FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

August 17, 2026

The Honorable Mehmet Oz, M.D.
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016.

Submitted electronically via regulations.gov

RE: CMS-4215-P: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program

Dear Administrator Oz,

On behalf of Families USA, thank you for the opportunity to comment on the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program proposed rule. As the longtime national nonprofit health consumer advocacy organization, Families USA works to ensure that everyone has access to high quality, affordable health care, including affordable prescription medication, particularly for older adults and people with disabilities who rely on Medicare.

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. U.S. drug prices remain nearly twice as high as prices in other comparable countries, even after rebates.[1] That is why **Families USA strongly supports the Centers for Medicare & Medicaid Services' (CMS') proposal to codify the Medicare Drug Price Negotiation Program into the U.S. Code of Federal Regulations (CFR), including codifying existing policies established under sub-regulatory guidance from the first three years of program implementation.**

The Medicare Drug Price Negotiation Program, as authorized by the Inflation Reduction Act of 2022, is a critical tool to addressing the underlying prices of certain medications and making prescription drugs more affordable and accessible for our nation's older adults and all those who rely on Medicare for their health and health care. By formally codifying the negotiation program policies into the CFR, CMS will ensure the program is fully protected by the force of law under the Administrative Procedures Act, safeguarding the integrity of the negotiation program and its ability to deliver lower drug prices for older adults and people with disabilities.

Families USA provides more detailed comments on several sections of the proposed rule, which we believe will ensure that the future rounds of negotiations continue to be successful in reducing high and unreasonable drug prices in the Medicare program:

- **II. B *Identification of Selected Drugs***
    - **II. B. 1.** *Publication of the Selected Drug List*
    - **II. B. 5. b.** *Calculation of Total Expenditures under Part B*
    - **II. B. 6. a. (1)** *Fixed combination drugs*
    - **II. B. 6. c. (1)** *Orphan Drug Exclusion from Qualifying Single Source Drugs*
- **II. F. 3. *Methodology for Developing the Initial Offer***

II. B. *Identification of Selected Drugs*

II. B. 1. *Publication of the Selected Drug List*

Families USA supports CMS' proposal to continue publishing an extended list of high-expenditure, negotiation-eligible drugs for each round of the negotiation program, but we oppose CMS' proposed cut to that public list from 50 to 30 prescription drugs.[2] While CMS frames this proposal as an effort to improve transparency, the result will be just the opposite.

Under the Inflation Reduction Act, CMS is mandated to select up to fifteen drugs for price negotiation by 2028 and up to 20 drugs by 2029 and every year after that.[3] For the final guidance issued under the Initial Price Applicability Year (IPAY) for 2028, CMS also committed to publishing a list of the top 50 high-expenditure drugs eligible for negotiation. This gave patients, researchers and advocates a clearer view into how CMS ranks drugs by Medicare expenditure, inclusive of the 15 drugs CMS ultimately selected for negotiation under the program in that year.[4] This proposed rule marks a departure from that practice, reducing the public list to only 30 high expenditure drugs and offering far less visibility into the growing number of drugs eligible for negotiation, including both high-spend Medicare Part B and Part D drugs.

We urge CMS to withdraw this provision and retain a more complete and accurate list of the 50 highest expenditure drugs. This negotiation-eligible list is one of the only fully public checkpoints in a process that is otherwise shielded by confidentiality protections around manufacturer data.[5] The longer list helps to ensure that eligible high-spending drugs across Medicare Part B and D are not inadvertently excluded from Medicare drug negotiation, and offers outside experts including researchers, lawmakers and advocates an opportunity to provide additional data and analysis to CMS to strengthen the drug negotiation program and best target other high-spending drugs for inclusion.[6]

Families USA urges CMS to reinstate its original commitment to publish the 50 highest spend drugs eligible for negotiation. This level of transparency is essential for overseeing upcoming changes to the Medicare Drug Price Negotiation Program — including a shift starting in 2028

to identifying negotiation-eligible drugs using both Medicare Part B and Part D expenditure data, and an increase in 2029 to 20 negotiation-eligible drugs per year.

