



## MANDATED REBATES AND “NEGOTIATION”: THE IRA PAVES A ROCKY ROAD FOR PHARMA AND BIOTECH INNOVATION

by Matt Wetzel

These days, when someone mentions the “IRA,” I no longer jump to a discussion of the history of conflict between Ireland and Britain, nor do I think of an Individual Retirement Account. Now, I cannot help but think of another IRA—the Inflation Reduction Act of 2022—and its potential negative and unknown consequences for the biotech and pharmaceutical industries in the United States.

The IRA—passed in the blink of an eye this summer—has introduced the most sweeping changes to how the U.S. government pays for pharmaceuticals and biologics in nearly 20 years. What had been mostly an unfulfilled campaign promise for decades—giving the federal government the authority to negotiate drug prices on behalf of Medicare—is now encapsulated into federal law.

Two clear points that emerge from the IRA’s byzantine statutory text on Medicare drug pricing:

- **First**, the IRA grants the government the authority to cap drug prices and set price controls on behalf of Medicare. There is minimal negotiation and no opportunity for drug makers to challenge these decisions. The IRA imposes minimal checks on the authority it delegates to the Centers for Medicare & Medicaid Services (“CMS”)—the federal agency tasked with implementing the IRA’s drug pricing provisions.
- **Second**, the IRA has the potential to wreak havoc on drug and biotech innovation by potentially driving manufacturers to choose among research and development projects, a choice that could delay the introduction of life-saving and life-changing medications. In fact, we have already seen multiple instances of just this, including CEOs making clear that the IRA’s long-term consequences will cause shifts in research and development priorities, mostly for the negative.

The 2003 federal law that created the Medicare prescription drug benefit—the Medicare Modernization Act (MMA)—also prohibited the government from “interfere[ing] with the negotiation between drug manufacturers and pharmacies and [Medicare Part D plans].” Congress wrote into this non-interference clause (which the IRA now eliminates) an explicit intention to remove government interference in order “to promote competition” in the pharmaceutical industry. And in removing this statutory limit on HHS’s authority, the IRA paves the way for a remarkable shift in policy.

### Inflation-Based Rebates

Part of the IRA’s significant changes to Medicare drug pricing have already gone into effect. The IRA’s inflation-based rebate requirements have not received significant media attention but became effective October 1, handing the government new tool to throttle drug price increases.

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The IRA mandates that the pace of drug price increases must match or lag the rate of inflation—or else manufacturers will owe steep rebates and potential fines. Pharmaceutical manufacturers, in other words, retain control over their pricing practices for drugs and biologics; but, to the extent that these prices increase at a pace faster than inflation, a manufacturer must pay Medicare for the difference. CMS calculates what the price of a drug would have been if its price increased by the rate of inflation, using a complex process involving a benchmark date set by statute and the rate of change in the consumer price index since that benchmark date. The amount owed by a drug manufacturer that increases its product’s price faster than the rate of inflation will vary based on whether the drug or biologic is the type that must be administered in the physician office or facility setting (for example, an infused drug or certain types of injectables) or whether it can be dispensed at a pharmacy or specialty pharmacy, among other considerations. These rebates will essentially make the Medicare program whole for any increases in pricing beyond inflation. Practically, this means the IRA’s provisions will slow the speed at which drug and biologics companies can increase their products’ pricing.

The government’s authority to force such rebates is unchecked. Procedurally, CMS will send a manufacturer an invoice with its decision about the rebate amount owed by the manufacturer (either quarterly basis or yearly, depending on the type of drug), and a manufacturer will have 30 days to pay. The IRA explicitly denies program participants administrative or judicial review. In other words, CMS decides *how* to calculate the rebate, calculates the rebate, and demands payment for the rebate; and the manufacturer has no administrative avenue for recourse nor can the manufacturer challenge CMS’s decision in court. As a result, the manufacturer could conceivably owe a substantial payment to the government and could face significant monetary penalties for failing to pay.

### “Negotiated” Pricing

Even more significant changes are coming. The common refrain these days is that the IRA gives the government the authority to negotiate pricing on the highest-cost drugs. In reality, the IRA authorizes the Medicare program to cap drug prices; and the “negotiation” component reflects a series of simple administrative exchanges more closely akin to allowing a manufacturer to comment on the government’s proposed pricing but not “negotiate” as would be commonly understood in the marketplace, with zero checks and balances on the government’s authority.

Here’s how “negotiation” works:

- CMS selects which drugs and biologics will be subject to the negotiation process. CMS will select from so-called “single-source” drugs and biologics (i.e. those without generic or biosimilar competition) which represent the highest-spend drugs and biologics under the Medicare program. After a ramp-up period of 2026-2028, starting in 2029, CMS will have authority to select 20 drugs and biologics each year to enter price negotiations.
- If a manufacturer’s product is selected for negotiation, the manufacturer must enter an agreement with CMS to negotiate. (If not, the manufacturer faces a significant excise tax.)
- CMS, which is currently looking to hire staff for the program, will make an initial offer. The IRA requires that the government include a justification for this initial offer but does not limit or provide confines around how this initial offer is calculated.
- The manufacturer has 30 days to respond, by either accepting the offer or proposing a counteroffer.
- CMS will respond to the counteroffer—not subject to any deadlines or timing restrictions, other than all “negotiations” must be concluded prior to November 1, two years prior to the applicability of the price cap. For example, negotiations for drug pricing in the year 2027 must be wrapped up by November 1, 2025.

- Negotiations end with CMS setting a “maximum fair price”—or MFP—or rather a cap that CMS will use to calculate how much Medicare will pay for a relevant drug or biologic. (“Fairness” apparently has a maximum limit.)

