FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

April 14, 2023

Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via email to Centers of Medicare and Medicaid Services

RE: Medicare Drug Price Negotiation Program Guidance

Dear Administrator Brooks-LaSure,

Families USA (FUSA) 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 people who rely on Medicare for their health coverage. Large drug corporations, in their efforts to maximize profits, too often raise 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 afford the prescription medications that they need due to cost.[ii]

FUSA applauds the Biden Administration and the Centers for Medicare and Medicaid Services (CMS) for taking the first major step in implementing the historic reform of prescription drug pricing in the Medicare program, issuing proposed program guidance for the negotiation process for selected drugs whose negotiated prices would be available beginning in 2026 (i.e., Initial Price Applicability Year 2026). We appreciate the opportunity to comment on this proposed guidance and appreciate all of the work from CMS to facilitate lower drug costs for millions of older adults and people with disabilities. There are aspects of the guidance that we support but chose not to reflect on in this comment in order to prioritize a few key areas of recommendations.

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

1. Soliciting Public Comments Regarding the Implementation of the Medicare Drug Negotiation Program
2. Section 60.3: Methodology for Developing an Initial Offer
3. Section 40.2.1: Confidentiality of Proprietary Information & Section 60.6: Publication of the MFP

4. Section 40.4: Providing Access to the MFP
5. Section 60.3.4: Consideration of Manufacturer-Specific Data & Section 100.2: Violations of the Agreement
6. Section 50.2: Evidence About Therapeutic Alternatives for the Selected Drug

1. Soliciting Public Comments Regarding the Implementation of the Medicare Drug Negotiation Program

Under the Administrative Procedures Act (APA), CMS is required to provide an opportunity for public comment on any proposed rules or regulations as they relate to any new or existing law. However, in the case of the IRA's drug price negotiation provisions, the IRA waived these requirements and directs CMS to implement many of the law's drug negotiation provisions through sub-regulatory "program instruction or other forms of program guidance" for the parts of the process that lead to maximum fair prices that take effect beginning in 2026, 2027, and 2028. Despite the IRA's waiving of APA requirements, CMS has indicated it will voluntarily solicit comments on a number of areas in its Medicare Drug Negotiation Proposed Guidance.

FUSA applauds CMS for voluntarily providing the public opportunities to submit feedback regarding implementation of the Medicare Negotiation Program, including soliciting comments for the majority of its draft guidance on the Medicare Drug Negotiation Program, as it relates to "Initial Price Applicability Year 2026." This is a critical step to ensuring that the needs of families and consumers are prioritized as CMS implements the Medicare Drug Negotiation Program, allowing the public, including consumer and patient advocates, sufficient opportunities to provide input to inform negotiation policy decisions.

2. Section 60.3: Methodology for Developing an Initial Offer

The IRA requires CMS to develop and apply a consistent methodology and process for negotiating with drug manufacturers to arrive at a maximum fair price. It clearly states that CMS must develop a negotiation process that "aims to achieve the lowest maximum fair price for each selected drug."

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 maximum fair price offer. However, the IRA provides no direction for how CMS should prioritize, weight, or define these factors when arriving at a pricing decision.

In the proposed guidance, CMS outlines its plan to calculate an initial maximum fair price offer to drug manufacturers based on a three-step process. First, CMS will identify therapeutic alternatives for the selected drug subject to negotiation and calculate the Part D net price(s) of those therapeutic alternatives.[iii,iv] Second, based on the prices of those therapeutic alternatives, CMS will begin developing an initial price offer, and adjust that offer "relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternatives," to arrive at a "preliminary price." Third, CMS will adjust the preliminary price based on a number of manufacturer-specific data. For example, CMS would lower the price depending on whether federal support was received for drug discovery and development or whether the selected drug has patents or exclusivities that last for a number of years.

We are appreciative of CMS' efforts in proposing a process for developing an initial price offer with limited statutory direction. We are also supportive of CMS' intent to adjust the maximum fair price 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, we are deeply concerned with CMS' proposed approach to anchoring the initial "preliminary price" based off Part D net prices of therapeutic alternatives.** There is substantial evidence that the drug prices paid by Medicare Part D are significantly inflated compared to the prices paid by other public payers within the United States, as well as prices paid by other comparable countries.[v,vi,vii] For instance, according to the Government Accountability Office, Part D net prices were at least two to four times higher than publicly available prices in comparable countries in 2020.[viii] We are 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 Medicare drug negotiation would undermine the Medicare Drug Negotiation Program and the program's ability to achieve meaningful cost savings for consumers and families. CMS acknowledges these concerns in their own proposed guidance, stating that the Part D net prices associated with the "therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit…."[ix]

