



Focus on Affordability: How States Can Build on the Inflation Reduction Act to Lower Prescription Drug Costs

For decades, Americans have endured the skyrocketing costs of prescription drugs. In August, Congress finally took action to address this problem by passing H.R. 5376, the Inflation Reduction Act of 2022 (Inflation Reduction Act). This historic law takes important steps to assist American families by making some lifesaving prescription drugs more affordable, but the act has significant limitations that prevent it from being a complete solution to out-of-control drug pricing in the United States.¹

States now have an exciting opportunity to enact innovative reforms that build on this new federal law in ways that can expand the affordability of prescription drugs for all payers and patients. This paper begins with a summary of the Inflation Reduction Act's accomplishments and limitations, then identifies an approach that states can pursue to achieve even greater prescription drug savings for people across the country.

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Accomplishments of the Inflation Reduction Act

Most notably, the Inflation Reduction Act allows the federal government, for the first time in history, to negotiate prices with drug companies for a small subset of high-cost drugs.

The list of drugs eligible for negotiation include brand-name biologic drugs without a generic or biosimilar equivalent, which are among the most expensive Medicare-covered drugs (under Part B or Part D). Drugs that qualify for negotiation must have also completed their U.S. Food and Drug Administration (FDA) exclusivity period.² Starting in 2026, the Medicare program will implement negotiated pricing for 10 drugs, with an additional 15 drugs added to the list each year beginning in 2027 and 20 drugs added to the list in 2029 and every year after. The secretary of the U.S. Department of Health and Human Services will leverage information from previous Medicare expenditures and pertinent manufacturer data to arrive at an agreed upon price that does not exceed the maximum fair price (MFP) of the drug. To ensure compliance with this process, manufacturers that refuse to negotiate or accept Medicare’s final pricing will be subject to an excise tax and financial penalties, respectively.

The Inflation Reduction Act also limits the rate at which drug manufactures can increase the Medicare prices of prescription drugs. Prices for approximately half of the prescription drugs covered by Medicare have historically increased faster than general inflation, causing access and affordability issues for beneficiaries.³ Starting in 2023, manufacturers that raise Medicare prices of their drugs faster than inflation will be required to provide rebates to the government covering the difference between the above-inflation price and the inflation-adjusted price. The government will establish these amounts using 2021 as the base year for determining relative price changes.

Finally, the Inflation Reduction Act restructures the Medicare Part D benefit to limit patients’ annual out-of-pocket costs for prescription drugs. Currently, there are no out-of-pocket caps for Medicare beneficiaries in Part D. Instead, beneficiaries are expected to pay 5% of the cost of their drugs once they reach the “catastrophic” phase of the benefit, with no limit on the total amount to be paid out of pocket.^{4,5} This has resulted in individuals spending thousands of dollars on necessary medication for conditions like cancer or rheumatoid arthritis.⁶ Beginning in 2024, patients will no longer have to pay 5% of the cost of their drugs in the catastrophic phase, and beginning in 2025, patients will have an out-of-pocket cap of \$2,000. The Inflation Reduction Act also includes a cap of \$35 per month for insulin medication for Medicare beneficiaries, taking effect in 2023.

For Those On Medicare, the Inflation Reduction Act



reduces the cost of some drugs.



limits price increases.



limits out-of-pocket costs.

Limitations of the Inflation Reduction Act

The Inflation Reduction Act sets a historic precedent for lowering prices of prescription drugs, but this act does not fully address the multipronged problem of high and rising drug costs in America. While the law's provisions are critical to increasing the affordability of prescription drugs for older individuals, **the Inflation Reduction Act does not:**

1. Allow price negotiation for most prescription drugs covered by Medicare.
2. Extend Medicare's negotiated prices to patients and payers outside of Medicare.
3. Reduce out-of-pocket costs, provide inflationary rebates or enact copay caps to patients and payers outside of Medicare.

As detailed above, price negotiation authorized under the Inflation Reduction Act is restricted to certain drugs using several criteria. These limits include whether drugs have completed their FDA marketing exclusivity period (a length of time that varies based on drug type) and if the drug is single-sourced. Multisource drugs, or drugs with market competition; orphan drugs; and drugs still within their FDA exclusivity period are exempt from negotiation under the Inflation Reduction Act. Moreover, since FDA exclusivity periods and patent terms do not always run concurrently, under the Inflation Reduction Act, the federal government has limited authority to negotiate prices during periods when competition is still legally restricted, a time when outrageously high prices can and do often occur. These factors — along with the two-year delay between when a price is negotiated and when that negotiated price reaches the market due to implementation procedures — will prolong the impact extraordinarily high drug prices have on people across the country.

Additionally, individuals in employer-sponsored health insurance programs and the commercial market will still be subject to manufacturers' high drug prices, which can have adverse effects on patients' health.⁷ For example, as drug manufacturers have continued to raise the price of insulin, many consumers with diabetes have been forced to ration their treatment despite the potentially deadly consequences.⁸ Though the Inflation Reduction Act establishes a copay cap for Medicare beneficiaries, it does not reduce insulin prices or apply the insulin copay cap to people with private health coverage.⁹

The Inflation Reduction Act Still Does Not



have price negotiations for most Medicare covered drugs.



enable patients & payers outside of Medicare to benefit from lower drug prices.



enable patients & payers outside of Medicare to benefit from reduced out-of-pocket costs, rebates and copay caps.

How states can build on the Inflation Reduction Act

While federal intervention on drug pricing will lower some drug costs over time, more needs to be done to address high prices for a wider array of drugs, especially for people who are not covered by Medicare. States can build on the Inflation Reduction Act by creating a prescription drug affordability board (PDAB) with the ability to establish key pricing reforms. Depending on its design, a PDAB is an independent body with the authority to review, investigate and regulate high-cost prescription drug prices statewide. PDAB legislation has been introduced throughout the U.S., most notably in Maryland.^{10,11}

In 2019, Maryland became the first state in the nation to create an affordability board, which closely examines the problem of high-cost drugs in the state and strategizes how to make prescription drugs more affordable for all Maryland residents. The board is currently looking into the benefits and risks of establishing upper payment limits for all purchases of certain high-costs drugs within the state, which should serve as a springboard for other states to pursue similar policies.¹² Upper payment limits cap what insurers can reimburse or what can be billed to a given purchaser for a prescription drug. PDABs with the authority to set upper payment limits as well as other key pricing regulations could ensure that prescription drugs are affordable for all individuals.

State PDABs could:

1. **Use** the Medicare MFP as a reference to create a statewide upper payment limit that applies to all prescription drugs within the state. Using the Medicare MFP as a statewide upper payment limit may also help reduce administrative costs by simplifying operations for providers and payers, who will only have to work with one price for a drug.
2. **Leverage** the Inflation Reduction Act's inflationary rebate formula to establish a similar rebate rule for manufacturers that increase drug prices faster than inflation for purchasers outside of Medicare. These rebates would help protect against manufacturers shifting costs to other payers due to the relatively low Medicare price for specific drugs.
3. **Establish** cost-sharing caps for patients enrolled in health insurance plans besides Medicare. The Inflation Reduction Act sets an out-of-pocket cap for Medicare beneficiaries of \$2,000 annually and an insulin copay cap of \$35 monthly. PDABs can mirror Medicare's cost-sharing thresholds, applying these caps to the private and commercial markets within the state, to ensure all patients are able to access affordable drugs and avoid high out-of-pocket costs.



Passing legislation that establishes PDABs with the authority to create drug pricing reforms will enhance the impact of the Inflation Reduction Act and ensure all individuals are able to access affordable drugs no matter where they live, what medications they need or what type of health coverage they have.

Establishing PDABs with the ability to enact the key pricing reforms listed above will allow states to create payment ceilings for prescription drugs that are ineligible for Medicare negotiations or protected by patents. These established drug pricing caps would also apply to all residents regardless of coverage type — a move that could have a significant impact on the economic health of families who need to purchase lifesaving drugs.

Conclusion

The rising costs of prescription drugs continue to be a top concern for many Americans. The Inflation Reduction Act will help address drug affordability for Medicare beneficiaries, but individuals with other health coverage will continue to encounter high drug prices. States should leverage the momentum of the Inflation Reduction Act to protect all individuals from high drug prices by replicating and expanding key provisions of this act. Passing legislation that establishes PDABs with the authority to create drug pricing reforms will enhance the impact of the Inflation Reduction Act and ensure all individuals are able to access affordable drugs no matter where they live, what medications they need or what type of health coverage they have.

Endnotes

¹ “H.R. 5376 - Inflation Reduction Act of 2022,” Congress.gov, accessed August 18, 2022, <https://www.congress.gov/bill/117th-congress/house-bill/5376>.

² Juliette Cubanski et. al., “How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?” Kaiser Family Foundation, August 18, 2022, <https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/>.

³ Juliette Cubanski and Tricia Neuman, “Prices Increased Faster than Inflation for Half of All Drugs Covered by Medicare in 2020,” Kaiser Family Foundation, February 25, 2022, <https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/>.

⁴ “Phases of Part D Coverage,” Medicare Interactive, accessed August 19, 2022, <https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/phases-of-part-d-coverage>.

⁵ Juliette Cubanski, Tricia Neuman, and Anthony Damico, “Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold Over Time,” Kaiser Family Foundation, July 23, 2021, <https://www.kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/>.

⁶ Juliette Cubanski, Wyatt Koma, and Tricia Neuman, “The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019,” Kaiser Family Foundation, February 1, 2019, <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>.

⁷ “High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost,” Council for Informed Drug Spending Analysis, November 18, 2020, <https://www.cidsa.org/publications/xcenda-summary>.

⁸ Nicole Rapfogel, Maura Calsyn, and Colin Seeberger, “7 Ways Drug Pricing Legislative Proposals Would Lower Costs for Consumers and Businesses,” Center for American Progress, July 26, 2021, <https://www.americanprogress.org/article/7-ways-drug-pricing-legislative-proposals-lower-costs-consumers-businesses/>.

⁹ Rapfogel, Calsyn, and Seeberger, “7 Ways.”

¹⁰ “Comparison of State Prescription Drug Affordability Board Bills,” National Academy for State Health Policy, March 15, 2021, <https://www.nashp.org/comparison-of-state-prescription-drug-affordability-board-bills/>.

¹¹ Hannah Markus and Sandra Wilkniss, *2020 State Legislation on Prescription Drug Affordability* (Washington, DC: Families USA, September 2020), https://familiesusa.org/wp-content/uploads/2020/09/RX-135_2020-Prescription-Drug-Legislative-Wrap-Up_D.pdf.

¹² “Maryland Prescription Drug Affordability Stakeholder Council: Supply Chain Report,” Maryland Prescription Drug Affordability Board, June 27, 2022, https://pdab.maryland.gov/documents/stakeholders/pdasc_supply_chain_rpt_prst.pdf.

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