FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare and Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

Re: CMS_FRDOC_0001-3836 Guidance: Inflation Reduction Act Medicare Drug Price Negotiation Program

Dear Administrator Brooks-LaSure,

On behalf of Families USA, I want to thank you for the opportunity to comment on the Medicare Drug Price Negotiation Program Draft Guidance for the Initial Price Applicability Year 2027 and the Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereafter referred to as "draft guidance"). Families USA is a leading national, non-partisan voice for health care consumers, dedicated to the achievement of high quality, affordable health care and improved health for all. Central to realizing that vision is reducing the burden of prescription drug costs on America's families.

The high and rising cost of prescription drugs in the United States is a profound health problem and a significant economic burden on our nation's families, including for people who rely on Medicare for their health coverage. Large drug corporations often seek to maximize their profits by raising the prices of both existing and new prescription drugs to obscene, price gouging levels. As a result, U.S. drug prices are nearly twice as high as prices in other comparable countries, even after rebates.[i] And millions of Medicare beneficiaries, particularly lower-income and Black and Latino beneficiaries, struggle to obtain the prescription medications that they need due to cost.[ii]

Families USA applauds the Biden Administration and the Centers for Medicare and Medicaid Services (CMS) for their continued work in implementing the historic prescription drug pricing reforms authorized by the *Inflation Reduction Act (IRA)*. Consumers across America are eagerly anticipating the announcement of the negotiated prices for the first ten drugs included in the Drug Negotiation Program and the implementation of those prices in 2026. This will undoubtedly lower drug costs for millions of older adults and people with disabilities.

Families USA also commends CMS for continuing to proactively engage with the public, and particularly consumers and those who directly represent their interests, to improve the negotiation process and incorporate early lessons learned before announcing the next 15 drugs for negotiation. We thank CMS for voluntarily providing the public with opportunities to submit feedback regarding implementation of the Medicare Drug Negotiation Program, and are particularly grateful for the opportunity to comment on this draft guidance.

We believe the experiences of the millions of people who rely on Medicare to access affordable prescription drugs must remain the focus of implementation efforts. To that end, this comment letter will provide recommendations across the following areas:

1. Section 60.4: The negotiation process;
2. Section 60.3.2: Developing a starting point for the initial offer; and
3. Section 40.4: Providing access to the MFP for 2026 and 2027.

Section 60.4: The Negotiation Process

The draft guidance describes the proposed negotiation process for the initial price applicability year 2027. Consistent with the year 2026 process, the proposed year 2027 process includes what CMS describes as "patient-focused events to seek verbal input from patients and other interested parties."[iii] CMS further states that it intends to include "patients, beneficiaries, caregivers, and consumer and patient organizations" to share their experiences related to selected drugs.[iv]

Families USA supports CMS in its goal of incorporating consumer experiences into the negotiation process. Incorporating the experiences of patients, their families, and caregivers is vitally important for CMS's understanding of the real-world implications of the prices set by drug companies. In the year 2026 process, CMS conducted listening sessions with various stakeholders for each of the ten drugs chosen. Those listening sessions were designed for participants to speak directly to CMS about how certain conditions impact patient lives and the lives of their caregivers or families, including the accessibility and affordability of the drugs under negotiation and any therapeutic alternatives.[v] However, the listening sessions for the year 2026 negotiation process included many participants who work at or are otherwise affiliated with organizations that receive funding from drug manufacturers.[vi] Many of these speakers failed to disclose their conflict-of-interest at the sessions, as disclosure was *voluntary*.[vii]

In order for CMS to accurately assess the needs and interests of consumers, and for that information to inform the negotiation process in a meaningful way, it is essential that any and all potential conflicts of interest held by those speaking at patient-focused events are clearly disclosed. Without this safeguard, drug manufacturers are incentivized to leverage their patient networks to obscure the true experience of consumers. In many cases, drug manufacturers may actually co-opt consumers' and patients' voices to advocate for the ability to continue abusing the drug supply chain and increasing prices, including through nefarious practices such as false threats of patients losing access to certain medications.[viii]

Ensuring the integrity of the process to collect input on the true consumer experience is paramount. Throughout the negotiation process, drug manufacturers have numerous opportunities to represent the importance of their drug, their financial interests, and their company's goals.[ix] In addition, drug manufacturers have the opportunity to submit data on the costs associated with the research, development, and manufacture of each drug up for negotiation and several opportunities to engage in dialogue with CMS as they participate in negotiations to establish the maximum fair price (MFP).[x] In contrast, patients do not have an additional forum to speak directly to CMS during the negotiation period.[xi] Without knowing whether participants in the listening sessions have conflicts of interest that might impact their feedback, CMS lacks critical information needed to weigh the information shared. Proper evaluation of potential speaker bias is critical for CMS to reach an MFP that is fair for the people who rely on the lifesaving and life sustaining medications being negotiated.