Based on the concerns above, **FUSA strongly encourages CMS to reassess its approach to developing a maximum fair price offer, avoiding the use of Part D net prices as a starting point.**

Instead, we encourage CMS to employ a cost-effectiveness approach to develop a preliminary price range, which could then be adjusted to arrive at a maximum fair price. Specifically, we recommend CMS establish non-biased (see discussion below at comment # 6) 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 a maximum fair price. 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 and reflective of the opportunity cost of the treatment in relation to the treatment's added net benefits for Medicare patients over time.[x]

We believe the cost effectiveness approach outlined above guarantees that the maximum fair price calculated by CMS truly reflects the therapeutic value of the drug subject to negotiation and, importantly, avoids relying on prices, such as Part D net prices, that are all too often the result of widespread market failures and pharmaceutical industry gaming.[xi] Further, this approach has the added benefit of providing the strongest financial incentives for drug manufacturers to focus on true therapeutic innovations.

3. <u>Section 40.2.1: Confidentiality of Proprietary Information & Section 60.6: Publication of the MFP</u>

The public reporting requirement of the final maximum fair prices and an explanation for how it arrived at each maximum fair price, including which factors were considered is important because it provides the public and other payers of prescription drugs with access to information on the value of select high-priced prescription drugs and what a fair price may be. This information is critical for the public and people who rely on Medicare for their health coverage to understand CMS' justification for arriving at a final maximum fair price for a selected drug, and to increase transparency around the underlying cost and value for the prescription drugs subject to negotiation. Additionally, this level of transparency is essential for other payers to be able to effectively negotiate the prices of prescription drugs with drug

manufacturers and exert downward pressure on the price of prescription drug price across the entire U.S. market. Notably, the IRA affords CMS wide discretion to decide which information used to calculate a maximum fair price is made public or is "proprietary" and not made public.

FUSA is disappointed with CMS' proposal to treat the vast majority of the manufacturer specific data it would receive as proprietary and therefore would not be public. CMS intends to keep the following information non-public, unless already made public through other means, such as: non-Federal average manufacturer price, research and development costs and recoupment, unit costs of production and distribution, pending patent applications, and market data and revenue and sales volume data.

FUSA is also disappointed with CMS' proposal to only provide "high level comments" when disclosing a public justification for how it arrived at a maximum fair price(s) during negotiation. CMS intends to only include high level comments explaining the maximum fair price without sharing any information that it deems as proprietary, such as research and development costs.

There is a strong public interest to ensuring the Medicare Drug Negotiation Program is achieving its statutory mandate of achieving the lowest maximum fair price possible. Without transparency into key data that CMS is using to inform a maximum fair price, the integrity of the Medicare Drug Negotiation Program is at heightened risk for industry gaming or sabotage. Further, making this data publicly available could help to spur competition in the private insurance market and help drive down prices for consumers and families who rely on private, employer sponsored insurance coverage. **FUSA strongly urges CMS to reconsider the extent to which it categorizes certain manufacturer specific data as proprietary and at a minimum make public the following information: non-Federal average manufacturer price, research and development costs and recoupment, and unit costs of production and distribution.**

Further, FUSA urges CMS to implement the IRA's reporting requirement in a way that publicizes as much information as possible. This includes which factors and value frameworks were used to come to their decision regarding a maximum fair price, as well as any information received from drug manufacturers.

4. Section 40.4: Providing Access to the MFP

To ensure the IRA and the Medicare Drug Negotiation Program truly results in lower drug prices for people who rely on Medicare, it is critical that families and consumers have access to the lower negotiated price at the pharmacy counter and at point of sale. In its proposed guidance, CMS has indicated 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." **FUSA applauds CMS for taking this critical step to ensure every consumer and family that relies on Medicare for their health care needs has access to and benefits from the lower negotiated price for drugs that are selected for Medicare negotiation.**

FUSA also applauds CMS for planning to conduct ongoing oversight and monitoring to ensure that every eligible individual, including all Medicare beneficiaries, have access to the lower negotiated prices for selected drugs. Continuous monitoring and oversight of drug manufacturers and pharmacies is critical to ensuring no entity across the prescription drug supply chain, including drug manufacturers, wholesalers, pharmacy benefit managers, or pharmacies, are taking advantage or gaming the Medicare Drug Negotiation to their benefit and to the detriment of consumers and families.

5. Section 60.3.4: Consideration of Manufacturer-Specific Data & Section 100.2: Violations of the Agreement

As CMS begins the drug negotiation process, it will request information from drug manufactures to inform its calculation of maximum fair prices and as part of the negotiation process. According to CMS' proposed guidance, this will include requesting information from drug manufacturers on their research and development costs; current costs of production; data on pending and approved patent applications; market data; sales information; and non-Federal average manufacturer price.