**Put another way, under the statute, a manufacturer has one opportunity to provide a counteroffer to CMS in the context of price negotiations—and CMS does not appear to have any limits or restrictions on whether it will accept, reject, or simply ignore that counteroffer.** Except for a floor on small biotech drugs during the first few years of the program’s operation, the statute does not establish pricing floors.

The program sets a price cap at the lowest of (a) a certain percentage of the “non-FAMP” price of the drug (a drug-pricing calculation that reflects what non-governmental customers pay for the product and that is currently used as part of the calculations for what the Department of Defense, the Department of Veterans Affairs, the Coast Guard, and the Public Health Service pay for drugs and biologics) or (b) the amount that Medicare paid for the drug in the prior year. The IRA caps the negotiated “maximum fair price” at 40%-75% of non-FAMP, depending upon how long the product has been on the market without competition. To put this in perspective, the VA pays 76% of non-FAMP for drugs and biologics that it purchases.

Keep in mind that the MFP is subject to a ceiling—not a floor—and the statute contains no provision that prohibits the government from “negotiating” a steeply discounted price of, for example, 25% of non-FAMP or lower. The IRA prohibits CMS from negotiating below 66% of non-FAMP for certain small biotech drugs in the 2029 and 2030 timeframe. Otherwise, the IRA does not prohibit CMS from starting the negotiation process at dramatically low prices, and as noted above, the language of the IRA appears to permit a manufacturer just one opportunity to make a counteroffer.

As with the inflation-based rebates, CMS’s authority in this area is unchecked. If a manufacturer does not participate or refuses to offer MFP-based pricing, the manufacturer could be subject to significant fines and penalties. **And like the inflation-based rebate, the IRA explicitly prohibits a manufacturer from any administrative challenge to the selection of a drug, the determination of whether a drug is eligible for negotiation, the determination of MFP, or the determination of whether a drug is subject to renegotiation. The IRA also prohibits judicial review of CMS’s pricing decisions.**

The IRA obviously does not offer true price “negotiations”; rather, it establishes a procedure for implementing price controls and caps.

## The Structure

The IRA’s price controls and caps will require new lawyers of bureaucracy. CMS has provided Congress with a proposed organizational chart for the 95 employees it plans to hire for IRA implementation. Bureaucratic additions include a new Division of Manufacturer Oversight and Compliance, a new Division of Manufacturer Data and Rebate Operations, and a Division of Rebate Agreements & Drug Price Negotiations, among other new branches of the federal government.

Notably, the IRA allows CMS to implement portions of the law through program instructions—not through notice-and-comment rulemaking. Put another way, the IRA gives CMS authority to create the rules of the program without stakeholder input for three years before it must seek the public’s input. Given that CMS is already devising its internal structure and given that the agency’s instructions will become *de facto* legal requirements for manufacturers, it is difficult to imagine that much will change in three years when the public and key stakeholders have a chance to provide their input.

## The Consequences

Pharmaceutical and biotech companies, as well as patients, will feel the consequences of the IRA's price caps and the inflation-based rebates in the years to come. These effects will become more obvious once CMS releases its program instructions and proposed regulations. Some of the questions that the IRA raises include the following:

- Will companies launch pharmaceutical and biologic products at a significantly increased price to minimize the throttling effects of the IRA's inflation-based rebates? Or will manufacturers consider the inflation-based rebate as a simple penalty for doing business, and raise prices despite the consequences? Conversely, in times of significant inflation, will some companies find cover for even greater price increases?
- Will commercial payors want the same deal as the government, especially given price-protection provisions and most-favored-customer clauses found in most PBM and payor agreements?
- Considering the complex calculations CMS uses under the Medicaid and 340B reimbursement programs, how significantly will the Medicare-program rebates manufacturers must pay increase, and how much lower will ceiling prices fall under the 340B program?
- Will manufacturers expedite their research on additional indications for an approved drug? Once the drug is subject to the IRA's price-negotiation provisions, they will apply to all indications—and companies may want to earn as much revenue as possible from additional indications once approved.
- Perhaps companies will shift focus from small molecules to biologics, which can yield an extra 4 years of protection from Medicare price caps. As a result, will the market experience an influx of more costly biologics as opposed to less expensive small molecule drugs?
- Could another consequence be a shift from research on multiple indications of the same molecule to research on different molecules to preserve each separate molecule's pricing integrity?
- Will companies in the rare-disease space limit their research to only one potential indication to preserve their protected status under the IRA, as the inclusion of a second orphan indication could expose a company to the drug pricing "negotiation" provisions?
- Will biologics companies encourage biosimilar companies to expedite their programs to be exempt from the IRA's negotiated pricing provisions for biologics?

Despite these open questions, one thing is certain—the IRA's provisions on drug pricing will have an impact on the pace of innovation and produce challenges for companies seeking to advance new technology. And the IRA will do so through an expanded federal bureaucracy with largely unchecked administrative procedures without the prospect of judicial review and largely without input and buy-in from the public. Whatever one thinks about pharmaceutical pricing, the IRA's approach is problematic at best.

## What's Next?

CMS will likely issue program instructions in the near term, especially because some of the IRA's provisions are already effective and the process for selecting drugs subject to the IRA's price "negotiation" provisions should start in 2023. CMS will hire nearly 100 people to implement the variety of drug pricing requirements from the IRA. Drug companies will continue to react—most likely negatively—to the IRA. And the only real impact patients will feel is in the IRA's downward pressure on innovation in the biotech and pharmaceutical space and, in at least some potential scenarios, further increased drug prices.