U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024)

Dear Deputy Administrator Seshamani:

The U.S. Chamber of Commerce ("the Chamber") Global Innovation Policy Center ("GIPC") once again urges the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") to re-evaluate the approach taken in the Agency's Draft Guidance, which proposes to implement the second year of the Medicare Drug Price Negotiation Program ("Program") established by the *Inflation Reduction Act* ("IRA"). The Chamber supports efforts to ensure every American has equitable access to life-saving medicines at fair market prices, from diabetes and weight loss drugs to new diagnostics and therapeutics combating some of the world's most debilitating diseases. However, we firmly believe that the Program itself, the steps taken thus far in implementing the Program, and the contemplated next steps of implementation are damaging the present and future of life-science innovation, which could curb positive health outcomes for Americans now and in the future.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports efforts to help mitigate obstacles to life-saving medicines but government price setting will create additional access challenges for Americans. The Chamber has significant concerns about the permanent effect this program will have on innovation. Though the detriment of these policies to the economy is wide-ranging, we have focused our comments on three primary areas:

1. **The impact of price controls on life-science innovation and patient access.**
2. **The significant definitional overreach of the IRA.**
3. **The implementation process and so-called "negotiation" provisions lack transparency.**

These concerns (which are illustrative, and do not represent the entirety of the problems inherent in the Program or in its past or proposed implementation) are outlined in more detail below.[1]

[1] As CMS is aware, the Chamber and other parties have challenged the Program in federal court as unconstitutional on several grounds. The fundamental legal defects in the Program further support the conclusion that CMS should reconsider the approach

I. The IRA's price controls negatively impact life-science innovation, thereby depriving American patients of access to new life-saving medications.

Congress and the business community both share in the goal of reducing barriers to patient access. The Chamber supports appropriate, effective efforts to help mitigate obstacles that patients might face in accessing and affording life-saving medicines. However, government price setting will create additional significant access challenges for American patients. A June 2023 study estimated that the IRA could, over a 10-year period, result in a reduction of 40% in approvals from the Food and Drug Administration ("FDA"). In addition, studies also show that price controls limit clinical research in cutting edge therapies, resulting in a reduction for some treatments and cures by as much as 75%.[2]

Analysis and experience in other countries also demonstrates that market-restrictive policies like the IRA's price controls deter future innovation, inhibit patient access, and limit patient choice. A 2024 study from the Chamber comparing the IRA to policies in countries shows that the IRA will result in 29% to 44% fewer products for American patients[3]. These estimates are in line with other research conducted on the potential impact of the IRA on life sciences research and development. For example, prior to the enactment of the IRA's price controls, out of 104 new oncology products released globally, 80% were approved by the FDA and made available in the U.S., while only 58% of those new medicines were similarly available in Europe. Likewise, while U.S. patients benefit from faster access to therapies, in several benchmark countries, approvals can be lengthy—an average of 133 days in Germany and up to 500 days in Spain[4].

Government intervention in the market's establishment of prices undermines the innovation ecosystem that has enabled the U.S. to become one of the most inventive countries in the world. Moving forward in this second round of so-called "negotiations," decisionmakers must consider the implications of the IRA's price controls on patients. Failure to do so will jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. The ability of American patients to access life-saving innovations in a timely manner depends on it.

II. CMS' definition of a Qualifying Single Source Drug represents a significant overreach and is overbroad.

As in previous guidance, CMS has improperly expanded the definition for medications subject to the IRA's "negotiation" process by identifying multiple drugs as negotiation-eligible based on their molecule, including newer drugs that would not otherwise qualify for "negotiation" on their own under the statute. This action greatly increases the therapies

---

set forth in the Draft Guidance. The Chamber respectfully submits that even if the Program were lawful (which it is not), sound policy would require CMS to change its proposed approach to implementation as these comments suggest.

[2] *From Innovation Oasis to Research Desert How Price Controls Imperil American Medical Innovation and the Search for Cures*, December 11, 2023, available at https://www.uschamber.com/intellectual-property/new-study-forecasts-devastating-impact-on-patients-and-medical-science-from-government-price-controls.

[3] *The True Cost of Price Controls: Patient Access Report 2024,* January 31, 2024, available at GIPC-2024-Patient-Access-Report.pdf (uschamber.com)

[4] *Id.*

detrimentally affected by price controls. By grouping these therapies together at the active-ingredient or moiety level, the guidance significantly reduces the incentives for future research into how these lifesaving medications can be improved. This overly broad definition is contrary to the IRA requirement that a medicine be approved for a specified number of years, and it will negatively impact the many patients who benefit from ongoing research into a molecule.

CMS has also improperly expanded the definition of a qualified medicine by creating a "bona fide marketing" standard, where the Agency will determine whether there is "meaningful competition" from a generic or biosimilar to determine whether a selected medicine remains eligible for "negotiation." The plain text of the IRA does not include a bona fide marketing standard, and accordingly CMS should remove this construct from the guidance. If there is *any* generic or biosimilar competition, then CMS must remove a selected medicine from negotiation because that medicine would no longer be a "qualifying single source drug" (QSSD). This overly broad concept will inappropriately allow CMS to continue implementing price controls on medicines that should no longer be subject to them.

III. The entire "negotiation" process lacks transparency and accountability.

Dubbed as a voluntary "negotiation"[5], the implementation process selected by this Agency has provided limited opportunities for stakeholder input. The Agency has held inappropriately constrained listening sessions as part of the 'negotiation' process, where feedback has been limited to feedback from patients only; patients were cut off from speaking and were selected to participate in an unclear way. Additionally, it should be emphasized that there is minimal public information on many key aspects of the entire "negotiation" and "agreement" process, further supporting the conclusion that this is not a negotiation at all, but rather a one-sided scheme for mandating prices. Given the impact that price controls will have on patient access and patient choice, the Agency should revise its implementation guidance to provide greater transparency and opportunities for public review and engagement.

IV. Conclusion

Implementation of the IRA's price controls poses a real threat to America's future as the world's leading life-science innovator. Additionally, arbitrary price controls, once implemented, will lead to patients waiting longer to receive, and having reduced access to, new medicines. The Chamber opposes misguided, market-restrictive, and legally defective efforts that limit patient access and choice and undermine the living life-science innovation ecosystem. If the Agency elects to ignore these impacts on American patients and, instead, moves forward with the IRA's implementation, it should at least revise this guidance to reduce definitional overreach and ensure an open, public, fully transparent "negotiation" process.

[5] In reality, this entire process is nothing but the result of government coercion. True negotiation occurs when private actors freely negotiate in good faith to reach a mutually agreeable price. The process outlined by CMS isn't negotiation in the true sense of the word but is instead an arbitrary, government compelled price setting process. Continuing to dub this process a "negotiation" ignores the reality of the legal and practical power of the government to set a price and compel a manufacturer to accept it.

Sincerely,

Tom Quaadman
Executive Vice President
Center for Capital Markets Competitiveness
U.S. Chamber of Commerce