II. B. 5. b *Calculation of Total Expenditures under Part B*

Families USA supports CMS' proposal to codify its method for calculating high-expenditure drugs under Medicare that is inclusive of traditional fee-for-service (FFS) Medicare and Medicare Advantage (MA) expenditures. In the IPAY 2028 final guidance – the first guidance to address how Part B drugs would be incorporated into the negotiation program – CMS finalized a policy to calculate the highest spend Part B drugs by combining FFS part B claims data with MA encounter data, adjusted to reflect what the drug units utilized in MA would have cost under traditional Medicare.[7] CMS now proposes to codify that approach, along with its parallel use of Part D Prescription Drug Event Data, which already captures both FFS and MA spending, to calculate highest expenditure Part D drugs**.** [8]

We strongly support this approach given that Part B claims data *alone* cannot accurately produce the level of expenditure for prescription drugs in the Medicare program. Instead, Part B claims data only reflects spending in traditional FFS Medicare and excludes MA plans entirely.[9] Given that more than half of Medicare beneficiaries are now enrolled in MA,[10] a calculation that ignores MA spending would systemically understate the true cost of any drug administered primarily or substantially to MA enrollees. This distortion in calculation would allow high-expenditure drugs to fall below the threshold used to determine if a drug was eligible for negotiation simply because a large share of its utilization occurs outside of FFS. In order to ensure appropriate price negotiation for the prescription drugs that generate the greatest financial burden on Medicare and its beneficiaries, CMS must codify a method that considers the full cost of a drug across both sides of the Medicare program.

While we support this approach, we also note that the accuracy of this method is only as good as the data underlying it. Because CMS relies on MA encounter data to establish the cost of drugs utilized in the MA program, it is essential for that data to be accurate and complete. Unfortunately, MA encounter data is notoriously incomplete and rife with data inconsistencies relative to FFS claims data.[11] These same data concerns have complicated efforts to strengthen MA payment more broadly, including through risk-adjustment and RADV audits.[12] Without complete and accurate encounter data, the true utilization and cost for any drug is likely to be significantly underestimated, directly affecting whether a drug is eligible for negotiation. **As a result, Families USA recommends CMS pair their proposed codification with 1) concrete steps to improve MA encounter data completeness and accuracy and 2) increased transparency into how CMS validates that data before using it to calculate negotiation eligibility – and do so in a way that does not delay finalizing the codification outlined above.**

II. B. 6. a (1) *Fixed Combination drugs*

Families USA strongly supports CMS' proposed change to the fixed-combination drug policy that would treat certain groupings of fixed-combination drugs and other drugs (combination or non-combination alike) as the same drug product for the purposes of determining eligibility for the Medicare Drug Price Negotiation Program when such drugs share at least one active ingredient and are owned by the same drug company.

Currently, CMS treats fixed-combination drugs (that is, products combining two or more active ingredients that aid in treating the same underlying illness or condition) and other drugs (combination or non-combination drug alike) that contain distinct sets of active ingredients as separate single-source drugs for the purposes of determining negotiation eligibility.[13] In other words, certain drugs or biological products that share overlapping active ingredients, but contain other non-overlapping active ingredients, are treated as separate single source drugs for the purposes of the Medicare Drug Price Negotiation Program.[14] This practice provides drug companies a significant gaming opportunity to engage in a form of "product hopping" by shifting their drug expenditures to a new drug with the same active ingredient but a different formulation or method of delivery to avoid selection for negotiation.[15] Ultimately, this significant loophole undermines the integrity of the Medicare Drug Price Negotiation Program, where companies can regularly keep their high-expenditure drugs below the negotiation threshold by fragmenting spending across technically "different" products.

CMS proposes an important step toward closing this loophole: certain groupings of fixed-combination drugs and other drugs (combination or non-combination alike) would be treated as one "single source drug" for Medicare price negotiation purposes. This would apply when the drugs 1) share at least one active ingredient, 2) are owned by the same company, and 3) differ only in that one contains a distinct active ingredient added to create a new formulation or route of administration — not to change the drug's therapeutic effect.[16] Their combined expenditures would then determine negotiation eligibility.

Families USA strongly supports this commonsense proposal, which, if enacted, will help safeguard the negotiation program against industry gaming, including by ensuring the program can accurately identify the drugs that cost Medicare and beneficiaries the most. As the fixed-combination drug market is large and growing rapidly — one estimate values the market at $109.17 billion in 2025 and projects it to reach $146.18 billion by 2035 – we urge CMS to finalize this policy as soon as possible.[17]

II. F. 3. Methodology for Developing the Initial Offer

CMS proposes to codify the process for developing an initial negotiation offer that they have built over the last three rounds of program guidance.[18] As part of this proposal, they would

codify the use of the price of therapeutic alternatives as the starting point for developing an initial pricing offer; Families USA does *not* support the use of prices for therapeutic alternatives as a starting point for developing the initial price offer in negotiation and encourages CMS to develop a method that is not founded upon existing high, inflated and irrational prices.

The IRA requires that CMS develop and apply a consistent methodology and process for negotiation with drug manufacturers to arrive at a maximum fair price (MFP). A vital step in the negotiation process is how CMS arrives at the initial price that it offers to drug manufacturers. The process CMS proposes to codify starts with identifying the price of therapeutic alternatives to the drug being negotiated.[19] The price is then adjusted by statutorily defined factors.[20] Finally, CMS adjusts the price with manufacturer-submitted data to arrive at an initial price offer for CMS to submit to manufacturers.[21] The law lists nine factors that CMS is required to consider when calculating an initial and final MFP offer, including comparative effectiveness research such as outcomes and patient experience data which is considered the gold-standard for assessing the value of therapeutic alternatives.[22] However, the IRA does not provide direction for how CMS should prioritize, weight, or define these factors.[23] What is made clear by the law is that the negotiation program's aim is to achieve "the lowest maximum fair price for each selected drug."[24]

Particularly given that federal law does not give direction to CMS for how to weigh these factors in determining the initial and final MFP offer, we continue to be deeply concerned with CMS' commitment to anchoring the initial offer to prices of therapeutic alternatives — prices that reflect the current flaws in drug pricing practices that lead to high and irrational drug prices in the first place. Instead, CMS should consider an approach more rooted in comparative effectiveness research and data. CMS itself acknowledges in the proposed rule that "the therapeutic alternative(s) may not be priced to reflect the clinical benefit of the selected drug."[251]Families USA is deeply concerned that Part D net prices and Part B Average Sales Price or Wholesale Acquisition Cost (as selected by CMS to represent the price of therapeutic alternatives) do not reflect the true and appropriate value of these medications. Therefore, relying on them as fundamental starting points for drug negotiation will undermine the negotiation program and its ability to achieve meaningful cost savings for the federal government, seniors, and people with disabilities.

Based on these concerns, **Families USA strongly encourages CMS to avoid using the price of therapeutic alternatives 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 to establish non-biased, cost-effectiveness targets or thresholds which can then be adjusted**

[1] https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-157

based on comparative effectiveness research, the prices of therapeutic alternatives, and other manufacturer-specific data.

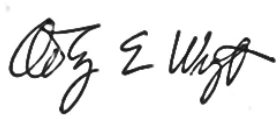
To calculate these targets, CMS should determine an upper and lower bound price per unit of health gained (as well as cost per condition-specific measure of clinical benefit) that it deems appropriate.[2627]This should also reflect the opportunity cost of the treatment in relation to the treatment's added net benefits for Medicare patients over time.[28] [29] We believe the cost effectiveness approach outlined above more closely ensures 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.

Conclusion

Families USA greatly appreciates CMS taking this important step in continuing implementation of the Medicare Drug Price Negotiation Program, by releasing this proposed rule and transitioning implementation of this vital law into the notice of proposed rulemaking. This historic health care reform promises to drastically reduce the high cost of prescription drugs and ensure that older adults and people with disabilities who rely on Medicare for health coverage have access to affordable, life-saving medications. Families USA thanks CMS for the work it has done since the IRA's passage to start lowering drug costs for people across the county 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 costs of prescription drugs.

Thank you for taking the time to review this comment. Please contact Hazel Law, hlaw@familiesusa.org, with any questions.

