

Summary: NICA, GCCA, PhRMA Litigation Asserts Price Setting Provisions in the Inflation Reduction Act are Unconstitutional

Last year, Congress enacted the Inflation Reduction Act (IRA), which included a number of health care provisions. In a positive step, the law made changes to Medicare Part D that will make a difference for some seniors at the pharmacy, like capping the annual amount seniors pay out of pocket and making out-of-pocket costs more predictable month to month. Unfortunately, it also put in place policies that mandate government-set prices for medicines covered by Medicare. These policies are expected to have a negative impact on access to medicines covered by Medicare Part B and Part D, in addition to discouraging continued drug development.

Background on IRA's Price Setting Provisions

The IRA directs the Department of Health and Human Services (HHS) to establish a “Drug Price Negotiation Program” for Medicare drug prices. Selected medicines are eligible for price setting as early as seven years after small molecule medicines (e.g., tablets, capsules and pills) are initially approved by the U.S. Food and Drug Administration (FDA) and 11 years after large molecule medicines (e.g., biologics that are injected or infused) are initially approved by the FDA.

This year, HHS will select 10 medicines for price setting, with increasing numbers of additional medicines selected over the next several years. Once a medicine is selected, manufacturers are forced into a so-called “negotiation” process where HHS sets a “maximum fair price” or an “MFP.” The statute defines the maximum fair price by setting ceilings with virtually no price floor. And the statute contains no limits on HHS’s discretion to set prices below the statutory ceiling. HHS doesn’t plan to release their explanation for how they’ve set the price of a medicine until months after that price has been published.

To force manufacturers to agree to the government-dictated price, the IRA imposes an escalating “excise tax” that begins at 186% of a medicine’s total sales revenue and reaches a maximum of 1900%. The only other option manufacturers have if they do not agree to the government’s price is to pull all of their medicines from Medicare and Medicaid – not just the medicine subject to price setting. It would take manufacturers a year or more to end their agreement with CMS and would require them to withdraw from Medicare and Medicaid entirely.

IRA's Price Setting Process Lacks Transparency, Accountability

The process HHS has proposed specifies that there will be no more than three meetings between a manufacturer and the agency during the price-setting process. HHS has even gone so far as to place a gag order on manufacturers, specifying they are not to communicate with anyone other than the agency throughout the process and that all documentation, even their own notes, must be destroyed.

During the process there is only one opportunity for patients and providers to weigh in, and it's only in writing, using a bureaucratic form with word limits that must be submitted shortly after selected medicines are announced.

Key implementation decisions are also exempt from public notice-and-comment procedures and from judicial review. In other words, HHS's discretionary decisions on how to implement the price setting process are not subject to public input on the "front end" before they are made, or to judicial review on the "back end" after they are made.

IRA's Price Setting Provisions Are Unconstitutional

The price setting provisions in the Inflation Reduction Act should be declared unconstitutional because of the following violations.

- **Separation of Powers:** Congress has impermissibly delegated broad authority to HHS to set prices within Medicare with no meaningful constraints on the agency's exercise of this new price-setting authority. This is in conflict with fundamental separation-of-powers and nondelegation principles in the Constitution.
- **Due Process:** Unlike virtually any other statutory program affecting the public, the price setting scheme denies manufacturers the right both to front-end input on how the policy will be implemented and to back-end judicial or administrative review after critical implementation decisions have been made. And HHS has proposed in guidance to make the process even less transparent, preventing manufacturers from disclosing any information about the price setting process. This violates the Plaintiffs' and their members' Fifth Amendment due process rights.
- **Excessive Fines:** The excise tax aims to force manufacturer compliance with the price setting scheme by imposing a staggering tax that serves as a severe penalty that violates the Eighth Amendment's Excessive Fines Clause. Imposed each day that a manufacturer has not agreed to "negotiate" it increases swiftly to 1,900% of a drug's total sales revenues.