ensure participants have ample time to prepare regardless of format. Further, if the agency hosts hybrid or in-person opportunities, reasonable lead time should be provided to allow participants to make cost-effective travel arrangements.

- 6. **Fair Disclosure Standards:** In the previous round, CMS required groups that receive funding from pharmaceutical companies regardless of amount to submit a disclosure in their request to participate in the listening session. However, this question singles out funding from one sector while ignoring the financial interests of other stakeholders (such as insurers, PBMs, or funders such as Arnold Ventures) that may have financial or ideological incentives to participate in the stakeholder process. We encourage CMS to either eliminate this question or broaden it to provide transparency regarding financial support of participating groups.
- 7. **Handling HIPAA Concerns:** CMS should address HIPAA concerns more flexibly. For instance, at least one participant from an advocacy organization was unable to discuss their caregiving experience without written power of attorney for a deceased family member. CMS should streamline processes to allow meaningful discussions without imposing excessive bureaucratic requirements.

CMS has asked for specific feedback on the potential discussion format and information administration proposals in the guidance. We recommend that CMS implement discussion-based formats for future patient-focused engagement sessions. These formats are significantly more welcoming to participants, as they allow for informal exchanges rather than requiring specific, prepared remarks. They also allow participants to answer questions and gain some understanding of how their contributions are being considered by the Agency.

During the previous listening sessions, the livestreamed format has also been noted as a barrier to patient and patient advocacy group participation. To balance the need for privacy and transparency, CMS should instead produce anonymized summaries to be posted publicly after the session. This approach, following Chatham House Rules, ensures that participants can speak freely without fear of attribution, encouraging more candid and valuable feedback. CMS should further consider a mix of hybrid and in-person meetings to encourage more widespread participation and enable a more conversational tenor where possible. As a supplement to hybrid and in-person meetings for those unable to participate at the scheduled time, CMS should offer alternative options to provide testimony. This flexibility would broaden participation and capture diverse perspectives that might otherwise be missed.

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Sessions should also be organized based on condition or therapeutic area, rather than by a specific drug. Organizing sessions around a specific therapeutic puts participants in the position of "defending" or "attacking" a certain brand of drug, as opposed to speaking more broadly about the landscape of treatments available and relevant patient-centered endpoints. It is often preferable to speak about clinical need, therapeutic alternatives, and relevant data holistically for relevant drugs, rather than either focusing only on a single drug or, alternatively, repeating the same information across multiple sessions. This will allow the Agency to collect more comprehensive feedback and have a clearer picture of patient experiences across different treatments.

CMS can continue to improve patient engagement by adopting best practices from organizations like the Food and Drug Administration and the Patient-Centered Outcomes Research Institute. These organizations have developed effective two-way discussion formats, often incorporating both in-person and virtual participation options. CMS could also look to international examples, such as the European Medicines Agency, for innovative patient engagement strategies. Further, the National Health Council has developed a number of tools to advance patient engagement and experience mapping. CMS has the chance to lead by example as more research and payer groups work to include the patient perspective in their models and assessments.

110. Formulary Inclusion of Selected Drugs and Resulting Incentives for Increased Abuse of Utilization Management Techniques

A recent report from the Government Accountability Office (GAO) found that, "Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively highergross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates." As a result, plans are at risk of losing significant rebate revenue when CMS sets a maximum fair price (MFP) for the drugs selected for negotiation. At the same time, plans are facing a significant increase in financial liability in the catastrophic phase of the benefit as a result of the Part D redesign, and constraints on premium growth through 2029. All of these factors will drastically increase incentives for plans to find levers by which to control their growing costs, including by narrowing formularies, adopting more rigorous utilization management strategies like prior authorization or step therapy, or promoting drugs other than those CMS has selected for negotiation. As a result, beneficiaries face a growing risk of

⁶ National Health Council. Capturing and Including the Patient Voice. https://nationalhealthcouncil.org/issue/patient-engagement/

⁷ Government Accountability Office. "Medicare Part D: CMS Should Monitor Effects of Rebates on Drug Coverage and Spending." 19 Sep 2023. https://www.gao.gov/assets/gao-23-107056.pdf

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burdensome or clinically inappropriate utilization management requirements, potential treatment delays, or loss of coverage altogether.

We support CMS's acknowledgement of these factors and stated concern that sponsors may be "incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers ... or by applying utilization management that is not based on medical appropriateness."8 We also believe that the draft guidance's reiteration of existing rules regarding formulary placement and tiering, as well as noting specific behaviors related to the placement of drugs selected for negotiation, is a good first step.9

However, given the high stakes for beneficiaries, the agency should go further. Increased application of UM - particularly when not clinically appropriate - puts patients at risk of delayed care and life-threatening adverse outcomes. For example, step therapy protocols require beneficiaries to take (often a series of) less expensive and potentially less efficacious medications first. In this case, beneficiaries must fail to show the desired clinical improvement before becoming eligible for coverage for the medication their physician or medical provider initially prescribed.

