Congress of the United States

Washington, DC 20515

February 1, 2023

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

Dear Administrator Brooks-LaSure,

As you know, Congress passed the *Inflation Reduction Act* (IRA) on August 7, 2022. The Senate Committee on Finance has the responsibility to oversee implementation of IRA provisions within our jurisdiction, including landmark policies to lower the cost of prescription drugs for millions of Americans. These monumental reforms will finally empower Medicare to negotiate drug prices, cap out-of-pocket spending on drugs in Part D, and limit insulin cost-sharing for seniors. As the co-author of the original drug price inflation penalties in the bipartisan *Prescription Drug Pricing Reduction Act of 2019*, I have a longstanding commitment to ensuring seniors and taxpayers are not footing the bill for excessive price increases. I look forward to working in tandem with the Centers for Medicare & Medicaid Services (CMS) to ensure the IRA's drug pricing policies deliver much-needed relief to patients, taxpayers, and the healthcare system.

I write today to inquire about CMS's progress towards implementing the Medicare inflation rebate provisions. This core component of the IRA's drug pricing reforms has already started to take effect. These provisions hold the pharmaceutical industry accountable for high prices by requiring manufacturers to pay a rebate to Medicare when they increase their drug prices faster than the rate of inflation. Medicare will penalize manufacturers for price increases that outpace inflation starting in October 2022 for Part D drugs and in January 2023 for Part B drugs administered by providers. If pharmaceutical manufacturers' keep their prescription drug price growth in check, then no penalty applies. The Congressional Budget Office estimates that the IRA's inflation rebate provisions will save Medicare \$63.2 billion over ten years from a combination of lower prescription drug price growth and manufacturer rebates owed.¹

Congress passed these reforms to address rampant, industry-wide price gouging in the United States. For example:

• Pharmaceutical manufacturers have reaped significant profits from persistent price increases on all Americans. According to Leerink, from 2014 to 2017, drug price increases alone accounted for more than half (\$14.3 billion) of sales growth in the United States for the 45 highest-revenue generating drugs.²

^{1 &}quot;Summary Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14," *Congressional Budget Office*, September 2022. https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

² Pagliarulo, N., "Price Increases on Top Drugs Drove Majority of Recent Growth, Analysis Finds," *BioPharma Dive*, October 2018. https://www.biopharmadive.com/news/price-increases-on-top-drugs-drove-majority-of-recent-growth-analysis-find/539337/.

- Credit Suisse reported that price increases in the United States accounted for 80 percent of net profits for 20 of the largest pharmaceutical manufacturers in 2014. Virtually 100 percent of the industry's profit growth was attributable to price increases in 2016.³
- In recent years, drug prices have continued to grow much faster than the rate of inflation. AARP's Rx Price Watch report found that the average annual specialty drug price increase was more than 3.5 times higher than inflation for 2020.⁴ The Kaiser Family Foundation found that price increases on 23 of the top 25 Part D also outpaced inflation over the same period.⁵
- According to the HHS Assistant Secretary for Planning and Evaluation (ASPE), more than 3,000 drugs took price increases in 2022. Between July 2021 and July 2022, price increases on 1,216 drugs outpaced inflation, with an average price increase of 32 percent.⁶

Recent reports indicate that pharmaceutical manufacturers are continuing their practice of price increases into 2023. Specifically, manufacturers have already increased prices on at least 872 drugs since January 1, reaffirming the importance of IRA's drug pricing reforms.⁷ The Finance Committee will be paying close attention to how the inflation rebate provisions work to lower prices for seniors and hold manufacturers accountable if they continue to raise prices beyond the rate of inflation. Please answer the following questions:

- 1. What is the implementation timeline for the inflation rebate provisions in the IRA and how will important policy decisions be communicated to interested stakeholders and beneficiaries? Please provide distinct responses for the Part B and Part D rebate provisions.
- 2. Please share breakdowns illustrating how the Part B and Part D rebates will be calculated. This will assist with stakeholder and beneficiary education about these provisions.
- 3. It is my strong hope that manufacturers that increase prices above inflation will be penalized promptly. What steps is CMS taking to help ensure invoices will go out on a timely basis?

7 Silverman, E. "Major Purchasers Predict Expensive New Therapies Will Keep Driving Drug Price Hikes." STAT, January 2023. https://www.statnews.com/pharmalot/2023/01/17/drug-prices-biosimilars-medicare-inflation-pbm/

³ Walker, J., "For Prescription Drug Makers, Price Increases Drive Revenue," *Wall Street Journal*, October 2015. https://www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750/.

⁴ Schondelmeyer, S. and Purvis, L., "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020," *AARP*, September 2021. <u>https://www.aarp.org/content/dam/aarp/ppi/2021/09/trends-retail-prices-specialty-drugs.doi.10.26419-2Fppi.00073.006.pdf</u>.

⁵ Cubanski, J. and Neuman, T., "Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020," *Kaiser Family Foundation*, February 2022. <u>https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/</u>.

⁶ Bosworth, A. et al., "Price Increases for Prescription Drugs, 2016-2022," *Assistant Secretary for Planning and Evaluation Office of Health Policy*, September 2022. <u>https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf</u>.

^{#:~:}text=Major%20purchasers%20predict%20expensive%20new%20therapies%20will%20keep%20driving

^{%20}drug%20price%20hikes&text=More%20than%20two%20dozen,uptick%20from%20a%20year%20ago; 46brooklyn. "Brand Drug List Price Change Box Score. https://www.46brooklyn.com/branddrug-boxscore.

Thank you for the hard work already underway to make the IRA's drug pricing reforms a reality. We all share the goal of delivering on the promise of prescription drug savings to seniors in Medicare. The information requested is critical to ensuring that Medicare beneficiaries understand the broad reach of the IRA and the inflation rebate provisions that intend to protect them.

I look forward to our continued partnership. If you have any questions, please contact Polly Webster at Polly_Webster@finance.senate.gov.

Sincerely,

Lon

Ron Wyden United States Senator Chairman, Committee on Finance

CC: Secretary Xavier Becerra, Meena Seshamani

Secretary Xavier Becerra, JD U.S. Department of Health & Human Services 200 Independence Avenue SW Washington, DC 20201

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