## Health Care on the Ballet

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# What the Election Could Mean for the Inflation Reduction Act's (IRA's) Medicare Reforms

A presidential election year puts a spotlight on the major parties' health policies, and this year is no different. Vice President Kamala Harris, the Democratic candidate for president, has touted the last four years of accomplishments under the Biden Administration as a foundation on which she will continue to build. Her vision embraces a strong role for the federal government in making health care more accessible and affordable. Meanwhile, the Republican candidate for president, former President Donald Trump, has revealed very little about his health policy agenda. However, what little President Trump has said combined with the platforms of Republican policy leaders surrounding Trump, many of whom played prominent roles in his Administration, promote a very different health care platform from Vice President Harris. A Trump Administration is likely to move away from a strong federal role in health insurance regulation in favor of increased private market strategies and, potentially, restrictions on Medicaid.

And presidential elections are not the only elections this year that will influence health policy. This November, there are a total of 468 seats up for election in Congress (33 Senate seats and all 435 House of Representative seats). State races are also featuring health policy prominently, including a few competitive races for governor, like the one in North Carolina where reproductive health is firmly on the ballot. These political races all have implications for the health policies that we will see in 2025 and beyond.

This fall, Health Care in Motion will highlight important health policy areas that may be impacted by the upcoming elections and what advocates for people with complex and chronic conditions need to know heading into November. We begin with the IRA's Medicare reforms, a signature accomplishment of the Biden Administration.

#### Where Does IRA Implementation Stand Heading into the Election?

The IRA is a <u>sweeping piece of federal legislation</u> signed into law by President Biden in August 2022. The law includes significant investment in climate and energy policies as well as major health care provisions, most notably changes to Medicare. One IRA provision likely to be influenced by the election is the law's groundbreaking rules on drug pricing negotiation. After a long political battle over the role of the federal government in Medicare drug prices—a divide that dates back to before the Medicare Part D program was first enacted in 2003—the IRA gives



the Secretary of the Department of Health and Human Services (HHS) the authority to negotiate with drug manufacturers for a fair price for drugs used in the Medicare program. The authority is somewhat narrow, allowing the federal government to negotiate the price of only a small number of drugs every year, but it is still an unprecedented step for drug pricing reform. For background on the drug pricing negotiation mechanics, check out this past issue of Health Care in Motion.

In August 2024, the IRA's drug pricing provisions reached a significant milestone, with the Centers for Medicare and Medicaid Services (CMS) <u>announcing the final negotiated prices</u> for the first ten drugs subject to negotiation. These prices were announced after months of data gathering and negotiation between CMS and the manufacturers, including <u>public listening sessions</u> with patient groups. These prices go into effect in January 2026.

CMS selected drugs for negotiation (first round)	List price (30-day supply)	Negotiated maximum fair price (30-day supply)	Percent difference from list to negotiated price
Januvia (diabetes)	\$527	\$113	79%
Fiasp (diabetes)	\$495	\$119	76%
Farxiga (diabetes, heart failure, chronic kidney disease)	\$556	\$178.50	68%
Enbrel (rheumatoid arthritis, psoriatic arthritis)	\$7,106	\$2,355	67%
Jardiance (diabetes, heart failure, chronic kidney disease)	\$573	\$197	66%
Stelara (psoriasis, psoriatic arthritis, crohn's disease, ulcerative colitis)	\$13,836	\$4,695	66%
Xarelto (blood clots, coronary or peripheral artery disease)	\$517	\$197	62%
Eliquis (blood clots)	\$521	\$231	56%
Entresto (heart failure)	\$628	\$295	53%



Imbruvica (blood cancers)	\$14,394	\$9,319	38%
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Source: CMS.gov, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (August 14, 2024)

CMS will announce the next slate of 15 drugs subject to negotiation by February 1, 2025, which will kick off another multi-month negotiation process similar to what we saw for the first ten drugs. CMS will announce maximum fair prices for this second set of drugs by November 30, 2025, with the negotiated prices that Medicare Part D plans will pay for these drugs going into effect on January 1, 2027.

#### The IRA's Drug Pricing Provision: What's at Stake on the Ballot?

The IRA's drug pricing provision is still in its nascent stage, and a political change in the White House or in Congress could derail implementation.

#### **Congress**

Repealing or changing an existing law takes an act of Congress. Right now, Republicans have a razor thin majority in the House, while Democrats maintain a razor thin majority in the Senate. But the November election could change this, enabling legislative changes to the IRA. If Democrats control at least one chamber, it is safe to say we will not see a repeal or rollback to the IRA, as it was the Democrats signature legislation and passed on a purely partisan line vote. If Democrats take both chambers, they may seek to build on the IRA, but opening up existing legislation for changes is a fraught endeavor, especially for something as politically charged as drug pricing. However, if control of Congress swings to Republicans, the IRA may be in danger. The policy agenda (known as Project 2025) being pushed by Republicans would repeal the IRA in its entirety. This would include repeal of the drug pricing provisions in addition to many other Medicare affordability provisions included in the IRA, like the \$35 cap on insulin cost sharing that has been in effect since 2023 and the \$2,000 annual out-of-pocket cap on cost-sharing for Medicare Part D that goes into effect in 2025. As anyone who followed the ACA's repeal and replace battle in 2017 well knows, taking away a popular piece of legislation is no easy task. The IRA's Medicare cost-sharing provisions are wildly popular, and rolling them back without a replacement plan may be politically treacherous.

#### **White House**

Even if control of Congress remains unchanged, a party change in the White House could still impact IRA implementation. Despite each presidential candidate taking relatively similar public stances on the high price of prescription drugs, a Trump Administration is more likely to include HHS officials who have friendly views of the pharmaceutical industry and may be less enthusiastic about flexing the federal government's negotiating powers to secure steep price cuts for Medicare. While the factors that CMS must use to guide a maximum fair price for each drug are set in the IRA, these factors are fairly broad, leaving CMS discretion to determine the contours and decide the relative weight of each factor. A new administration could also choose to reduce the HHS workforce charged with implementing the law, which might slow down implementation.

A new administration could also influence how vigorously (if at all) the IRA drug pricing provisions are defended in the <u>multiple lawsuits drug manufacturers have brought</u> challenging the law since it went into effect. If these lawsuits are not resolved before a new president takes office, the next administration could simply choose not to



defend the law in court. This has happened before—most notably when the Trump Administration <u>opted not to</u> <u>defend the ACA</u> from legal challenges. While this would not mean that the challengers to the law automatically win (in the case of the ACA lawsuit, for instance, state attorneys general stepped in to defend the law), it does make defending the law more difficult.

As always, elections matter. The IRA's Medicare reforms are among many health policies that could change drastically depending on the outcome of the presidential and other races. Watch this space in the coming weeks as Health Care on the Ballot explores how the election might impact other key health policies.

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