Further, many beneficiaries may have selected their current plan because it resulted in the lowest out-of-pocket (OOP) cost burden. 10 However, given the new OOP cap on beneficiary costs in Part D, changes to plans' benefit parameters may result in a different plan having lower expected OOP costs. As a result, more beneficiaries are expected to switch plans in 2025 than in a typical year. However, when beneficiaries switch plans, they may be required to go through their new plan's UM structure (or, to have the process knowledge and capability to file for an exception with their new plan) to maintain continued access to drugs on their care plan. This is particularly problematic with step therapy, where a beneficiary may be required to stop their current medication and go back to take a medicine they have previously taken but that has not worked. These scenarios are likely to be seen in the real-world, given the increased "churn" in MA plan enrollment and projected expansion in UM protocols following from plans' increased liability in the catastrophic phase of the benefit.

⁸ 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. Sec. 110. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-quidance-ipay-2027-and-manufacturereffectuation-mfp-2026-2027.pdf

⁹ Ibid.

¹⁰ Gretchen Jacobson, Faith Leonard, Elizabeth Sciupac, and Robyn Rapoport. "What Do Medicare Beneficiaries Value About Their Coverage?" 22 Feb 2024. https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicarebeneficiaries-value-about-their-coverage

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As mentioned above, CMS has recognized the importance of these issues but has thus far declined to take important steps to strengthen formulary standards, increase transparency, and strengthen oversight. While CMS asserts that the agency "does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS's revised guidance for ... 2026 are warranted," we disagree. The agency should not wait until harmful behavior is observed – especially when the impact on beneficiaries would not be evident in data patterns until significantly later – in order to take action. Post hoc changes once harms are already being experienced by beneficiaries are not appropriate, given that interruptions or delays in access can, in some cases place beneficiaries at risk of delayed care that can result in irrevocable loss of function or adverse outcomes.

We encourage CMS to take the following actions (as proposed in a report developed by Manatt, with support from the Alliance, and released on June 26, 2024) to protect beneficiaries, all of which the agency should be able to do with existing regulatory authority. The recommendations¹¹ from Manatt include:

1. Require that drugs selected for negotiation—for which CMS has established a maximum fair price—be given preferred formulary status, without utilization management. Current CMS rules only encourage placement of drugs selected for negotiation on preferred tiers with limited utilization management, by requiring plans to submit a clinical justification if they attempt otherwise. However, this provides no guarantees, and it would have CMS resource implications for reviewing each submitted justification. Moreover, CMS's guidance on reviewing clinical justifications is vague. Instead, CMS could adopt a blanket rule protecting drugs selected for negotiation. This could be supported by CMS's authority to disapprove plan designs likely to discourage enrollment. A plan tiering design that steers beneficiaries away from drugs selected for negotiation and towards drugs not selected with higher out-of-pocket costs to the beneficiary is likely to discourage enrollment of beneficiaries who need a particular drug that has been selected for negotiation. CMS could also justify this by setting reasonable minimum standards for plans.

CMS could also give additional guidance on the clinical justifications it will require for non-preferred treatment or utilization management of drugs selected for negotiation. This guidance could address more directly what a might constitute a valid justification.

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¹¹ Manatt Health. "Patient Impact of the Inflation Reduction Act Administrative Options to Address Changed Incentives for Formulary and Utilization Management." June 2024. https://www.manatt.com/Manatt/media/Documents/Articles/AAR-Patient-Impact-of-the-IRA_2024-06_d.pdf

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2. Adopt a public "watchlist" for specific adverse formulary decisions that CMS will not approve, to keep PDP sponsors from excessive narrowing of formularies.

When CMS disapproves a formulary design or utilization management practice, it could do more than simply require the sponsor to correct it. Instead, CMS could publicly announce to all sponsors that it has identified that specific practice as an issue, and that it will be on the lookout for it going forward. This could create clarity for plans and discourage the submission of similar plan designs. It could also give CMS an opportunity to demonstrate that the agency is being proactive in addressing noncompliance with formulary requirements. PDP sponsors who repeatedly submit formularies that require correction could be required to implement a corrective action plan to better consider their formularies before submission.

3. Commit additional resources to formulary reviews so as to identify access issues before such issues can harm beneficiaries.

The importance of protecting beneficiaries through the first few years of IRA's implementation suggest CMS should devote additional resources specifically to formulary reviews and PDP sponsor monitoring. The IRA appropriates \$341 million to CMS to implement the IRA's Part D improvements. It would be prudent to devote some of those funds to expand the teams and tools used for the ordinary annual formulary review process and Part D plan monitoring functions.

4. Explicitly and publicly identify more situations where plans must cover more than two drugs per category or class to ensure that formularies provide adequate coverage of drugs commonly used by beneficiaries.

Current CMS policy is that it follows "widely accepted treatment guidelines" and "general best practice" to determine whether a formulary has adequate coverage. It also published a list of commonly prescribed drug classes in 2010 for use in formulary reviews. This guidance is vague and out of date. Instead, CMS could publish more detailed lists of key areas where it demands adequate coverage on formularies, including specific minimum numbers and types of medications.

5. Improve plan transparency so beneficiaries can more easily see when drugs have utilization management restrictions.

Beneficiaries shopping for coverage may struggle to easily identify when a plan they are considering has a utilization management restriction for a drug they take. Likewise, they

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may not know to look and see if a plan disfavors drugs selected for negotiation. CMS could adopt rules and improve transparency of this information by including it prominently in the Medicare Plan Finder and make specific utilization management policies easily searchable and accessible. Likewise, CMS could place a flag in the Plan Finder on plans that disfavor drugs selected for negotiation, to alert beneficiaries in advance.

6. Enforce minimum payment rates to pharmacies, to prevent sponsors from diverting patients away from community pharmacies.

CMS could ensure broad access to covered Part D drugs at beneficiaries' chosen pharmacy by requiring that PDP sponsors pay at least the pharmacy's acquisition cost for covered drugs. While CMS ordinarily does not "interfere" in the negotiations between plans and pharmacies, this could be construed as falling within CMS's authority to set "reasonable and relevant" reimbursement terms plans must meet to satisfy the "any willing pharmacy" rule.

7. Actively monitor appeals, grievances and exception requests filed by beneficiaries with their plans, to have near real-time view of access issues.

CMS could closely monitor rates of beneficiary appeals of coverage denials, complaints to plans about coverage and exception requests for coverage of drugs not on formulary or for preferred status of a non-preferred drug. Upticks in these processes could be leading indicators of specific problems on specific plan formularies that CMS could act on quickly. CMS currently collects this data on a quarterly basis, and perhaps not in sufficient detail to identify specific drug products or policies that trigger additional appeals. By increasing the pace and detail of this collection, CMS could improve its visibility and act more quickly. Additional regular audits of plans would demonstrate situations where plans are inadequately processing and reviewing appeals and exceptions. Publication of this data and CMS's enforcement activity could demonstrate that the agency is acting proactively.

8. Improve appeals and grievance processes, to reduce the burden of challenging a plan's coverage decision.

CMS might also consider taking steps to improve the efficiency of the appeals process to relieve patients and providers of the burden of filing an appeal or a formulary or tiering exception request. These processes are the best immediate mechanism available to beneficiaries facing challenges with coverage or authorizations, and having

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them run smoothly is an important protection for 2025 and beyond. For example, CMS could consider requirements for seamless electronic prior authorization, appeals and exception requests. CMS could also ensure that beneficiaries are aware of these processes through better communication and education on rights to appeal or request an exception. Finally, CMS could make exception requests easier to obtain, such as by adopting a presumption in favor of granting an exception. This would support a reduction of administrative burden, as data has shown that millions of prior authorization requests are submitted annually, with most appeals of prior authorization denials being overturned.

9. Adopt new actuarial equivalence tests to more accurately and quantitatively track whether plan sponsors are offering sufficient coverage of drugs selected for negotiation.

To protect beneficiaries in 2025, CMS could improve the sensitivity of its actuarial equivalence test to protect against adverse formulary tiering of drugs selected for negotiation. Beginning in 2026, CMS could separately test the actuarial equivalence of out-of-pocket costs of drugs selected for negotiation to ensure that sponsors are actually offering an actuarily equivalent benefit for these drugs. In so doing, CMS will likely prevent PDP sponsors from quietly inflating the out-of-pocket costs for drugs selected for negotiation through inferior formulary tiers.

Conclusion

Thank you for the opportunity to provide input and comment on the draft guidance. The Alliance remains hopeful that CMS will put patient care and experience at the forefront of the negotiation process. Should you have any questions, please contact Adina Lasser, Public Policy Manager, at alasser@agingresearch.org.

Sincerely,

Michael Ward

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Vice President of Public Policy and Government Relations

Adina Lasser

Public Policy Manager

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