While we applaud CMS for confirming that manufacturers would be subject to civil monetary penalties if manufacturers knowingly provide false information to CMS as part of the Medicare Drug Negotiation Program, **FUSA is deeply concerned that CMS is proposing to rely on the "assumptions and calculations" related to certain manufacturer specific data, such as research and development costs, that are reported to CMS by manufacturers with limited oversight or independent verification.** Drug manufacturers often game government reporting systems to their benefit. For example, it was found that many manufacturers have misclassified their drugs as generics, thus paying significantly less in rebates under the Medicaid Drug Rebate Program, resulting in more than a billion dollars in overcharges.[xii]

FUSA strongly encourages CMS to develop additional guardrails in order to closely scrutinize any data reported by drug manufacturers on their drug sales and related prices. CMS should rely on independent data sources whenever possible and consider contracting with an audit firm or firms for any otherwise unaudited manufacturer data. It is essential that all of the information used to inform the Medicare negotiations are accurate and complete to ensure that CMS has the information it needs to calculate *truly* fair prices.

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

In their effort to consider alternate treatments for selected drugs, CMS is required to not use measures that would evaluate or weight the life of an elderly, disabled, or terminally ill person as any less than another life. This guidance bars CMS from using Quality Adjusted Life Years (QALYs) as a measurement tool. **There are many promising frameworks and methodologies to help assess health care value, and that importantly do not discriminate on the basis of disability, age, or any other protected status; we are supportive of restrictions for the use of QALYs and strongly encourage CMS to identify other measurement tools to assess therapeutic value.**

We want to specifically highlight usage of "Equal Value of Life Years Gained," or EvLYG, which is a metric that measures gains in length of life of a given treatment in a way that ensures that all years of life are valued equally.[xiii] EvLYG is an evaluation tool we support CMS using, as it allows for a treatment's value and quality to be assessed without disproportionately affecting certain populations.

Conclusion

Families USA greatly appreciates CMS for taking this important step to implementing the Medicare Drug Negotiation Program. Authorized by the IRA, this historic health care reform holds the promise of reducing the high cost of prescription drugs and helping ensure that consumers and families that rely on

Medicare for health coverage truly have access to affordable, live-saving medications. Families USA looks forward to continuing to work with CMS on the implementation of this program, as well as other efforts to lower the high cost of prescription drugs.

Thank you for your time in considering these comments. Please contact Aaron Plotke (APlotke@familiesusa.org) and Hazel Law (HLaw@familiesusa.org) with any questions.

Sincerely,

Frederick Isasi

Executive Director
Families USA

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[i] Mulcahy AW, C.; Tebeka, M.; Schwam, D.; Edenfield, N.; Becerra-Ornelas, A. International Prescription Drug Price Comparisons. 2021; https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf. Accessed November 12, 2021.

[ii] Tarazi, W., Finegold, K., Sheingold, S., De Lew, N., and Sommers, BD. Prescription Drug Affordability among Medicare Beneficiaries (Issue Brief No. HP-2022-03). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2022

[iii] According to CMS' proposed guidance, therapeutic alternatives will only include pharmacological treatments (as opposed to non-pharmacological treatments), and only treatments covered by Medicare Part D.

[iv] If no therapeutic alternatives exist or the prices of the therapeutic alternatives exceed the statutory ceiling price, CMS proposes to base the initial starting point price based off the Federal Supply Schedule (FSS) or "Big Four Agency" price. If the FSS or "Big Four Agency" price exceeds the statutory ceiling price, then CMS proposes to use the statutory ceiling as the starting point for the initial price offer.

[v] Government Accountability Office, *Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, GAO-21-111, January 14, 2021.

[vi] Mulcahy AW, C.; Tebeka, M.; Schwam, D.; Edenfield, N.; Becerra-Ornelas, A. International Prescription Drug Price Comparisons. 2021; https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf. Accessed November 12, 2021.

[vii] 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, April 28, 2021.

[viii] Ibid.

[ix] See page 49, CMS, *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.* March, 15, 2023.

[x] This recommendation is based on the Institute for Clinical and Economic Review's *2020-2023 Value Assessment Framework*, January 31, 2020 (Updated February 3, 2022). For more information, see https://icer.org/wp-content/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf.

[xi] Families USA, *Our Broken Drug Pricing and Patent System Diverts Resources Away from Innovation and into Mergers, Patent Gaming and Price Gouging,* August 2021. *https://familiesusa.org/wp-content/uploads/2021/08/RX-2021-209_Innovation-Drug-Pricing-Issue-Brief.pdf*

[xii] Department of Health and Human Services, Office of Inspector General, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates* (OEI-03-17-00100) (HHS OIG, December 2017), https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf

[xiii] ICER, *The QALY: Rewarding the Care that Most Improves Patient's Lives*, December 2018.