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April 14, 2023

Joint Comments Regarding Medicare Drug Price Negotiation Guidance

Dear Dr. Seshamani,

Thank you for the opportunity to provide stakeholder feedback as CMS works to enact the new drug price negotiation and inflationary rebate systems established through the Inflation Reduction Act.

Our groups, representing patients, consumers, health care providers and public health experts are committed to ensuring access to affordable medicines and eager to support successful implementation of the law. Many of us have invested years working towards passing laws including these policies, and appreciate that CMS is committed to implementing the objectives of lowering prescription drug prices and reducing costs for millions of older adults and people with disabilities.

We are filing these comments today to register our serious concerns with CMS' proposed approach for developing its negotiated price offer starting point. We strongly urge CMS not to move forward with this approach and to consider other proposed options.¹

Section 60.3 outlines the proposed methodology from CMS for developing an initial price offer in drug price negotiations. CMS proposes in section 60.3.2 to take as a starting point for developing its initial negotiated price offer the average prices available for therapeutic alternatives for the selected drug.

Below, we articulate two major concerns with this approach.

1. Starting with the prices of therapeutic alternatives will lead to ongoing inappropriately high prices.

Evidence shows that drug prices paid under Medicare Part D are significantly higher than those paid under other health programs in the United States, including Medicaid and the Department of Veterans Affairs, as well as those paid in other wealthy countries.^{2,3,4}

¹ Some of the undersigned groups have proposed to use health technology assessments to arrive at a starting point for determining initial price offers in negotiations, while others propose to take a holistic approach to the factors provided in Section 1194(e) of the Act to determine a price based on the cost of innovation and promoting therapeutic advancements. These proposals are clarified further in individual comments provided to CMS from Families USA, Public Citizen, and others.

² 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.

³ 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 April 7, 2023.

⁴ 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.

Current inappropriately high prices, which burden Medicare beneficiaries and taxpayers, are the underlying reason that Congress passed and President Biden signed a law to empower Medicare to negotiate in the first place.

These prices are set by drug corporations under monopoly conditions to maximize profits, while plans face broad coverage obligations under Medicare Part D. Taking prices of therapeutic alternatives set under these conditions as the starting point for developing negotiated price offers would in turn bias the system towards inappropriate high, unfair prices.

2. Starting with the prices of therapeutic alternatives would be a missed opportunity for the law to provide virtuous systemic impact.

In support of its negotiated price offer starting point proposal, CMS argues that “[the prices of therapeutic alternatives] is an important factor when considering the overall benefit that the treatment brings to Medicare beneficiaries.” We agree that pricing of a medicine and its therapeutic alternatives impact Medicare beneficiaries, but we do not believe it follows that prices of therapeutic alternatives should dictate the starting point of prices CMS negotiates.

Rather than provide virtuous systemic impact, the current process CMS is considering would reduce incentives for manufacturers of therapeutic alternatives to lower their prices. Using existing drug prices that have not been negotiated by CMS as the basis for negotiations risks building inertia for higher prices into the system. By instead negotiating a maximum fair price through alternate methods, articulated by some of our organizations in individual comments, CMS’ negotiation process could help reduce the prices of the alternative therapies, since the manufacturers of the alternatives may try to compete on price with that of the negotiated product.

Thank you again for your time and attention. The decisions CMS faces now have the potential to impact pricing and access to medicines for millions of people for years to come. Please reconsider your approach to developing a starting point in negotiations to help ensure Medicare beneficiaries and taxpayers do not continue to pay inappropriately high drug prices.

Sincerely,

Public Citizen
ACA Consumer Advocacy
Arkansas Community Organizations
Center for Medicare Advocacy
Culinary Health Fund
Doctors for America
Georgians for a Healthy Future
Health Care Voices
Knowledge Ecology International
Medicare Rights Center

Families USA
MomsRising
Rights & Democracy
Salud y Farmacos
Social Security Works
T1International USA
U.S. PIRG (Public Interest Research Group)
United States of Care
Unity Fellowship of Christ Church-NYC
VOCAL-NY