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April 13, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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,

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on initial guidance from the Centers for Medicare & Medicaid Services (CMS) regarding the **Medicare Drug Price Negotiation Program** (Negotiation Program). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals, including through our national helpline.

General Comments

Based on this experience, we know people with Medicare are uniquely impacted by high and rising drug prices. This is partly due to utilization and health status. Over two-thirds of Medicare beneficiaries have multiple chronic conditions¹ and Part D enrollees take 4 to 5 prescriptions per month, on average.² Many live on fixed or limited incomes that cannot keep pace with rapidly escalating drug prices. Half of all beneficiaries, nearly 30 million people, live on \$29,650 or less per year, and one quarter have less

¹ Centers for Medicare & Medicaid Services, "Multiple Chronic Conditions" https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main.

² Leigh Purvis, *et al.*, "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) <http://www.aarp.org/rxpricewatch>.

than \$8,500 in savings.³ Health care costs comprise a large and disproportionate share of beneficiaries' limited budgets: nearly 30% of Medicare households spend 20% or more of their income on health care, compared to only 6% of non-Medicare households.⁴ Out-of-pocket costs for prescription drugs represent a significant share of this amount, accounting for nearly one out of every five beneficiary health care dollars.⁵ Most people with Medicare cannot afford to pay more for care.

Callers to our national helpline regularly report struggling to afford the prescription medications they need to maintain their health and well-being. And they are not alone. In 2021, over 5 million people with Medicare are estimated to have had difficulty paying for their prescriptions, with Black and Latino beneficiaries being disproportionately affected.⁶ That same year, nearly twenty percent of older adults said they had not filled a prescription in the past two years, most due to affordability concerns.⁷ Yet, drug costs continue to climb—price hikes on brand name medications have exceeded the rate of inflation every year since at least 2006.⁸

The Inflation Reduction Act's (IRA) Negotiation Program could provide much-needed relief, lowering prices, increasing medication adherence, and improving outcomes. We commend CMS for this timely initial guidance, and respectfully offer the following comments on bolstering **Affordability, Accuracy, and Transparency**.

Affordability

We ask CMS to revisit plans to base aspects of the initial maximum fair price on Part D net prices for therapeutic alternatives. Evidence consistently shows these prices are inflated; Medicare Part D pays significantly higher drug prices than other health programs in the U.S. and abroad.⁹ According to the Government Accountability Office, Part D net prices were up to four times higher than comparable countries in 2020.¹⁰ Using these flawed payments as anchor points would bake overpayment into the

³ Wyatt Koma, *et al.*, "Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic" Kaiser Family Foundation (April 24, 2020) <https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>.

⁴ Juliette Cubanski, *et al.*, "The Financial Burden on Health Care Spending: Larger for Medicare Households than for Non-Medicare Households" Kaiser Family Foundation (March 1, 2018) <https://www.kff.org/medicare/issue-brief/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households/>.

⁵ Kaiser Family Foundation, "10 Essential Facts about Medicare and Prescription Drug Spending" (January 29, 2019) <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>.

⁶ U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation "Prescription Drug Affordability among Medicare Beneficiaries" (January 19, 2022), <https://aspe.hhs.gov/reports/medicare-prescription-drugs>.

⁷ AARP, "Consumer Views on Prescription Drugs Survey" (July 2021) https://www.aarp.org/content/dam/aarp/research/surveys_statistics/health/2021/drug-prices-older-americans-concerns.doi.10.26419-2Fres.00476.001.pdf.

⁸ Leigh Purvis, *et al.*, "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) <http://www.aarp.org/rxpricewatch>.

⁹ See, *e.g.*, Government Accountability Office, "Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017" (January 14, 2021) <https://www.gao.gov/products/gao-21-111#:~:text=What%20GAO%20Found,in%20the%20Part%20D%20program>; Mulcahy, *et al.*, "International Prescription Drug Price Comparisons" (2021) https://www.rand.org/pubs/research_reports/RR2956.html; Government Accountability Office, "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France" (April 28, 2021) <https://www.gao.gov/products/gao-21-282>.

¹⁰ Government Accountability Office, "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France" (April 28, 2021) <https://www.gao.gov/products/gao-21-282>.

Negotiation Program and undermine the IRA's ability to achieve meaningful cost savings for current and future beneficiaries.

Instead, we urge CMS to use a cost-effectiveness approach. We recommend establishing targets for a preliminary price range which could then be adjusted based on relevant factors (such as comparative effectiveness research, the prices of therapeutic alternatives, and other manufacturer-specific data) to arrive at a maximum fair price.

Accuracy

CMS notes that in calculating maximum fair prices, the agency will rely on cost and projection data from drug manufacturers. However, CMS does not discuss plans to independently verify these "assumptions and calculations." This is problematic. As for-profit companies, drug manufacturers will necessarily be incentivized to create a financially favorable environment. Past industry behavior even provides a template. An OIG review of the Medicaid Drug Rebate Program found manufacturer reports misclassified drugs in ways that benefitted their bottom line, but cost Medicaid over one billion dollars.¹¹

Not all drug companies are bad actors and not all profit-seeking behaviors are deliberate. Guardrails are therefore needed to prevent similarly intentional, as well as inadvertent, cost-shifting and rebate losses in Medicare. We strongly urge CMS to rely on independent information, to carefully review all collected data, and to conduct both random and for-cause audits .

Transparency

We recognize the IRA affords CMS discretion in releasing information and feedback requests. We applaud CMS for soliciting these and other public comments and encourage the agency to maximize transparency throughout the implementation process.

Accordingly, we ask CMS to reconsider restricting access to information regarding the maximum fair price methodology. While we understand the desire to avoid revealing details the drug manufacturers consider to be proprietary, they must not be allowed to use this as a shield; our health system needs more transparency and accountability, not less.

Program integrity and implementation obligations demand CMS release as much data as possible. This includes the factors and value frameworks used to determine a maximum fair price, as well as any information received from drug manufacturers. These details are necessary to advance general and payer understanding of the cost and value of the negotiated drugs. Without it, other insurers will be unable to effectively negotiate—limiting downward pricing pressure and the IRA's impact, potentially derailing opportunities for further reform.

¹¹ 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" (December 2017) <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>.

Publicizing this information would also serve as a mechanism for oversight and help encourage accurate, complete manufacturer reporting. The IRA's landmark Negotiation Program must not be shrouded in secrecy.

Conclusion

Thank you again for the opportunity to provide comment. For additional information, please contact me at LCopeland@medicarerights.org or 202-637-0961 or Julie Carter, Counsel for Federal Policy at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

A handwritten signature in cursive script that reads "Lindsey Copeland".

Lindsey Copeland
Director of Federal Policy
Medicare Rights Center