



April 14, 2023

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Submitted electronically 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 Dr. Seshamani:

On behalf of our nearly 38 million members and all older Americans nationwide, AARP appreciates the opportunity to comment on the March 15, 2023, memorandum of proposed initial guidance pertaining to the implementation of the Medicare Drug Price Negotiation Program. AARP strongly supported the Medicare Drug Price Negotiation Program (hereinafter “Program”) and the other prescription drug-related policies contained in the Inflation Reduction Act of 2022 that will help address high prescription drug prices and costs. It is not fair or right to ask patients and taxpayers to continue paying for prescription drugs that have been priced based on what the market will bear. Successful implementation of the new federal law will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price they can afford. It will also generate billions in savings for the Medicare program.

AARP commends CMS for soliciting input from the public on this guidance and appreciates its efforts to ensure that patients, caregivers, and health care providers have a voice in the negotiation process. AARP strongly believes that the needs of Medicare beneficiaries should remain paramount as the agency implements the Negotiation Program. To realize the savings that were intended, we encourage CMS to ensure that the negotiation process achieves the lowest possible maximum fair price (MFP) for each selected drug. It is also important for the agency to provide as much transparency as possible to help ensure that the public has confidence that MFPs are in fact fair and appropriate. CMS should place a high priority on conducting robust outreach and education for Medicare beneficiaries and health care providers to ensure that they are aware of the MFPs for selected drugs. These efforts should include clear, consumer-friendly reporting and appeals processes for when an MFP is not provided as required under the law.

AARP also strongly supports the collection and consideration of appropriate clinical evidence, including non-discriminatory drug value assessments, to inform CMS’ evaluations of selected drugs. We also support efforts to help ensure program integrity and reduce opportunities for drug companies to game the system.

While the statute that created the Program is broadly prescriptive, the agency is tasked with developing many specific details for the operation of the Program in a number of important areas. Below we offer more specific comments in response to the initial guidance.

Identification of Qualifying Single Source Drugs and Selected Drugs

AARP recognizes that section 30 of the initial guidance is considered final and not subject to comment, but nonetheless expresses its strong support for the agency's approach to establishing the date of approval or licensure that will determine when a drug is eligible for the negotiation process. By design, virtually all drug companies will have already made billions of dollars from selected drugs prior to the start of the negotiation process. Waiting 9 or 13 years, respectively, before an MFP for a traditional or biologic drug becomes available is already a very long period of time for beneficiaries and Medicare to be paying prices based on what the market will bear. Drug companies should not be given the opportunity to extend this period for longer.

AARP also supports CMS' approach to temporarily delay the selection of certain brand name biologic drugs for negotiation to protect against potential gaming of the selection process by drug companies. More specifically, AARP applauds CMS' approach that will assess whether there is a high likelihood that a competing biosimilar will enter the market in the two years after a brand name biologic drug becomes otherwise eligible for negotiation, which we believe will help curtail potential gaming of the system. AARP also appreciates that brand name biologic drug companies that enter into agreements with biosimilar drug companies that require or incentivize them to submit a delay request to CMS or restricts the quantity of the biosimilar that may be sold will not be able to benefit from this exemption. Such "pay for delay" gaming is well-known for its harmful impact on competition and helping to artificially maintain high prescription drug prices.

Supporting and Encouraging Further Transparency

AARP supports and strongly encourages transparency to the greatest extent possible in all aspects of the Program and especially throughout the negotiation process. While the statute limits how CMS can use or disclose propriety information, the statute nonetheless directs the agency to identify what information is in fact proprietary. AARP encourages the agency to consider, within the confines of the law, what is in the best interest of the Program and the public when determining which information is proprietary and to favor making relevant information publicly available whenever possible. This is especially important when the agency posts the MFP negotiated for a selected drug and its justification, where a high level of transparency will help instill confidence that the MFP represents the lowest price that the agency can reasonably obtain.

Negotiation Factors Regarding Therapeutic Alternatives and Consideration of Evidence from Any Interested Party

AARP supports CMS' decision to allow any interested party to submit data and evidence to CMS about therapeutic alternatives to drugs selected for negotiation. AARP agrees that

information from members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties, can play an important role in informing the agency's negotiating position. However, AARP is also extremely concerned that the amount of information that is submitted could be overwhelming and strongly encourages CMS to develop guardrails, potentially informed by best practices used by other health authorities, to help ensure that such input is meaningful and useful to the process.

AARP supports CMS' proposal to identify each FDA-approved indication for selected drugs and to identify therapeutic alternative(s) for each indication of the selected drug. We also agree that indications for therapeutic alternative(s) should include both FDA-approved indications *and* off-label uses that are supported by appropriate clinical evidence. In addition, AARP strongly supports CMS' decision to consider research on real-world evidence in Medicare-aged populations. AARP is aware that many prescription drugs are not tested under real-world conditions prior to FDA approval and appreciates the potential usefulness of this data in the negotiation process, and notes that CMS' interest could help encourage more drug companies to engage in such research.

AARP recognizes and supports the statutory prohibition against using evidence from comparative clinical effectiveness research that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. However, AARP believes that there are health measures that do not violate this prohibition and that non-discriminatory drug value assessments are an extremely valuable source of information, and strongly supports using as much of such research as possible in the negotiation process. AARP also supports CMS' intent to consider studies that clearly separate prohibited evidence from other evidence that is relevant to the negotiation process.

AARP broadly supports the definitions included in Appendix C of the guidance, as such terms are applied for purposes of the negotiation process.

Developing Maximum Fair Price

AARP supports the proposed starting points for the initial offer for the MFP, including using the Medicare Part D net price and/or Average Sales Price (ASP) of therapeutic alternative(s) (or, in the case of multiple therapeutic alternatives, the range of net prices or ASPs) as the starting point; and using the Federal Supply Schedule or Big Four Agency price as the starting point if there is no therapeutic alternative or if use of the net price or ASP would result in a starting point higher than the statutory ceiling price. In the case of drugs with multiple therapeutic alternatives, AARP encourages CMS to consider using the lowest net price or ASP of all the alternatives as the starting point for the initial offer to help ensure that the MFP is the lowest price possible. AARP strongly supports adjusting the starting point for the initial offer based on clinical benefit, which will help ensure that the MFP reflects the value of the selected drug to Medicare beneficiaries and subpopulations of interest. AARP appreciates the breadth of evidence that CMS intends to include in this process and urges CMS to consider including non-discriminatory drug value assessments when appropriate and available. AARP also strongly supports the considerations CMS outlined for comparing the effectiveness and clinical benefit between a selected drug and its therapeutic alternatives and believes the considerations to be meaningful comparison points. Specifically, AARP supports CMS' intent to consider health outcomes,

intermediate outcomes that indicate a change in health outcomes, validated surrogate endpoints that predict a relevant health outcome, patient-reported outcomes, and patient experience. We also support CMS' intent to prioritize studies focused on the impact of the selected drug and its therapeutic alternatives on individuals with disabilities, the elderly, individuals who are terminally ill, and other patient populations represented among Medicare beneficiaries. AARP encourages CMS to also prioritize studies with participants from diverse racial and ethnic backgrounds that, as of 2021, make up an estimated 26 percent of the Medicare population.

Additionally, AARP supports the method specified for adjusting the preliminary price based on manufacturer reported data, and believes the method described will encourage an informed and appropriate initial offer amount. Specifically, AARP supports CMS' decision to compare research and development (R&D) costs to the relevant drug company's global, total lifetime net revenue in order to determine whether it has recouped its R&D costs. AARP supports a downward adjustment to be applied to the preliminary price if the unit cost of production and distribution is lower than the preliminary price; if the discovery and development funding was received from Federal sources; if the average commercial net price is lower than the preliminary price; or, if the selected drug has patents and exclusivities that will last for a number of years.

AARP strongly encourages CMS to develop a stringent process for validating manufacturer-submitted data, as it is essential that data used to inform the negotiation process are as accurate and complete as possible.

Finally, AARP appreciates the information that CMS intends to publish on its website regarding MFPs, including an explanation for the final price, and strongly urges CMS to publish as much information as possible. A high level of transparency will help ensure that the public has confidence that MFPs are fair and appropriate.

Consumer Protection, Oversight, and Manufacturer Compliance

AARP supports strong program integrity protections for the Medicare Drug Price Negotiation Program and seeks to ensure that the negotiation process captures as many high-cost drugs as possible. Thus, we are concerned that selected drugs cannot be replaced if they subsequently face generic or biosimilar competition and are removed from the negotiation process. We believe that this requirement has created the potential for gaming of the system and encourage CMS to take such actions as it can, consistent with the statute, to capture as many selected drugs in the negotiation process as possible for each initial price applicability year.

AARP is also concerned with the agency's reliance on a Primary Manufacturer (the holder of the NDA/BLA) to ensure that Secondary Manufacturer(s) (listed as the manufacturer in the NDA/BLA that markets the drug under an agreement with NDA/BLA holder) make the MFP for a selected drug available to MFP eligible individuals. While we are encouraged that the guidance speaks to the issue, AARP urges CMS to regularly monitor whether manufacturers, be they primary or secondary, are fully compliant with their duties under the law and guidance with respect to all duties under the Program. If manufacturers are not fully compliant, then appropriate sanctions should be promptly implemented to foster compliance.

As noted earlier, AARP strongly encourages CMS to develop a simple, straightforward process for beneficiaries and health care providers to report instances when eligible individuals do not

receive the MFP, and to seek reimbursement for any overpayments. The agency should also develop clear, concise educational materials and conduct regular outreach to beneficiaries, health care providers patient advocacy groups, State Health Insurance Assistance Programs (SHIPs), Area Agencies on Aging, and Medicare Part D plan sponsors on the Program generally. CMS should seek feedback from consumer advocates and organizations that work with Medicare beneficiaries about best practices and should also consider more targeted efforts as needed.

Both the statute and the initial guidance require CMS to monitor bona fide marketing to determine whether a drug is a qualifying single source drug. That monitoring is designed to ensure that the presence in the market of a generic drug means that there is robust and meaningful competition in the market. AARP strongly urges CMS to monitor for unusually low market penetration for new generic drugs that does not represent meaningful competition for a high-cost drug that would have otherwise been subject to negotiation. Strong oversight of whether competition is in fact bona fide is one of the pillars of program integrity that will ensure the success of the Program in lowering costs of medicines for the Medicare program and its beneficiaries.

Finally, the civil money penalties (CMPs) that the statute imposes for violations of the Program agreements are essential enforcement mechanisms to help ensure the goals of the Program are realized. For example, it is important for the integrity of the negotiation process that the information submitted to CMS for purposes of those negotiations be both comprehensive and accurate. While the goal is for full and honest disclosure of the requisite information to CMS for the negotiation process, it is important that manufacturers know the financial implications of any failure to do so. AARP encourages the judicious use of CMPs to ensure integrity in the negotiation process.

We thank you for the opportunity to submit comments on the initial guidance for the Program and look forward to its strong implementation. For decades, people in this country have paid the highest prices in the world for prescription drugs – often three times higher than people in other countries. Now is the time to change that. Effective implementation of this Program will represent a major victory for families across the country who are struggling to afford their prescriptions. It will also help encourage and appropriately reward the development of truly innovative products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need.

If you have any questions, please do not hesitate to contact me or Gidget Benitez at gbenitez@aarp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a stylized flourish at the end.

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs