U.S. Chamber of Commerce

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June 24, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Oz:

The U.S. Chamber of Commerce ("Chamber") appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' ("CMS's") Draft Guidance implementing Initial Price Applicability Year 2028 ("IPAY 2028") of the Medicare Drug Price Negotiation Program created by the Biden Administration under the Inflation Reduction Act ("IRA"). While we commend the Trump Administration for its efforts to ensure American patients have access to life-saving medicines, we have significant concerns regarding the potential negative impacts of the Draft Guidance on patient access, biopharmaceutical innovation, and the broader healthcare ecosystem.[1] As we explain below, the draft guidance is problematic, in large measure, because it carries forward interpretive and policy decisions made by the Biden Administration that do not comport with the law and do not reflect President Trump's policy direction.

As a threshold matter, we believe that CMS continues to make decisions regarding the IRA's price controls in a black box that lacks needed transparency. We understand the Draft Guidance to reaffirm that CMS will not disclose information about how it will set medicine prices until months after these decisions are made. This lack of transparency undermines CMS's stated commitment to "learning from, collaborating with, and engaging with the public" by keeping key stakeholders in the dark about how it will set prices until it is too late to provide effective input.

This is particularly true in the context of CMS's attempts to engage patients and providers. The Draft Guidance fails to offer insight into how collected data are used and leaves the door open for parties to submit discriminatory cost-effectiveness measures, including those based on the Quality-Adjusted Life Year (QALY). These measures carry the risk of undervaluing the lives of seniors, the disabled, and the

[1] As CMS is aware, the Chamber and other parties have challenged the IRA's price-control program in federal court as unconstitutional on several grounds. The Chamber respectfully submits that even if the IRA program were lawful (which it is not), both sound policy and legal considerations would require CMS to improve the approach set forth in the Draft Guidance, as explained in this letter.

chronically ill. We note that the IRA provides that in using evidence concerning comparative effectiveness, CMS "shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."

For both reasons, and separate from the Chamber's additional concerns detailed below, we strongly recommend that CMS adopt a more transparent, collaborative approach, providing timely and detailed information, subject to all necessary precautions to protect trade secrets and confidential business information, about the price-setting process to all stakeholders, but most especially America's innovative life-science companies and chronically ill patients.

Turning to the Chamber's additional policy-specific concerns with the draft guidance, we set forth three key concerns here.[2] First, we understand that the draft guidance would maintain the previous Administration's improper and legally invalid decision to adopt an overly broad definition of a qualifying single source drug (QSSD). The IRA defines a QSSD as one approved under its own new drug application (NDA) or biologics license application (BLA). However, CMS's policy disincentivizes innovation by treating products with the same active ingredient or moiety as the same QSSD, even if they are approved under different applications. This approach is inconsistent with the statutory language and deviates from the established Food and Drug Administration's approval framework for NDAs and BLAs, undermining incentives to develop new indications, forms of administration, or combination products that could demonstrate safety and efficacy in additional diseases or provide real-world utility and accessibility enhancements. This means there is effectively no age limit for CMS to subject a medicine to price-setting, even if it has just launched, has a different trade name, or represents a significant advancement for patients.

For example, new products that utilize innovations like subcutaneous (SC) administration can save patients 2.7–3 hours per visit[3], cut active healthcare provider

[2] These concerns do not represent the entirety of the problems inherent in the program or in its past or proposed implementation. Some of the concerns also apply to the previous Administration's CMS guidance, which we urge this Administration to revisit with a fresh approach that better reflects a policy of supporting innovation and economic growth. For more information about flaws in the previous Administration's guidance implementing the program, please see, for example, our letter to CMS of July 2, 2024, commenting on the Draft Guidance implementing IPAY 2027 of the program, at https://www.uschamber.com/intellectual-property/u-s-chamber-submits-comments-on-medicare-drug-price-negotiation-program.

[3] Soefje SA, et al. Clinical Administration Characteristics of Subcutaneous and Intravenous Administration of Daratumumab in Patients With Multiple Myeloma at Mayo Clinic Infusion Centers. JCO Oncol Pract. 2023 Apr;19.

time by nearly 50%[4], and lower the risk of infusion-related reactions.[5] These advancements address critical unmet needs and are meaningful by improving access, reducing treatment burden, and enhancing the overall patient experience—particularly in community, rural, and resource-limited settings. Accordingly, we urge CMS to reverse this policy and stay consistent with the statute by identifying QSSDs by distinct NDA or BLA.

Second, we are concerned that CMS has failed to adopt changes to the Orphan Drug Exclusion that would better protect development by maintaining orphan incentives. Moreover, CMS has stopped seeking input on what actions it can take to best support orphan drug development in the implementation of the price-setting program. We strongly urge CMS to seriously evaluate the impact of its interpretation on orphan drug development incentives and reopen this policy for consideration.

Finally, we are concerned with how the draft guidance could impact generic and biosimilar competition. While most brand medicines with an approved and marketed competitor at the time of selection are exempt from price setting, the timing for selection in the law predates the typical timeline for generic and biosimilar competition. Exacerbating this issue, the Draft Guidance would maintain another unsound decision made by the previous Administration by providing that CMS will evaluate whether a competitor is engaged in "bona fide marketing"—an arbitrary standard that is not consistent with the statute. Relying on this ill-defined concept means that marketed generics or biosimilars would be forced to compete against medicines with government-set prices, significantly reducing the incentive to bring them to market. We recommend that CMS amend its approach to ensure that the reference drug's Maximum Fair Price (MFP) becomes inapplicable immediately upon generic market entry.

We also recommend that CMS not pursue the potential alternative approach, described on page 131 of the draft guidance, for developing a starting point for an initial offer for a selected drug that would rely in major part on the unit cost of production and distribution of the drug. Such an approach would disincentivize innovation, compromise future patient access, and promote the inefficient development of medicines. Accurately estimating unit costs is prohibitively challenging at the product level, and undue reliance on this consideration in price-setting would penalize life sciences companies for pursuing efficiencies, ultimately resulting in fewer advances in treatment options and less progress in areas of unmet need.

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[4] https://www.merck.com/news/mercks-investigational-subcutaneous-pembrolizumab-with-berahyaluronidase-alfa-demonstrates-noninferior-pharmacokinetics-compared-to-intravenous-iv-keytruda-pembrolizumab-in-pivotal/

[5] Usmani SZ, Nahi H, Mateos MV, et al. Final analysis of the phase III non-inferiority COLUMBA study of subcutaneous versus intravenous daratumumab in patients with relapsed or refractory multiple myeloma. Haematologica. 2022;107(10):2293–2302

In conclusion, the Chamber believes that CMS's Draft Guidance would make an already harmful law worse, in significant part because it maintains decisions made by the Biden Administration that are either unlawful, inconsistent with President Trump's policy direction, or both. Throughout the Draft Guidance, CMS has failed to consider the risks to patient access and future innovation. The Guidance should therefore be revised to conform more faithfully with the mandate of section 3(a) of President Trump's Executive Order 14273 (Apr. 15, 2025), which provides that CMS's guidance "shall … minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States." Ultimately, CMS has disregarded concerns brought forth by stakeholders and put American patients' access to medicines further at risk. We strongly urge CMS to adopt a more thoughtful and inclusive approach that prioritizes patient access, innovation, and the long-term sustainability of the biopharmaceutical industry.

Thank you for your time and attention. We look forward to collaborating with CMS to develop market-oriented solutions that enhance affordability and access without compromising the innovation that drives life-saving breakthroughs.

Sincerely,

Marty Durbin
Senior Vice President, Policy
President, Global Energy Institute
U.S. Chamber of Commerce