CMS should therefore *require* the disclosure of conflicts of interest for all participants in the patient listening sessions so that they can discern which participants have specific ties to drug manufacturers, and better understand the influences behind the experiences and interests presented in those sessions.

Section 60.3.2: Developing a Starting Point for the Initial Offer

The IRA requires CMS to develop and apply a consistent methodology and process for negotiating with drug manufacturers to arrive at an MFP. It clearly states that CMS must develop a negotiation process that "aims to achieve the lowest maximum fair price for each selected drug."[xii] A vital step in the negotiation process is how CMS arrives at the initial price that it offers to drug manufacturers. The law lists nine factors that CMS is required to "consider" when calculating an initial and final MFP offer. However, the IRA provides no direction for how CMS should prioritize, weight, or define these factors when arriving at a pricing decision.

The proposed guidance outlines the plan to reach the initial MFP offer for the price applicability year 2027. Aside from making small adjustments to consider Coverage Gap Discount Payments (CGDP) and 2026 MFP for therapeutic alternatives, the proposed guidance states CMS will "[use] the same approach that the agency used for initial price applicability year 2026."[xiii]

This means: First, CMS will identify therapeutic alternatives for the selected drug subject to negotiation. As laid out in the guidance, to determine the starting point for the initial MFP offer, CMS will use the lower of either:[xiv]

a. Net Part D Plan Payment and Beneficiary Liability, which reflects the total gross covered drug cost (TGCDC), net of direct and indirect renumeration (DIR), and coverage gap discount program payments, or
b. MFP for initial price applicability year 2026 selected drugs, if applicable.

In other words, CMS will use the Part D Net price or the previously negotiated MFP for a therapeutic alternative in creating a starting point for the initial MFP offer.

Second, based on the prices of those therapeutic alternatives, CMS will adjust the initial price offer based on statutorily defined factors, including but not limited to: therapeutic advance represented by the drug and costs of existing therapeutic alternatives; prescribing info for the drug and therapeutic alternatives; comparative effectiveness of the drug and therapeutic alternative; and unmet medical needs that the drug and therapeutic alternatives address.[xv] These factor adjustments will help CMS to arrive at a "preliminary price."

Third, CMS will adjust the preliminary price based on a number of manufacturer-specific data.

We strongly support CMS adjusting the MFP offer based on comparative effectiveness research, such as patient-reported outcomes and patient experience data as well as manufacturer-specific data (e.g., research and development costs, unit costs of production). However, as noted in our April 2023 comment letter pertaining to the first round of drug negotiation guidance, we continue to be deeply concerned with CMS's approach that anchors the initial price point to Part D net prices of therapeutic alternatives.[xvi] Substantial evidence shows that the drug prices paid by Medicare Part D are significantly inflated compared to the prices paid by other public payers within the U.S., as well as prices paid by other comparable countries.[xvii] For instance, according to the Government Accountability Office (GAO), Part D net prices were at least two to four times higher than publicly available prices in comparable countries in 2020.[xviii] CMS even acknowledges these concerns in their proposed guidance, stating "the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit."[xix]

We are deeply concerned that Part D net prices do not reflect the true value of these medications and relying on them as a fundamental starting point for drug negotiation will undermine the Medicare Drug Negotiation Program and its ability to achieve meaningful cost savings for consumers and families. Additionally, we are deeply concerned that the continued use of Part D net prices to establish CMS's initial price offer to drug companies sets a dangerous precedent for the future of Medicare drug negotiations by preserving the use of inflated drug prices in establishing prices. And that this will ultimately lead to CMS adopting these status quo higher prices as the standard for initiating drug price negotiations. In the long term, this could serve to drive up the cost of prescription drugs, threatening the very intent of the IRA to establish fair and rational prices for prescription drugs for our nation's families.