Sincerely,



Anthony Wright

Executive Director

[1] Andrew W. Mulcahy, Chrisopher M. Whaley, Mahlet Gizaw, et al, "International Prescription Drug Price Comparisons," RAND, Jan 2021, https://www.rand.org/pubs/research_reports/RR2956.html
[2] 91 FR 36236, https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program
[3] 42 U.S. Code § 1320f-1, https://www.law.cornell.edu/uscode/text/42/1320f-1
[4] "Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028," CMS, September 2025, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf
[5] Kate Meyer and Jeremy Sharp, "New Confidentiality and Transparency Provisions Are Critical to Successful Medicare Drug Price Negotiations," The Commonwealth Fund, October 2023, https://www.commonwealthfund.org/blog/2023/new-confidentiality-and-transparency-provisions-are-critical-successful-medicare-drug
[6] 42 U.S. Code § 1320f-1, https://www.law.cornell.edu/uscode/text/42/1320f-1; Rachel Sachs and Richard G. Frank, "Analyzing the expansion of the Medicare drug price negotiation program to Part B," Brookings, April 2025, https://www.brookings.edu/articles/analyzing-the-expansion-of-the-medicare-drug-price-negotiation-program-to-part-b/
[7] " Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028," CMS, September 2025, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf
[8] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program
[9] "Medicare Data," UCSF Division of Geriatrics Department of Medicine, https://peppercenter.ucsf.edu/medicare-data
[10] Jeannie Fugelsten Biniek, Meredith Freed, Nancy Ochieng, and Tricia Neuman, "Medicare Advantage Enrollment Grew by About 1 Million People, Mainly Due to Special Needs Plans," KFF, February 2026, https://www.kff.org/medicare/medicare-advantage-enrollment-grew-by-about-1-million-people-mainly-due-to-special-needs-plans/
[11] "Ensuring the accuracy and completeness of Medicare Advantage encounter data," MedPAC, June 2019, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch7_medpac_reporttocongress_sec.pdf ; "ENCOUNTER DATA SUBMISSION AND PROCESSING GUIDE, Medicare Advantage Program," CMS, November 2022, https://csscoperations.com/internet/csscw3_files.nsf/F2/2022ED_Submission_Processing_Guide_20221130 .pdf/$ FILE/2022ED_Submission_Processing_Guide_20221130.pdf
[12] Wynda Clayton, "Rethinking Risk Adjustment: Treading Carefully into the Next Chapter of Rick Adjustment (Part II), RAAPID, April 2025, Rethinking Risk Adjustment: MA Encounter Data & Its Pitfalls; Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts o...; "The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight," HHS OIG, February 2023, https://oig.hhs.gov/documents/evaluation/2820/OEI-03-21-00380-Complete%20Report.pdf; "Ensuring the accuracy and completeness of Medicare Advantage encounter data," MedPAC, June 2019,https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch7_medpac_reporttocongress_sec.pdf
[13] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105; https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-300/subpart-B/section-300.50; " Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum

Fair Price in 2026, 2027, and 2028," CMS, September 2025, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf

[14] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028," CMS, September 2025, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[15] Kristi Martin and Rachel Sachs, "Administration Releases Medicare Drug Price Negotiation Program Proposed Rule For 2029," Health Affairs, June 2026, https://www.healthaffairs.org/content/forefront/administration-releases-medicare-drug-price-negotiation-program-proposed-rule-2029

[16] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105

[17] "Fixed Dose Combination Drug Market," Market Research Future, (updated) May 2026, https://www.marketresearchfuture.com/reports/fixed-dose-combination-drug-market-37352

[18] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105

[19] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105

[20] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105

[21] 91 FR 36236 , https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-105

[22] "H.R.5376 An act to provide for reconciliation pursuant to title ii of S. Con. Res. 14," 117th Congress, https://www.congress.gov/bill/117th-congress/house-bill/5376/text; "Comparative Effectiveness to Evaluate Prescription Drugs," NCSL, October 2022, https://www.ncsl.org/health/comparative-effectiveness-to-evaluate-prescription-drugs; "Comparative Effectiveness Research: Foundational to Healthcare Value Efforts," Healthcare Value Hub, June 2020, https://healthcarevaluehub.org/resource/2020/comparative-effectiveness-research-foundational-to-healthcare-value-efforts/

[23] "H.R. 5376- An act to provide for reconciliation pursuant to title II of S. Con. Res. 14," 117th Congress, https://www.congress.gov/bill/117th-congress/house-bill/5376/text

[24] "H.R. 5376- An act to provide for reconciliation pursuant to title II of S. Con. Res. 14," 117th Congress, https://www.congress.gov/bill/117th-congress/house-bill/5376/text

[25] 91 FR 36236, https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program#h-157

[26] "2020-2023 Value Assessment Framework," ICER, January, 2020 (Updated 3 February, 2022), https://icer.org/wpcontent/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf.

[27] This recommendation is based on: Institute for Clinical and Economic Review. "2020-2023 Value Assessment Framework," 31 January, 2020 (Updated 3 February, 2022), https://icer.org/wpcontent/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf.

[28] "2020-2023 Value Assessment Framework," ICER, January, 2020 (Updated 3 February, 2022), https://icer.org/wpcontent/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf.

[29] https://icer.org/wpcontent/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf