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Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted by email to IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Director Seshamani:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the above captioned guidance (the "Guidance") setting forth CMS' proposed policies for implementing the Medicare Drug Price Negotiation Program (Negotiation Program) for initial price applicability year 2026.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Our comments are addressed below in the order in which they appear in the Guidance.

Section 30.3.1

The manufacturer of a biosimilar biological product (Biosimilar) may request, prior to the selected drug publication date, a delay in the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar on the selected drug list. AMCP urges CMS to consider how to mitigate potential unintended consequences such as possible barriers to entry for new biosimilars and market forces that may exert upward pressure on prices.

Section 40.4 – Providing Access to the MFP.

In the guidance, CMS proposes to define "providing access to the MFP" to mean that the amount paid by the dispensing entity for the selected drug is no greater than the maximum fair price (MFP). To accomplish this, CMS proposes to require that the entity that holds the New

Drug Application(s) or Biologics License Application(s) for the selected drug (Primary Manufacturer) provide access to the MFP to dispensers (including pharmacies) in one of two ways: (1) by ensuring the price paid by the dispensing entity is no greater than MFP; or (2) by providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. CMS thus intends to allow access to MFP by dispensers either at the point-of-sale or through the provision of retrospective reimbursement for the difference. Primary Manufacturers would be required to ensure that dispensers are reimbursed the difference between their acquisition cost and the MFP within 14 days.

AMCP believes it will be critical for dispensers, including pharmacies, to have access to MFP pricing at the point-of-sale. Existing supply chains do not generally contemplate payment directly from the manufacturer to the dispensing entity, nor are wholesalers and specialty distributors (who supply drugs to pharmacies) under any obligation to comply with the requirements to offer MFP. Fortunately, there is strong precedent and a clear model for facilitating manufacturer price concessions at the point-of-sale, already built into the existing Medicare Part D program. Under the Coverage Gap Discount Program (CGDP), CMS utilizes a third-party administrator (TPA) to aggregate Part D data, distribute invoices to manufacturers, and reimburse Part D plans for advancing access to the manufacturer discount at the point-of-sale. This existing framework for the CGDP (which CMS has indicated will be largely carried over with the transition to the new Manufacturer Discount Program (MDP) in January 2025) is the most effective approach to facilitate access to the MFP at the point-of-sale, and would fulfill the agency's policy goal of ensuring that stakeholders receive the full benefit of the MFP at the time of dispensing an MFP-eligible drug.

AMCP encourages CMS to explicitly recognize the roles of Part D plan sponsors and pharmacy benefit managers (PBMs) in being able to facilitate access to MFP prices at the point-of-sale through the existing CGDP framework or a framework modeled on this program.

Section 50.1. Manufacturer-Specific Data.

Section 1194(e) of the IRA directs CMS, for purposes of negotiating the MFP of a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offer. These factors are required to be reported by the Primary Manufacturer and include research and development (R&D) costs; current unit costs of production and distribution; prior Federal financial support for novel therapeutic discovery and development; data on pending and approved patent applications; exclusivities recognized by the FDA and FDA applications and approvals; and market data and revenue and sales volume data in the United States. As described in Appendix C of the Guidance, CMS is adopting a number of definitions to guide its data collection efforts. On March 21, 2023, CMS announced in the Federal Register an Information Collection Request (ICR) Form, as required by the Paperwork Reduction Act (PRA), for Negotiation Data Elements under Sections 11001 and 11002 of the IRA. AMCP intends to separately comment on this ICR request.

Overall, AMCP believes the definitions in Appendix C are comprehensive and clear but that some definitions may need to be fine-tuned over time as experience with the program brings additional context. For example, the definition of "global, total lifetime net revenue for the selected drug" may be more of an administrative lift than necessary if subtracting the "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price

concessions or similar benefits" turns out not to be particularly impactful against overall global R&D costs and global revenue.

Section 50.2. Evidence About Therapeutic Alternatives for the Selected Drug.

The IRA requires CMS to consider "evidence about therapeutic alternatives" for purposes of negotiating an MFP for the selected drug. The factors on therapeutic alternatives CMS must consider include the extent to which the selected drug represents a therapeutic advance and the extent to which the selected drug and the therapeutic alternatives address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy. CMS must also consider the FDA-approved prescribing information for the selected drug and therapeutic alternatives, and evidence on the comparative effectiveness of the selected drug and its therapeutic alternatives.

AMCP's members are at the forefront of evaluating therapeutic alternatives through our role on Pharmacy & Therapeutic Committee where we design value-based, patient-focused formularies built around scientific evidence. This collective experience in value-based formulary design leads us to support CMS' reliance on therapeutic alternatives as an important factor for negotiating an MFP for a selected drug while urging caution about the potential for unexpected consequences. AMCP urges caution that the comparison with the therapeutic alternative may exert unanticipated market pressures, potentially increasing the comparator's price. AMCP also believes that CMS should consider safety and efficacy of the selected drug versus the therapeutic alternative.

AMCP supports CMS' approach to aligning the value of selected drugs with meaningful therapeutic alternatives. In the guidance, CMS states that it intends to consider evidence about therapeutic alternatives submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties. AMCP appreciates an approach that relies on public feedback and stakeholder solicitations to arrive at appropriate therapeutic alternatives, given the complexities involved in evaluating clinical evidence and placing drugs on formularies. Therapeutic alternatives can serve as a useful benchmark and guide the decision-making process, helping to meet medical needs and assuring clinical effectiveness. CMS' robust approach to assessing therapeutic alternatives, including considering a variety of patient-centered factors, supports value for patients.

Section 60.3. Methodology for Developing an Initial Offer.

In developing an initial offer, CMS intends to identify therapeutic alternatives, if any, for the selected drug; use the Part D net price for the therapeutic alternatives to determine a starting point for developing an initial offer; evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternatives) for the purposes of adjusting the starting point using the negotiation factors, resulting in the preliminary price; and further adjust the preliminary price by the negotiation factors to determine the initial offer price.

AMCP supports CMS' approach to relying on the net price of therapeutic alternatives as the starting point for negotiating for the selected drug. AMCP agrees with CMS' plan to use the net prices from Part D as this is a more accurate reflection of revenue than the listed price. This approach mirrors the approach used by many payers when developing formularies, including an assessment of the value of the drug, performed after the clinical evaluation, by evaluating the net cost, market share, and drug utilization trends of clinically similar medications.

As CMS continues to develop the Negotiation Program, AMCP urges the agency to ensure that there are no unintended consequences that could undermine existing market-based negotiations. While CMS intends to address the renegotiation process in greater detail in future guidance, it is important to note that one of the limited circumstances in which the statute allows for renegotiation is for a "material change" to the manufacturer-specific negotiation factors, which CMS *is* proposing to define in this Guidance. In particular, CMS is proposing in Appendix C to define "market data and revenue and sales volume data" to include the average net unit price of the selected drug for Part D plan sponsors. This raises the concern that a manufacturer negotiating discounts or rebates in excess of the MFP could be risking the prospect of renegotiation, unless CMS clarifies in future guidance that such negotiations *will not* suffice to qualify as a "material change" to the manufacturer-specific negotiation factor that would require a selected drug to undergo renegotiation. In the absence of such clarity, AMCP is concerned that market-based negotiations will be hampered, essentially resulting in the MFP becoming a ceiling for any future negotiations.

Section 70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect.

Under the IRA a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.

Biosimilar and generic competition are critical to lowering the overall cost of therapies and enhancing formulary competition. As a result, CMS should take all steps necessary to remove impediments to market-based negotiations to ensure that "robust and meaningful" competition from generic or biosimilar entrants is encouraged. In particular, expeditious removal of a selected drug when removal criteria are met will be essential to allow Plan D sponsors and PBMs to fulfill their role of promoting substitution of generics and biosimilars as lowest net cost products, where applicable. At a time when health care expenditures are escalating at alarming rates, greater access to safe and effective biosimilars and generics can aid in reducing prescription drug expenditures for patients and payers.

Section 110. Part D Formulary Inclusion of Selected Drugs.

As noted in the Guidance, CMS intends to require Medicare Part D plans to include in their Part D formularies "each covered Part D drug that is a selected drug" during 2026 and all subsequent years for which the MFP of the selected drug is in effect. While AMCP has not provided comment on Section 30 of this Guidance (as the agency noted it is not open for comment), it is important to note that the proposed broad interpretation of qualifying single source drugs (QSSD) raises concerns about formulary inclusion of selected drugs. Most notably, AMCP notes that CMS' broad approach to defining QSSDs may lead to an increased number of unique marketed products subject to MFP each year. QSSD is defined to include all dosage forms and strengths of the drug with the same active moiety, meaning potentially dozens of drugs, including multiple NDAs, would fall under the same QSSD definition. We are particularly concerned about drugs with the same active ingredient but different modes of administration. There may be substantial cost variation among different modes of

administration. There is a risk that the MFP could be set too low, causing potential issues for patient access. CMS should also consider what could happen if the drug's dosage forms overlap between Part B (for example, infused dose form) versus Part D (oral dose form). It is therefore critical that CMS clarify that the agency will not require formularies to include every dose form and strength of the QSSD, including new formulations. While such an interpretation is clearly not supported by the statute and would fundamentally undermine value-based formulary design, clarity on this issue is critical to avoid disrupting formulary negotiations.

An approach that requires formulary coverage of all dosage forms and strength of the QSSD, including new formulations, is out of step with current practice and would harm the market-based negotiations that currently underly the Part D program. Current practice involves evaluation of the indications and differences in safety, efficacy, and cost. If there are differences based upon formulation, then step requirements or medical justification are often considered for a specific dosage form. There can often be significant cost differences between a tablet or capsule formulation, an injectable, and an oral solution for any given product. There might also be reasons (e.g., swallowing disorders, G- or J- tubes, advanced conditions that impact swallowing) that justify the specialized or more costly dosage form, but these could be addressed by medical necessity review. AMCP recommends that plans be required to cover at least one dosage form, with an option for members and/or providers to request an alternative medically necessary dosage form. This would allow health plans to cover medically necessary dosage forms without the potential burden and increased costs of covering all dosage forms regardless of medical necessity.

Finally, AMCP encourages CMS to provide clarity that the formulary inclusion requirement does not otherwise disrupt existing formulary management tools, including value-based tools such as utilization management (UM) that are used to ensure that drugs are provided in the safest and most cost-efficient manner. CMS should continue to allow Part D plans the flexibility to implement UM edits on selected drugs to ensure safety and appropriate utilization. The initial guidance notes that the negotiated drugs must be on formularies but does not require a specific tier. AMCP supports this flexibility for plans when building their formularies.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

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