Based on these concerns, **Families USA strongly encourages CMS to avoid the use of Part D net prices as a starting point for developing an MFP initial offer. Instead, we encourage CMS to employ a cost-effectiveness approach to develop a preliminary price range, which could then be adjusted to arrive at an MFP. Specifically, we recommend CMS establish non-biased cost-effectiveness targets or thresholds that serve as an initial price range for each selected drug, and which could then be adjusted based on comparative effectiveness research, the prices of therapeutic alternatives, and other manufacturer-specific data to arrive at an MFP.**

To calculate these targets, CMS should, in consultation with the HHS Office of the Assistant Secretary for Planning and Evaluation, determine an upper and lower bound cost or price per unit of health gained (as well as cost per condition-specific measure of clinical benefit) that it deems

appropriate.[xx] This should also reflect the opportunity cost of the treatment in relation to the treatment's added net benefits for Medicare patients over time.[xxi] We believe the cost effectiveness approach outlined above guarantees that the MFP calculated by CMS truly reflects the therapeutic value of the drug subject to negotiation and, importantly, avoids relying on prices that are all too often the result of widespread market failures and pharmaceutical industry gaming.[xxii] Further, this approach has the added benefit of providing the strongest financial incentives for drug manufacturers to focus on true therapeutic innovations.

Section 40.4: Providing Access to the MFP for 2026 and 2027

To ensure the IRA and the Medicare Drug Negotiation Program truly result in lower drug prices for people who rely on Medicare for their health care, eligible beneficiaries must have access to the lower negotiated price at point of sale. In the proposed guidance, CMS reiterated it plans to require that the negotiated price of a Part D drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale.[xxiii] **Families USA applauds CMS for maintaining this policy to ensure every consumer and family that relies on Medicare for their health care has access to and benefits from the lower negotiated price for drugs selected for Medicare negotiation.**

CMS is also clear that drug companies themselves are responsible for ensuring that the MFP reaches all those consumers who are eligible for it. **Families USA supports CMS in this position and its work to hold drug companies accountable to the prices that are negotiated and to seniors' and people with disabilities' access to those medications.** At the core of the issue of access is the issue of affordability. Medication is not truly accessible if the people who need it cannot afford to buy it. It is, and should always be, the responsibility of the drug companies to provide their products — people's lifesaving and sustaining prescription medications — at the price that is fairly negotiated.

Conclusion

Families USA greatly appreciates CMS taking this important step in continuing implementation of the Medicare Drug Negotiation Program authorized by the IRA by releasing this proposed negotiation guidance for the price applicability year 2027. This historic health care reform promises to radically reduce the high cost of prescription drugs and help ensure that consumers and families that rely on Medicare for health coverage have access to affordable, live-saving medications. Families USA thanks CMS for the work it has done since the IRA's passage to start lowering drug costs for our nation's seniors and people with disabilities, and we look forward to continuing to work in partnership with CMS on the implementation of this program, as well as other efforts to lower the high cost of prescription drugs

Thank you for taking time to review this comment. Please contact Ben Anderson at banderson@familiesusa.org or Hazel Law at hlaw@familiesusa.org with any questions.

Sincerely,

Sophia Tripoli

Senior Director of Health Policy

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[iii] Centers for Medicare and Medicaid Services. "Draft Guidance on the Medicare Drug Price Negotiation Program, Section 60.4, page 89," 3 May, 2024, https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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[v] "Initial Price Applicability Year 2026 Policy and Public Input," Centers for Medicare and Medicaid Services, (last modified) 3 May, 2024, https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/2026-policy-and-public-input.

[vi] Lim, David. "Pharma-affiliated groups not disclosing ties at Medicare listening sessions," Politico Pro, 2 November 2023, https://subscriber.politicopro.com/article/2023/11/pharma-affiliated-groups-not-disclosing-ties-at-medicare-listening-sessions-00124872.

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[ix] "Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027," Centers for Medicare and Medicaid Services, May 2024, https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf.

[x] "Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027," Centers for Medicare and Medicaid Services, May 2024, https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf.

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[xiii] Centers for Medicare and Medicaid Services. "Draft Guidance on the Medicare Drug Price Negotiation Program, Section 60.3.2, page 82," 3 May, 2024, https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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[xv] Public Law 117-169, Sec. 1194 (e), 16 August, 2022, https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf

[xvi] "Comment letter RE: Medicare Drug Price Negotiation Guidance," Families USA, 14 April, 2023, https://familiesusa.org/wp-content/uploads/2023/04/FUSA-CMS-Negotiation-Guidance-Comment-Letter.pdf.

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[xviii] Government Accountability Office. "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France," GAO-21-282, 28 April, 2021.

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